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

FORM 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2002

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to .

Commission File Number 0-12128

MATRITECH, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-2985132**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification Number)**
330 Nevada Street Newton, Massachusetts	**02460**
(Address of Principal Executive Offices)	**(ZIP Code)**

Registrant's telephone number, including area code: (617) 928-0820

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
None	**N/A**

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $.01 Par Value
(Title of Class)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☑ Yes ☐ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). ☐ Yes ☑ No

Aggregate market value, as of March 3, 2003 of Common Stock held by non-affiliates of the registrant: $58,528,456 based on the last reported sale price on the NASDAQ Stock Market.

Number of shares of Common Stock outstanding on March 3, 2003: 32,132,243.

Documents Incorporated by Reference

The registrant intends to file a Definitive Proxy Statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2002. Certain portions of such Proxy Statement are incorporated by reference in Part III of this report.

PART I

Item 1. *Business.*

Overview

Matritech, Inc. (the "Company" or "Matritech" or "we") has developed and now manufactures and markets innovative cancer diagnostic products based on our proprietary nuclear matrix protein ("NMP") technology. The nuclear matrix, a three-dimensional protein framework within the nucleus of cells, plays a fundamental role in determining cell type by physically organizing the contents of the nucleus, including DNA. We have demonstrated that there are differences in the types and amounts of nuclear matrix proteins and other proteins found in cancerous and normal tissue and believe the detection of differences in properly selected proteins provides clinically useful diagnostic information about cellular abnormalities such as cancer. Using our proprietary technology and expertise, we have developed and commercialized non-invasive or minimally invasive cancer diagnostic tests for bladder cancer and have developed and licensed proprietary diagnostic reagents for cervical cancer which are being utilized in the development of a cervical cancer screening system by our licensee. In addition we have programs underway using new technologies such as mass spectrometry to develop additional tests for prostate, breast and colon cancer. Our objective is to develop tests that will be more accurate than existing tests and will result in lower treatment costs and an improved standard of patient care.

In all our programs, we intend to use the basic technologies (i.e., methods for detecting, measuring identifying and reproducing cancer-associated proteins) in development programs undertaken by us or our licensees to create products or services which will generate medically useful information. We have identified three principal approaches to delivering this information, two of which are types of products — our Lab Test Kits and Point-of-Care Test Devices — and the third of which is a Proprietary Laboratory Procedure, in all cases based on our technologies. Each of these approaches uses our technology in a different way as described below:

Lab Test Kits, such as the NMP22[1] Test Kit, which are generally sold for use in appropriately licensed clinical laboratories or doctor's office laboratories to perform lab testing services. These laboratories perform a service, only upon a physician's prescription, which uses our products to test patient specimens. After testing, the laboratory provides the data it generated using the Lab Test Kit in a written report. The information in the report helps the physician determine the presence or absence of cancer.

Point-of-Care Test Devices, such as the NMP22 BladderChek Device, which are generally sold for use in a medical facility or physician's office by medical personnel who need not be licensed to perform laboratory tests. Point-of-Care Test Devices are similar to the urine-based pregnancy test devices and the blood-based glucose test strips sold in pharmacies, but they are sold for use only pursuant to a physician's order. These devices generate information which helps physicians determine the presence or absence of cancer.

Proprietary Laboratory Procedures, which are under development using our technologies for prostate and breast cancer. Proprietary Laboratory Procedures are laboratory analytical procedures to measure clinically useful proteins which are custom designed to the instrumentation and techniques of a specific clinical laboratory. Proprietary Laboratory Procedures will help us gain early market exposure and enable physicians and laboratories to gain preliminary clinical experience with our technologies prior to our developing Lab Test Kits or Point-of-Care Test Devices. Proprietary Lab Procedures are likely to be confined to a limited number of licensed clinical laboratories who would be expected to invest in the development and marketing of a lab testing service specific to their equipment, processes and personnel

[1] NMP22® is a registered trademark and BladderChek™, NMP35™, NMP48™, NMP66™, NMP179™ and Matritech™ are trademarks of Matritech, Inc. All other trademarks, service marks or trade names used in this report are the property of their respective owners.

and would not be marketed to other laboratories as are Lab Test Kits. Such Proprietary Lab Procedure, if developed in compliance with appropriate regulations, is not expected to require approval of the U.S. Food and Drug Administration ("FDA") prior to launch. It is anticipated that this approach would be used for technologies which have not been made available as Lab Test Kits or Point-of-Care Test Devices. After appropriate clinical testing, the Proprietary Laboratory Procedure could also be used to generate information to help physicians determine the presence or absence of cancer.

Our current cancer diagnostic products are limited to bladder cancer detection. In the United States the Point-of-Care Test Device is marketed to U.S. urologists and oncologists pursuant to an exclusive contract with Cytogen, Inc. (NASDAQ:CYTO), a manufacturer and marketer of cancer diagnostic products. In addition, our Lab Test Kit is marketed jointly by Fisher Scientific and by us to appropriately licensed clinical laboratories. In Germany, both Point-of-Care Test Devices and Lab Test Kits are marketed directly to German physicians and laboratories and to European diagnostic product distributors through Matritech, GmbH, our wholly owned subsidiary in Europe. Matritech GmbH also markets diagnostic products manufactured by Hitachi and others to laboratories and physicians, principally in Germany. We have also established distribution arrangements in Asia to market our cancer diagnostic products, principally in China, Japan and Korea.

We intend to expand our product line to include Lab Test Kits and Point-of-Care Test Devices to detect proteins associated with prostate cancer (NMP48), proteins associated with breast cancer (NMP66) and proteins associated with colon cancer (NMP35). In addition, we intend to find clinical laboratory partners to help us develop Proprietary Lab Procedures and to create early market awareness using our technologies for prostate, breast and colon cancer similar to an arrangement we have negotiated with Mitsubishi in Japan. We have also licensed certain rights to our cervical cancer proteins (NMP179) to Sysmex, Inc., an international diagnostic device company, for use in a new, non-slide-based system they are developing for cervical cancer testing. For further discussion of this multi-faceted approach to the market, see each of the specific cancer programs outlined in the following paragraphs.

Matritech was incorporated in Delaware in October 1987. Our headquarters are located at 330 Nevada Street, Newton, Massachusetts, 02460, and our telephone number is (617) 928-0820.

Matritech's Product Development Programs

The following table summarizes some of the important aspects of each of our product development programs as discussed in more detail below. Because any summary may leave out details you think are important, please use this as a guide to reading and understanding the material which follows. The data in the table is qualified and expanded in the detailed sections following the table.

Program	Product	Indication	Stage of Development	FDA Status	Principal FDA Approved Competitive Products	Partners and Their Role[2]
NMP22 Bladder	Lab Test Kit	Monitoring	Commercialized	Approved	BTA UroVysion ImmunoCyt	(1) Fisher — U.S. — Distributor (2) Konica — Japan — Distributor (3) Diagnostic Products Corporation — World — Automated Kit Manufacturer and Distributor
NMP22 Bladder	Lab Test Kit	Diagnosis	Commercialized	Approved	None	
NMP22 Bladder	Point-of-Care Test Device	Monitoring	Commercialized	Approved	BTA	(1) Cytogen — U.S. — Urology/Oncology Distributor (2) MBL — Japan
NMP22 Bladder	Point-of-Care Test Device	Diagnosis	Approvable	Approvable	None	
NMP179 Cervical	Non-Slide-Based System	Screening	Research and Development	To be Determined	SurePath	(1) Sysmex, Inc — World — Manufacturer and Marketer for Non-Slide-Based System
NMP48 Prostate	None yet	Not Determined	Research and Development	To be Determined	PSA	
NMP66 Breast	None yet	Not Determined	Research and Development	To be Determined	Mammography TRUQUANT®BR RIA CA27.29, CA15.3	(1) Mitsubishi Kagaku Medical, Inc — Japan
NMP35 Colon	None yet	Not Determined	Research and Development	To be Determined	CEA CA19.9	

[2] We have other distributors which are not classified as partners in this table because they have not paid upfront fees in excess of $50,000, do not have cumulative sales in excess of $500,000 and do not have rights other than those of a conventional distributor.

Bladder Cancer Program (NMP22)

Our first cancer program to reach commercialization is focused on detecting bladder cancer. This program is based on discoveries first made by Company scientists in 1993 about certain proteins ("NMP22") in the urine of bladder cancer patients which were generally present at much lower levels or completely absent in patients without bladder cancer. This program has resulted in two products — a Lab Test Kit and a Point-of-Care Test Device — to generate medically useful information.

NMP22 Test Kit for Bladder Cancer. Our first product, the NMP22 Test Kit for bladder cancer (the "NMP22 Lab Test Kit"), was approved for sale in the United States by the FDA in 1996 for use in detecting occult or rapidly recurring bladder cancer in patients with previously diagnosed disease. In this product, our proprietary reagents to detect NMP22 in a semi-automated 96-well microtiter plate format are used by licensed clinical laboratories to test urine specimens. Exclusive of the time to transport the specimen to the lab and the time to deliver the test report to the physician, the test requires about four hours to deliver a completed result. In 2000, the FDA approved the NMP22 Lab Test Kit for use in testing individuals who have had no previous diagnosis of bladder cancer but who have symptoms of or are at risk for bladder cancer.

Test Results: In clinical studies conducted by Matritech and independent researchers and published in multiple journal articles, the NMP22 Lab Test Kit has demonstrated clinical utility as an aid in detecting bladder cancer. The FDA's original approval was based upon data generated during a clinical trial involving more than 700 subjects at 14 clinical trial sites, including bladder cancer patients, patients with other cancers, patients with non-cancerous urinary conditions (such as urinary tract infections) and healthy

subjects. We believe that when the NMP22 Lab Test Kit is used as part of the diagnostic work-up for bladder disorders, it gives physicians a valuable non-invasive tool to help them determine whether an individual's symptoms are caused by bladder cancer or by a non-life-threatening condition. Many of the journal articles cited previously report that the NMP22 Lab Test Kit has the potential to enhance patient management and that it is an effective test for bladder cancer.

Approach to Market: In 1994, we entered into an exclusive agreement with Konica Corporation ("Konica") to distribute our NMP22 Lab Test Kit in Japan. In 1998, the Japanese Ministry of Health and Welfare ("Koseisho") also approved the NMP22 Lab Test Kit for sale in Japan for use in screening previously undiagnosed patients for bladder cancer. In 1998, we and Fisher Scientific Company, L.L.C. ("Fisher") entered into a co-exclusive distribution agreement for the NMP22 Lab Test Kit in the United States. In 1999, the State Drug Administration in the People's Republic of China approved the NMP22 Lab Test Kit for sale for the detection and management of bladder cancer. The NMP22 Lab Test Kit is currently being marketed in Southeast Asia and China by U. S. Summit. The NMP22 Lab Test Kit has been commercially available in Europe since 1995 and is distributed through our European subsidiary, Matritech GmbH, and other distributors throughout Europe. We have retained substantially all worldwide manufacturing rights for the NMP22 Lab Test Kit as well as co-marketing rights with Fisher in the United States.

Fully-Automated Version of NMP22 Lab Test Kit: In 2001, we entered into an eight-year, non-exclusive product supply and marketing agreement with Diagnostic Products Corporation ("DPC") (NYSE:DP) enabling DPC to develop and market an automated version of our NMP22 Lab Test Kit (the "Automated NMP22 Lab Test Kit"). DPC sells this product in international markets and is conducting trials to demonstrate the substantial equivalence of this automated version to our FDA-approved NMP22 Lab Test Kit in order to gain FDA approval for marketing the product in the U.S. DPC currently reports that they have over 7,000 automated instruments capable of performing NMP22 testing in clinical laboratories worldwide.

NMP22 BladderChek Test Device. Our second product for bladder cancer, the NMP22 BladderChek Test Device (the "NMP22 BladderChek Device"), was approved for sale in the United States by the FDA in 2002 for use in identifying the recurrence of bladder cancer in patients with previously diagnosed disease. In this product, our reagents to detect NMP22 are utilized in a device similar to a urine-based point-of-care pregnancy test device to measure NMP22 in patient urine specimens. Physicians or the staff in their offices can perform the test during the patient's visit. In February 2003, the FDA notified us that the NMP22 BladderChek Device is approvable for use in testing individuals who have no previous diagnosis of bladder cancer but who have symptoms of or are at risk for bladder cancer. Final approval will be granted following the satisfactory completion of FDA inspections of our manufacturing facilities and those of our principal subcontractor for the NMP22 BladderChek Device, which we expect by the end of May 2003. Since there is no time required to transport the specimen to the lab and no time required to deliver the test report to the physician, the device delivers a completed test result in about 30 minutes.

Test Results: In clinical tests for FDA submission, the NMP22 BladderChek Device demonstrated a greater than 90% concordance with the NMP22 Lab Test Kit.

Approach to Market: In 2001, we signed a six-year exclusive (subject to certain minimum purchase requirements) agreement with Timm Medical Technologies Inc. ("Timm") providing for the distribution, upon FDA approval, of the NMP22 BladderChek Device in the United States to urologists. Endocare, Inc. (Pink Sheets: ENDOPK) acquired Timm in May 2002. Endocare and we agreed to terminate the original distribution agreement in September 2002. Concurrently we signed a 5 year and two months exclusive (subject to certain minimum purchase requirements) agreement with Cytogen, Inc., a manufacturer and marketer of cancer diagnostic products, providing for the distribution of the NMP22 BladderChek Device to urologists and oncologists in the United States. The agreement also provides price discounts to Cytogen if they exceed the minimum purchase requirements.

In 2001, we announced that we had signed a six-year agreement with U.S. Summit Company ("US Summit") for the exclusive (subject to certain minimum purchase requirements) distribution of the NMP22 BladderChek Device in Southeast Asia. In 2001, this agreement was expanded to include the People's Republic of China. In 2001, we announced that we were shipping the NMP22 BladderChek Device to

international distributors and customers. In March 2002 we signed a seven-year agreement with MBL of Nagoya, Japan for the exclusive (subject to certain minimum purchase requirements) distribution of the NMP22 BladderChek Device in Japan. MBL is currently conducting the clinical trials necessary for submission to Koseisho for regulatory approval in Japan.

Cervical Cancer Program (NMP179)

We have also identified a nuclear matrix protein associated with cervical cancer and cervical pre-cancerous conditions ("NMP179") and have conducted preclinical studies investigating the utility of using this protein in conjunction with routine and follow-up cervical testing. Pap smears, the principal diagnostic test for cervical cancer, analyze cervical tissue cells using visual techniques. NMP179 was developed to reduce the time for and increase the accuracy of visually identifying cervical cells which need further visual inspection by a pathologist.

Test Results: In 1999 we published results of a clinical investigation conducted in collaboration with physicians from Brigham and Women's Hospital (Boston, MA) and Women and Infants Hospital (Providence, RI). In this study NMP179 correctly identified 79% of samples with low and high grade cervical intraepithelial lesions, including 29 of 30 samples with high-grade precancerous lesions (HSIL). The test was correctly negative in 70% of the samples without evidence of disease.

Approach to Market: During 2002 we licensed exclusively the world-wide use of NMP179 technology for automated, non-slide-based laboratory instruments to Sysmex, Inc., a leading manufacturer of automated laboratory instruments based in Kobe, Japan. By combining our NMP179 technology with Sysmex' expertise in flow cytometry, image analysis and laboratory automation, we expect Sysmex to develop new systems which will automate the process of screening Pap smears. Sysmex believes that such automation will reduce human errors inherent in existing procedures and reduce the overall cost of Pap smear analysis. When development is complete, we expect Sysmex will submit this system to the FDA as a class III device subject to a premarket approval ("PMA") regulatory process.

As a part of this transaction, Sysmex purchased shares of our common stock at a premium, agreed to pay us milestone payments based on reaching certain research and product development goals, committed to make minimum quarterly payments to support our research, contracted to purchase all NMP179 reagents from us and will pay us a royalty on all reagent sales related to their Pap smear screening system.

Prostate Cancer Program (NMP48)

In 1999, we entered into collaboration with Alan Partin, M.D., Ph.D., Professor of Urology at Johns Hopkins University School of Medicine, to develop an improved prostate cancer test. During 1999, our scientists, using a research configured, low-throughput mass spectrometer instrument ("research mass spec"), discovered the existence of certain proteins ("NMP48") in the blood of prostate cancer patients that were generally not present in the blood of normal individuals (i.e., those without detectable prostate malignancy). Our current scientific goal is to develop sample preparation and testing methods to enable our clinical lab partners to conduct a Proprietary Lab Procedure based on a high-throughput mass spectrometer instrument ("high-throughput mass spec") that will be more reproducible, controlled and cost effective than the research procedures used in making the initial discovery. We have not completed a Lab Test Kit, a Point-of-Care Test Device or a Proprietary Lab Service to measure NMP48. However, if such developments lead to a Proprietary Lab Procedure and if such procedure is developed in compliance with appropriate regulations, it is not expected to require FDA approval prior to launch. When the Proprietary Laboratory Procedure is completed, our scientists will commence development of products for routine use by all laboratories such as a Lab Test Kit and a Point-of-Care Test Device.

Test Results: A discovery research study published in 2001 authored by Dr. Partin and our scientists using the research mass spec technology reported elevated levels of the NMP48 proteins in all 36 men tested with prostate cancer, including all of the eight men who had test values for PSA (a widely used test to screen for prostate cancer) in the normal range. NMP48 was not found in the blood of any of the 20 men tested who were believed not to have prostate cancer based on evaluations by digital rectal exams and PSA test values.

This discovery study did not use the reproducible, controlled and cost effective methods required in the clinical trials of NMP22 and NMP179, and investors should expect that a reproducible, controlled and cost effective Lab Test Kit, Point-of-Care Test Device or Proprietary Lab Procedure, if successfully developed, will not have clinical performance equal to these discovery research results.

Approach to Market: We are investigating opportunities to utilize the NMP48 proteins in a Proprietary Lab Procedure. We have had discussions with potential clinical laboratory partners and expect to enter into an agreement with one of them during 2003. All of the blood specimens for use in generating reproducible and controlled clinical data prior to launching a Proprietary Lab Procedure have been collected. Like all blood-based research specimens at Matritech, these specimens have been stored in freezers at −80 degrees Centigrade since they were collected and are available for immediate evaluation as soon as an appropriate test is developed. Clinical trials to investigate the performance of NMP48 in detecting prostate cancer began enrolling patients and collecting blood specimens in April 2002 and completed enrollment in October 2002. Nine sites in the United States and one in Germany collected specimens from over 700 men. Approximately 450 of these patients have had biopsies performed due to elevated PSA results, abnormal digital rectal exams or other suspicious conditions. NMP48 results will be compared to biopsy outcome. In addition, blood specimens from over 100 individuals with cancers other than those of the prostate and from more than 100 men with normal PSA values and unremarkable digital rectal exams were collected for comparison. Results of testing these specimens using a Proprietary Lab Procedure for NMP48 are anticipated in 2003 but are dependent upon completing appropriate arrangements with a clinical laboratory partner. Consequently, the timing of the launch of a testing service using our NMP48 prostate cancer technology will depend upon concluding a satisfactory agreement with such a partner and upon completion of development of a satisfactory Proprietary Lab Procedure with the partner.

We do not yet have any NMP48 prostate cancer distribution arrangements for Lab Test Kits or for Point-of-Care Test Devices. We will consider some of our NMP22 distributors when we are in the final stages of product development.

Breast Cancer Program (NMP66)

In 1999 our scientists, using a research mass spec, discovered the existence of certain proteins (“NMP66”) in the blood of breast cancer patients that were generally not present in the blood of women without detectable breast malignancy. Our current scientific goal is to develop sample preparation and testing methods to enable our clinical lab partners to conduct a Proprietary Lab Procedure based on a high-throughput mass spec that will be more reproducible, controlled and cost effective than the research procedures used in making the initial discovery. We have not completed a Lab Test Kit, a Point-of-Care Test Device or a Proprietary Lab Service to measure NMP66. However, if such developments lead to a Proprietary Lab Procedure and if such procedure is developed in compliance with appropriate regulations, it is not expected to require FDA approval prior to launch. When the Proprietary Laboratory Procedure is completed, our scientists will commence development of products for routine use by all laboratories such as a Lab Test Kit and a Point-of-Care Test Device.

Test Results: A discovery research study published in 2001 authored by our scientists using the research mass spec technology reported elevated levels of NMP66 in 45 of the 46 patients tested with breast cancer or its precursors, including all of the five patients who had early stage cancer with no lymph node involvement and four of the five patients who had ductal carcinoma in situ. NMP66 was not found in the blood of any of the 23 patients tested who were believed not to have breast cancer and was found in only one of the five patients with diagnosed benign breast disease. This discovery study did not use the reproducible, controlled and cost effective methods required in the clinical trials of NMP22 and NMP179 and investors should expect that a reproducible, controlled and cost effective Lab Test Kit, Point-of-Care Test Device or Proprietary Lab Procedure, if successfully developed, will not have clinical performance equal to these discovery research results.

Approach to Market: We are investigating opportunities to utilize NMP66 in a Proprietary Lab Procedure. We believe that NMP66 found in the blood of women with breast cancer may enable physicians to

obtain breast cancer diagnostic information, whether through products or procedures when successfully developed, that is more accurate than the blood testing services that are presently available and that complements and supplements the widely used mammography testing services. We have entered into an agreement with Mitsubishi Kagaku Medical, Inc., a division of Mitsubishi Chemical ("Mitsubishi") whereby they or their designees will serve as our clinical laboratory partner for a Proprietary Lab Service and pursuant to which they will have a right of first refusal to acquire distribution rights for the Japanese market to any Lab Test Kits or Point-of-Care Test Devices for NMP66 that we may develop. We have had discussions with potential U. S. clinical laboratory partners and expect to conclude an agreement with one of them during 2003. All of the blood specimens for use in generating reproducible and controlled clinical data prior to launching a Proprietary Lab Procedure have been collected. Clinical trials to investigate the performance of NMP66 in detecting breast cancer began enrolling patients and collecting blood specimens in 2001 and completed enrollment in July 2002. Seven sites in the United States and three in Germany recruited over 800 women. Approximately 400 of these patients have had biopsies performed due to suspicious findings on mammograms or palpable lumps. NMP66 test results will be compared to biopsy outcome. The other 400 women comprise the control group and have had at least two consecutive mammograms with no suspicious results. We believe that these specimens will be sufficient to demonstrate the clinical utility of a test based on NMP66. We expect to conduct the specimen testing in collaboration with a clinical laboratory partner using the test procedure we develop jointly with them. Consequently, the timing of the launch of a testing service using our NMP66 breast cancer technology will depend, in Japan, upon developing a satisfactory Proprietary Laboratory Procedure with Mitsubishi and in the U.S. and elsewhere, upon concluding a satisfactory agreement with appropriate clinical lab partners and developing a satisfactory Proprietary Laboratory Procedure with the partner.

We do not yet have any NMP66 breast cancer distribution arrangements for Lab Test Kits or for Point-of-Care Test Devices.

Colon Cancer Program (NMP35)

During 1999, our scientists, using a research mass spec, discovered the existence of certain proteins ("NMP35") in the blood of patients with colon cancer, which were generally not present in the blood of individuals without cancer or in the blood of patients with certain benign conditions of the lower digestive tract. After developing Proprietary Lab Procedures for NMP48 and NMP66, we will apply technology developed for those tests to the process of developing a Proprietary Lab Procedure for detecting NMP35 proteins. Such Proprietary Lab Procedure, if developed in compliance with appropriate regulations, is not expected to require FDA approval prior to launch. When the Proprietary Laboratory Procedure is completed, our scientists will commence development of products for routine use by all laboratories such as a Lab Test Kit and a Point-of-Care Test Device.

Test Results: A study published in 2001 authored by our scientists using the research mass spec technology reported elevated levels of NMP35 in all 47 patients tested with colon cancer or its precursors, including all of the six patients who had polyps and all of the four patients who had diverticulitis. NMP35 was not found in the blood of any of the 20 patients tested who were believed not to have colon cancer. This discovery study did not use the reproducible, controlled and cost effective methods required in the clinical trials of NMP22 and NMP179 and investors should expect that a reproducible, controlled and cost effective Lab Test Kit, Point-of-Care Test Device or Proprietary Lab Procedure, if successfully developed, will not have clinical performance equal to these discovery research results.

Approach to Market: We expect to delay any product development or market approaches until we have successfully launched either our prostate or breast cancer programs. Consequently, the timing of the launch of a testing service to detect NMP35 will depend upon multiple factors including, but not limited to, launching either our NMP48 or our NMP66 Proprietary Laboratory Procedures, concluding a satisfactory agreement with a clinical laboratory partner for NMP35 and developing a satisfactory Proprietary Lab Procedure for NMP35 with such partner. Blood specimens for use in generating reproducible and controlled clinical data prior to launching a Proprietary Lab Procedure have been collected. Clinical trials to investigate the performance of blood based proteins in detecting colon cancer and to collect blood specimens began enrolling patients in 1996 and completed enrollment in 1998. These samples were collected as part of a colon cancer

development program begun in 1995 and terminated in 1998. Sixteen sites in the United States recruited over 1000 volunteers, both male and female. Approximately 650 of these patients have had colonoscopies performed due to the presence of blood in the stool, a history of high risk polyps or other risk factors. In addition to this high risk population, 70 individuals with known benign diseases of the colon and 298 volunteers with no known colorectal disorders were recruited as control groups. We believe that these specimens will be sufficient to demonstrate the clinical utility of an NMP35 based test, when developed, for the differential diagnosis of individuals exhibiting symptoms such as rectal bleeding.

Other Diagnostic Products. In 2000, we acquired ADL GmbH, now called Matritech GmbH, a European distributor of diagnostic testing products, including our NMP22 Lab Test Kit for bladder cancer. In addition to our products, Matritech GmbH distributes allergy and other diagnostic testing products on behalf of several manufacturers with which it holds distribution agreements. The most significant of such distribution agreements is with Hitachi Chemical Diagnostics ("Hitachi"), entered into in 1997. This agreement grants Matritech GmbH an exclusive right to market and distribute Hitachi's CLA Allergy Test System in Germany, subject to minimum annual purchase commitments. In 2000, Matritech GmbH entered into a 5-year extension of the distribution agreement with Hitachi providing for exclusive rights to market and distribute the product in Germany and Austria subject to minimum purchase commitments.

Cancer Diagnostics Market

The cancer diagnostics market is composed of several overlapping categories, each corresponding to a stage in the identification and management of the disease. The categories are screening, diagnosing, staging, selecting therapies, monitoring and evaluating prognosis. Cancer screening tests and procedures are used to identify asymptomatic disease in individuals who may (or may not) have risk factors for the disease, but who have no specific evidence of the disease. Screening tests such as mammograms, PSA tests and Pap smears do not yield a final diagnosis. A definitive diagnosis of cancer is usually made after microscopic examination of the suspected cancerous cells. Following diagnosis, additional tests can be used to monitor the course of the disease and the patient's response to treatment. These monitoring tests may be repeated at regular intervals, often every three months, and may be continued for the life of an individual in order to detect the recurrence of cancer. In addition, diagnostic tests are also used to evaluate a patient's prognosis and to select appropriate therapy. Patients identified as having a high risk of recurrence will be monitored more closely and may receive more aggressive treatment.

Accurate *in vitro* diagnostic assays can reduce the need for more invasive or expensive procedures for detecting and managing cancer, such as biopsy, surgery, bone scans and other *in vivo* imaging procedures. In the United States, blood-based or urine-based cancer diagnostic assays have generally been approved by the FDA for monitoring patients with known history of disease. Only two such tests have been approved for use in detecting cancer in previously undiagnosed individuals — the PSA test for prostate cancer and our NMP22 test for bladder cancer.

Ideally, a fluid-based cancer diagnostic assay for use in a clinical laboratory should be both sensitive and specific. Clinical sensitivity refers to the percentage of cases in which the assay correctly identifies the presence of disease. Clinical specificity refers to the percentage of cases in which the assay correctly identifies the absence of disease. Clinical sensitivity and specificity percentages reported from studies and trials of cancer diagnostic products may not be directly comparable, as results may be affected by laboratory-to-laboratory variation, differences in specimen handling, the number of subjects studied, variability in the stages of disease present in the subject population and the demographic composition of the subject population, among other factors.

Technology

The nuclear matrix, a three-dimensional protein framework within the nucleus of cells, helps organize active genes ("DNA") in the nucleus. In this way, the nuclear matrix plays a fundamental role in determining cell type and cell function. Although the specific mechanisms of action are not yet fully understood, our scientists and independent scientists have demonstrated that there are differences in the types and amounts of

nuclear matrix protein found in cancerous and normal tissues and also among different types of normal cells. These differences create opportunities to develop tests which may be not only specific for cancer but also specific for a certain organ or type of tissue, thus providing greater information to physicians and patients. Independent academic investigators have reported the cell type specificity of nuclear matrix proteins in papers published in scientific journals which reported nuclear matrix proteins specific to bone, kidney, prostate, breast and colon cancer tissues. Matritech also has demonstrated that cell death, including cell death related to early tumor development, results in the release of nuclear matrix proteins into bodily fluids. As a result, elevated levels of certain nuclear matrix proteins have been found in the bodily fluids of cancer patients. We are not aware of any other cancer marker, or class of markers, which exhibit this level of clinical specificity and sensitivity.

Mass spectrometry (both research mass spec and high-throughput mass spec) activates proteins (both nuclear matrix proteins and others) in a specially prepared serum or urine sample and detects the molecular weight of those proteins present by measuring the time it takes for them reach a detector in the instrument with an opposite electrical charge. In general, the laser in a mass spectrometer imparts energy in a non-destructive way to the proteins in a specimen. These energized proteins bear a charge adequate to cause them to reach the detector. Preparing samples according to a reproducible and controlled protocol is a critical technical step required to eliminate substances which may interfere with the detection of targeted proteins. Mass spec technology enables us to characterize useful proteins by their molecular weight and then begin the process of identifying and isolating them and developing antibodies to the most useful of those identified.

Developing products from promising proteins discovered using our original two-dimensional gel procedure and, more recently, mass spectrometry has invariably involved serious reproducibility problems. In our early history, independent research scientists using the methods disclosed in our patents and two-dimensional gels reported different cancer-related nuclear matrix proteins than our own scientists. In recent years, other scientists and we, using the procedures and equipment provided by mass spec manufacturers, have generated different test results than earlier stage research. We believe that our experience in reducing variability and making reproducible, controlled tests and test protocols is an important strength of ours. However, as has been the case in the development of all our products, we expect to encounter technical challenges during product development. We will continue to make investments in attempting to overcome these challenges in order to achieve the reproducibility needed to provide medically useful products.

We have developed medically useful diagnostic products for bladder cancer using our nuclear matrix protein technology and are striving to make similar developments for detecting other forms of cancer using research mass spec and high-throughput mass spec technology. However, the economic value of our technology or any other diagnostic technology is based on the clinical utility of the information generated, not on the fundamental biochemistry of the technology or on its performance in discovery research. Therefore, while we are basing our research programs on the data we have generated during discovery research, our physician customers will base their long-term purchase decisions on the clinical information they obtain and whether such information helps them make medical decisions. One of the most important roles of the FDA is to require manufacturers like us to conduct reproducible and controlled clinical trials to demonstrate that our products generate information which is, among other things, limited in variability from one lab to another and likely to be of value to physicians. The data generated by our FDA clinical trials, not the data reported during the discovery phase, is the only basis upon which physicians can appraise clinical value. However, it should also be understood that the perceived value of this clinical information (even if generated by an FDA-approved test) is likely to differ from physician to physician.

Our nuclear matrix protein technology is licensed from the Massachusetts Institute of Technology (“MIT”). Under the current terms of our license from MIT, our worldwide license is exclusive until the expiration of all claims contained in these patents in 2006. We have made additional discoveries related to nuclear matrix proteins and other useful proteins discovered using mass spec technology and have filed our own patent applications on such advances in the United States, as well as corresponding applications and patent rights in selected foreign countries. To date, Matritech has been granted sixteen additional United States patents relating to such discoveries.

Marketing and Sales

Distribution of diagnostic tests poses challenging sales and marketing issues to their developers and manufacturers, especially for new devices. These challenges arise because the purchasers of diagnostic lab test kits (i.e., the clinical laboratories) are not typically the orderers of the test (i.e., the treating physicians). It is not unusual for the sales person offering a new diagnostic test to be told by the laboratory manager that the lab will not buy the new test, no matter how well it performs, until physicians start to order the test. On the other hand, tests which are purchased by physician office laboratories (where the ordering physician owns all or part of the purchasing laboratory) or devices which can be sold directly to the treating physician (like our NMP22 BladderChek Device) do not encounter these challenges because the purchase by a treating physician requires no second sale to a clinical laboratory.

Developing demand for our NMP22 BladderChek Device among urologists is the principal goal of our sales and marketing activity in 2003. To launch the NMP22 BladderChek Device in the U.S., in September 2002 we signed an approximately five-year exclusive agreement with Cytogen, Inc. for NMP22 BladderChek Device sales to urologists and oncologists and concurrently agreed with Endocare to terminate our original distribution agreement. The Cytogen agreement requires them to purchase from us product (valued at current prices) equal to at least $25 million over the term of the agreement (the "Planned Purchases") in order to retain exclusive distribution rights for the NMP22 BladderChek Device to the urology and oncology marketplace. The agreement also provides price discounts if their unit purchases exceed the Planned Purchases. We also sell our NMP22 Lab Test Kit in the United States to selected clinical laboratories. In 1998 we entered into a distribution agreement with Fisher, granting Fisher the co-exclusive right with Matritech to distribute the NMP22 Lab Test Kit to hospitals and commercial laboratories within the United States. To launch the NMP22 BladderChek Device in the United States, we have hired a five-person sales force to support sales to urologists and oncologists and, where appropriate, to general practitioners and to support the marketing efforts of our U.S. distributor. For sales of NMP22 BladderChek Devices to urologists and oncologists, all sales are deemed to have been made by Cytogen; for our direct sales of the NMP22 Lab Test Kit to laboratories, we receive all revenue.

Our European subsidiary, Matritech GmbH, which was acquired in 2000, sells our products in Europe to urologists, laboratories and to other European distributors. Matritech GmbH currently has three full-time sales representatives who are principally devoted to selling our tests to laboratories and to physicians in Germany

In 1994, we entered into an agreement with Konica to distribute the NMP22 Lab Test Kit in Japan. In 2001, signed a six-year agreement with US Summit for the exclusive (subject to certain minimum purchase requirements) distribution of the NMP22 BladderChek Device in Southeast Asia. Later in the year, this agreement was expanded to include the People's Republic of China. In the rest of the world, we sell the NMP22 Lab Test Kit through distributors.

We have retained rights to sell all of our products in the United States except for (1) the Automated NMP22 Lab Test Kit which has been developed and launched internationally by DPC using proprietary antibodies sold by Matritech to DPC (2) the NMP22 BladderChek Device in the urology and oncology market and (3) any products developed by Sysmex based on NMP179.

One company, Institut Fur Klinische, accounted for 12% of our revenues in fiscal 2002. Two companies, Institut Fur Klinische and Fisher, accounted for 14% and 11% respectively, of our revenues in fiscal 2001. Two companies, Konica and Fisher, accounted for 13% and 18% respectively, of our revenues in fiscal 2000. No other company accounted for more than 10% of our total revenues in fiscal 2002, 2001 or 2000.

During the years ended December 31, 2000, 2001 and 2002, 19%, 15% and 11%, respectively, of our total product sales were from customers in the United States and 81%, 85% and 89%, respectively, were from customers in foreign countries. Product sales generated outside the United States during the years ended December 31, 2000, 2001 and 2002, were primarily from Europe. See Note 11 of Notes to Consolidated Financial Statements — "Segment and Geographic Information."

Foreign Operations

In June 2000, we acquired all of the outstanding shares of capital stock of Gesellschaft fur Allergie, Diagnostika und Laborkonzepte ("ADL"), now called Matritech GmbH, a European distributor of diagnostic testing products, including our NMP22 Lab Test Kit and the NMP22 BladderChek Device. Matritech GmbH is located in Freiburg, Germany. This acquisition was accounted for as a purchase, and accordingly the results of operations of Matritech GmbH from June 28, 2000 forward are included in our consolidated statements of operations.

At December 31, 2002, approximately 10% of our total assets were located at the German subsidiary, and approximately 74% of our revenue and 22% of our expenses, including cost of product sales, for fiscal year 2002 were related to this European operation.

Third-Party Reimbursement

Our ability to successfully commercialize our products will depend in part on the extent to which reimbursement will be available from government health administration authorities, private health insurers and other third-party payors. We believe that FDA approval of a diagnostic product facilitates third-party reimbursement for the testing service based on that diagnostic product, but reimbursement for services based on FDA approved products may not be available or, if available, may be inadequate.

In the case of private insurance, the reimbursement of any medical test, whether it is FDA approved or for investigational use only or for research use only, is at the sole discretion of the patient's individual carrier. The decision to reimburse can be made on a case-by-case basis (as is done for research therapies) or on a system-wide basis (such as screening mammography). Historically, the decision to reimburse for a new medical procedure or test is made by the carrier's medical director or review committee. This group will base its reimbursement decision on published clinical data and information provided by treating physicians. Even if a procedure has been approved for reimbursement, the insurance carrier may not continue to reimburse the procedure.

Health care reform is an area of continuing national and international attention and a priority of many government officials. Certain reform proposals, if adopted, could impose limitations on the prices we will be able to charge in the United States and elsewhere for our products or the amount of reimbursement available for tests based on our products from government agencies or third-party payors.

Currently Matritech management believes that U.S. laboratories performing NMP22 tests using the NMP22 Lab Test Kit and physicians performing such tests using the NMP22 BladderChek Device are being reimbursed by most insurance carriers, including the carriers managing Medicare reimbursement programs. However, management is certain that reimbursement is not universal and is working, on a case-by-case basis, with our distributor, individual physicians and laboratories to obtain reimbursement where requested. In Germany management believes that most patients receiving a test result from either the NMP22 Lab Test Kit or the NMP22 BladderChek Device are not reimbursed by insurance carriers or federal healthcare reimbursement programs and are paying for the test themselves.

Manufacturing and Facilities

We currently assemble our NMP22 Lab Test Kits in a portion of our 22,500 square-foot facility in Newton, Massachusetts and rely on subcontractors for certain components and processes. Matritech's NMP22 BladderChek Device is produced by a contract manufacturer experienced in the assembly of point-of-care devices. Our lease for our Newton facility requires annual base rental payments of $405,000 and expires on December 31, 2005. We have a first option to extend the lease for an additional five years at a base rent agreed upon with the lessor consistent with market rates in 2005.

We have retained all manufacturing rights for our products and products under development, except for (1) the Automated NMP22 Lab Test Kit which is being developed by DPC using proprietary antibodies sold by Matritech to DPC, (2) any products developed by Sysmex based on NMP179 and (3) certain rights that

could be granted to Konica, our NMP22 Lab Test Kit distribution partner in Japan, if we fail to perform under our agreement with Konica.

We currently rely on sole suppliers for certain key components for the NMP22 Test Kit and assembly for our NMP22 BladderChek Device. In the event that these suppliers are unable to supply these components or assemblies for any reason, we would seek alternative sources of supply or assembly, which could require reapproval by the FDA for such alternate suppliers. Although we attempt to maintain an adequate level of inventory to provide for these and other contingencies, should our manufacturing process be disrupted as a result of a shortage of key components or a revalidation of new components or the failure of an assembler to meet our requirements, there can be no assurance that we would be able to meet our commitments to customers. We are also subject to the FDA's Good Manufacturing Practice ("GMP") requirements. See "Government Regulation" below.

Competition

Matritech is not aware of any other company selling diagnostic or therapeutic products based on nuclear matrix protein technology. We have notified one company that its announced intention to develop certain products is likely to infringe certain claims contained in patents owned by or licensed to Matritech. However, competition in the development and marketing of cancer diagnostics and therapeutics, using a variety of technologies, is intense.

There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of cancer diagnostic testing products. Many of these organizations have financial, manufacturing, marketing and human resources greater than ours. Matritech expects that our diagnostic products will compete largely on the basis of clinical utility, accuracy (sensitivity and specificity), ease of use and other performance characteristics, price, patent position as well as on the effectiveness of our marketing partners and us.

We expect that our Lab Test Kits and our Point-of-Care Test Devices will compete with existing FDA-approved clinical tests, including tests known as BTA, UroVysion and ImmunoCyt bladder cancer tests, which have been approved for monitoring bladder cancer; a test known as CEA, which is used primarily for monitoring colorectal and breast cancers; a test known as CA19.9, which is used primarily for monitoring colorectal and gastric cancers; a test known as PSA, which is used primarily for monitoring and screening prostate cancer; and tests known as TRUQUANT® BR RIA, CA15.3 and CA27.29 which are used for monitoring breast cancer. We are also aware of a number of companies that have announced that they are engaged in developing cancer diagnostic products based upon oncogene technology.

In a larger sense, our diagnostic products also compete with more invasive or expensive procedures such as surgery, bone scans, magnetic resonance imaging and other *in vivo* imaging techniques. Matritech believes that our products, if successfully commercialized, will improve patient management and lower overall costs by providing accurate information and, in some cases, by providing alternatives to these invasive or costly procedures.

A number of companies are attempting to develop automated instruments for Pap smear screening that would compete with the instruments and systems which Sysmex intends to develop using NMP179. These companies are developing computerized image analysis techniques to automate much of the work currently done by cytotechnologists. To date, one of these instruments has been approved by the FDA for primary screening of Pap smear slides and for rescreening a percentage of slides previously identified by a cytotechnologist as normal, and several companies are proposing to submit applications for a similar system in the next couple of years.

The FDA approved a cervical disease diagnostic product, Hybrid Capture II ("HCII"), for use in detecting HPV, the viral infection believed to be the cause of all cervical cancers. Although many women, especially those under 35 years of age, are infected with this virus and test positive for HPV, most do not progress to cervical cancer. Nevertheless, the test for HPV may be selected by some gynecologists and clinical pathologists to identify women at higher risk of developing cervical cancer.

In addition, competing diagnostic products based on other technologies may be introduced by other companies and could adversely affect our competitive position. As a result, our products may become obsolete or non-competitive. See "Management's Discussion and Analysis of Financial Condition and Results of Operations — Factors That May Affect Future Results — We face intense competition and our technology may become obsolete" below.

Patents, Licenses and Trade Secrets

Matritech's diagnostic technology is protected by claims contained in patents owned by MIT and licensed to us and by patents owned by us. The MIT license relates to three United States patents owned by MIT which expire in 2006 and corresponding foreign patents granted and/or patent applications pending in Canada and selected countries in Europe and Asia. MIT has exclusively licensed to us worldwide rights to the nuclear matrix protein technology contained in these patents in exchange for royalties payable until expiration of the underlying patent rights. The protection offered by these patents extends to the detection and measurement of nuclear matrix proteins, or associated nucleic acids, using antibody or gene probe formats, as well as to certain assay methods exploiting nuclear matrix proteins.

Matritech has filed additional United States patent applications and, in certain circumstances, foreign counterparts in one or more countries including Australia, Canada and selected countries in Europe and Asia on additional developments relating to the nuclear matrix protein technology and to other cancer marker related technologies. We currently have sixteen additional United States patents and nine pending patent applications on file in the United States relating to these additional developments. Certain of our United States patents provide additional protection for our NMP22 Lab Test Kit and for our NMP22 BladderChek Device until 2014. It is our practice to file additional patent applications when we believe our scientists have made commercially significant discoveries whether they relate to nuclear matrix proteins or not. We believe that any patents that may issue from our applications will provide competitive protection for our products after expiration of our license from MIT.

We also will continue to rely on our unpatented proprietary information and trade secrets to maintain our commercial position. We have developed a Point-of-Care product (similar in appearance and function to over-the-counter type pregnancy kits) that use lateral-flow absorbent test strips having antibodies located at different positions along the test strips. Our NMP22 BladderChek Device uses these test strips, and we are investigating whether the manufacture, use, sale, or import of products that include these test strips in certain jurisdictions may require us to obtain patent licenses from third parties. We are pursuing such licenses where appropriate. There is no guarantee, however, that we will be able to obtain the appropriate patent licenses to permit us to make, use, sell, or import such products in the United States or in other countries.

Government Regulation

Diagnostic Products

The products we intend to market and manufacture are subject to extensive regulation by the FDA, and, in some instances, by foreign governments. Proprietary Lab Procedures, being services rather than products, do not require FDA review before being made commercially available. If such procedure involves the use of an antibody or similar reagent, the FDA submission required is for the analyte specific reagent which requires a 30 day review.

Pursuant to the Federal Food, Drug and Cosmetic Act of 1976, as amended, and the regulations promulgated thereunder (the "FDC Act"), the FDA regulates clinical testing, manufacturing, labeling, distribution, and promotion of medical devices such as our products. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket approval for devices, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device manufactured or distributed by us.

In the United States, medical devices and diagnostics are classified into one of three classes (class I, II, or III) on the basis of the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness. Under FDA regulations, class I devices are subject to general controls such as labeling, premarket notification and adherence to GMPs. Class II devices are subject to general and special controls (for example, performance standards, postmarket surveillance, patient registries and FDA guidelines). Generally, class III devices are those which must receive premarket approval ("PMA") by the FDA to ensure their safety and effectiveness (for example, life-sustaining, life-supporting and implantable devices, or new devices which have not been found substantially equivalent to legally marketed devices). Lab Test Kits for the diagnosis of cancer are class III devices and are submitted as PMAs to the FDA. Point-of-Care Test Devices for diagnosis of cancer are also class III devices for which PMAs or PMA supplements must be submitted if a Lab Test Kit version has been previously approved.

Before a new device can be introduced into the U.S. market, the manufacturer must generally obtain marketing approval through the filing of either a 510(k) notification or a PMA. 510(k) approval will be granted if the submitted information establishes that the proposed device is "substantially equivalent" to a legally marketed class I or II medical device, or to a class III medical device for which the FDA has not called for a PMA. This is often the route of approval for tests used in monitoring for disease. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, or that additional information or data is needed before a substantial equivalence determination can be made. A request for additional data may require that clinical studies of the safety and efficacy of the device be performed.

Commercial distribution of a device in the U.S. for which a 510(k) notification is required can begin only after the FDA issues an order finding the device to be "substantially equivalent" to a predicate device. It generally takes from three to twelve months from submission to obtain a 510(k) approval, but may take longer. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, or that additional information is needed before a substantial equivalence determination can be made.

A PMA application must be filed if a proposed device is not substantially equivalent to a legally marketed class I or class II device, or if it is a class III device for which the FDA has called for PMAs. A PMA application must be supported by valid scientific evidence which typically includes clinical trial data to demonstrate safety and the effectiveness of the device. The PMA application must also contain the results of all relevant bench tests, laboratory and animal studies, a complete description of the device and its components, and a detailed description of the methods, facilities and controls used to manufacture the device, as well as proposed labeling.

Upon receipt of a PMA application, the FDA makes a threshold determination as to whether the application is sufficiently complete to permit a substantive review. If the FDA determines that the PMA application is sufficiently complete to permit a substantive review, the FDA will accept the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the PMA. An FDA review of a PMA application can take as long as two years from the date the PMA application is accepted for filing, and occasionally longer. The review time is often significantly extended as a result of the FDA requiring more information or clarification of information already provided in the submission. During the review period, an advisory committee, typically a panel of clinicians and/or other appropriate experts in the relevant fields, will likely be convened to review and evaluate the application and recommend to the FDA whether to approve or disapprove the device. The FDA is not bound by the recommendations of the advisory committee but generally follows them. Toward the end of the PMA review process, the FDA generally will conduct an inspection of the manufacturer's facilities to ensure that the facilities are in compliance with applicable GMP requirements.

If the FDA's evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions which must be met in order to secure final approval for sale of the device. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter, authorizing commercial marketing of the device for certain indications. If the FDA's evaluations of the PMA application or manufacturing facilities are not favorable, the FDA will delay or deny approval of the PMA application or

issue a "not approvable letter." The FDA may also determine that additional clinical trials are necessary, in which case approval may be substantially delayed while additional clinical trials are conducted and submitted. The PMA process can be expensive, uncertain and lengthy. A number of devices for which FDA approval has been sought by other companies have never been approved for marketing.

Once a device has been approved, modifications to the device, its labeling, or manufacturing process may require review by the FDA using PMA supplements or a new PMA. PMA supplements often require the submission of the same type of information required for an initial PMA submission, except that the supplement generally is limited to that information needed to support the proposed change from the product approved in the original PMA.

Although clinical investigations of most devices are subject to the investigational device exemption ("IDE") requirements, clinical investigations of *in vitro* diagnostic tests ("IVD") are exempt from the IDE requirements, including FDA approval of investigations, provided the testing is non-invasive, does not require an invasive sampling procedure that presents significant risk, does not introduce energy into a subject, and the tests are not used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure. IVD manufacturers must also establish distribution controls to ensure that IVDs distributed for the purposes of conducting clinical investigations are used only for that purpose. Pursuant to current FDA policy, manufacturers of IVDs labeled for investigational use only ("IUO") or research use only ("RUO") are encouraged by the FDA to establish a certification program under which investigational IVDs are distributed to or utilized only by individuals, laboratories, or health care facilities that have provided the manufacturer with a written certification of compliance indicating that (1) the device will be used for investigational or research purposes only, and (2) results will not be used for diagnostic purposes without confirmation of the diagnosis under another medically established diagnostic device or procedure. In addition, the certification program requirements for IUO products should include assurances that all investigations or studies will be conducted with approval from an institutional review board ("IRB"), using an IRB-approved study protocol and patient informed consent and that the device will be labeled in accordance with the applicable labeling regulations. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study provided such compensation does not exceed recovery of the costs of manufacture, research, development and handling.

In 1996, the FDA approved Matritech's NMP22 Lab Test Kit for bladder cancer for sale in the United States as a predictor of occult or rapidly recurring bladder cancer following therapy, such as surgical excision of cancerous tissue. In 2000 the FDA approved the expanded claim of our NMP22 Lab Test Kit for the additional use of diagnosing previously undiagnosed individuals who have symptoms of or are at risk for bladder cancer.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences with the use of the device. Device manufacturers are required to register their establishments and list their devices with the FDA, and are subject to periodic inspections by the FDA and certain state agencies. The FDC Act requires devices to be manufactured in accordance with GMP regulations which impose certain procedural and documentation requirements upon us with respect to manufacturing and quality assurance activities.

Labeling and promotional activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The FDA actively enforces regulations prohibiting the promotion of devices for unapproved uses and the promotion of devices for which premarket approval has not been obtained. Consequently, in the United States we cannot promote the NMP22 Lab Test Kit for any unapproved use. Failure to comply with these requirements can result in regulatory enforcement action by the FDA that would adversely affect our ability to conduct testing necessary to obtain market approval for these new uses and, in addition, could have a material adverse effect on our business, financial condition and results of operations.

Our products are also subject to a variety of state laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those states or localities. Manufacturers are also subject to numerous federal, state and local

laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. Compliance with such laws and regulations now or in the future could result in significant additional expense or result in material adverse effects upon our ability to do business.

Foreign Sales

Export of unapproved products subject to the PMA requirements must be approved in advance by the FDA for export unless they are approved for use by the regulatory authorities in any member state of the European Union and certain other countries, in which case they may be exported to any such country without FDA approval. To obtain FDA export approval, when it is required, certain requirements must be met and information must be provided to the FDA, including, with some exceptions, documentation demonstrating that the product is approved for import into a country to which it is to be exported and safety data from animal or human studies. In some cases the FDA may not grant export approval when such approval is necessary, and some countries to which the devices are to be exported may not approve the devices for import. Failure on our part to obtain export approvals, when required, could significantly delay and impair our ability to continue exports of our devices and could have a material adverse effect on our business, financial condition or results of operations.

The introduction of our developmental-stage and FDA-approved cancer diagnostic products in foreign markets will also subject us to foreign regulatory registrations and/or approvals which may impose additional substantial costs and burdens. International sales of medical devices are subject to the regulatory requirements of each country. The regulatory review process varies from country to country. Many countries also impose product standards, packaging requirements, labeling requirements and import restrictions on devices. In addition, each country has its own tariff regulations, duties and tax requirements. In Germany, where we began selling our NMP22 Lab Test Kit for bladder cancer in 1995, no regulatory approval comparable to the United States PMA is required prior to public sale of diagnostic products. In 1998, Koseisho approved the NMP22 Lab Test Kit for sale in Japan for use in screening previously undiagnosed patients. In 1999, the State Drug Administration in the People's Republic of China approved the NMP22 Lab Test Kit for sale in the People's Republic of China for the detection and management of bladder cancer. Our NMP22 BladderChek Device has been registered for sale, if required, in most of the major markets where we currently have sales. The approval by the FDA and foreign government authorities is unpredictable and uncertain. Delays in receipt of, or a failure to receive, such approvals, or the loss of any previously received approvals, could have a material adverse effect on our business, financial condition and results of operations.

Changes in existing requirements or adoption of new requirements or policies could adversely affect our ability to comply with regulatory requirements. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. We may be required to incur significant costs to comply with laws and regulations in the future which could have a material adverse effect upon our business, financial condition or results of operations.

CLIA

Pursuant to the Clinical Laboratory Improvement Amendments ("CLIA"), the FDA assigns a complexity category to each new *in vitro* diagnostic test. This category will determine the rigor of quality control that must be followed by purchasers and users of the device and, thus, can affect purchasing decisions of laboratories and hospitals. In addition, as part of the premarket review process, manufacturers must establish that the device's quality control instructions are commensurate with CLIA quality control requirements for that device. The review period for *in vitro* diagnostic tests may be extended due to these new CLIA requirements. The NMP22 Lab Test Kit has been designated as a high complexity device. The NMP22 BladderChek Device has been CLIA-waived by the FDA which means it can be performed in the physician's office by staff who do not need specialized certification.

Other

In order for us to conduct preliminary studies or clinical trials at a hospital or other health care facility, our research collaborators must first obtain approval from the Institutional Review Board ("IRB") of the hospital or health care facility. In each case, a written protocol must be submitted to the IRB describing the study or trial, which is reviewed by the IRB with a view to protecting the safety and privacy of the institution's patients.

In addition to the regulatory framework for clinical trials and product approvals, we are subject to regulation under federal, state and local law, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and possible future local, state, federal and foreign regulation.

Employees

As of March 1, 2003, we had 50 full-time employees, 16 of whom were engaged in research and development. Our future success depends in part on our ability to recruit and retain talented and trained scientific, technical, marketing and business personnel. We have been successful to date in hiring and retaining such personnel, but competition for these kinds of personnel is intense. None of our employees are represented by a labor union, and we consider our relations with our employees to be good.

Research and Development

Matritech's future success will depend in large part on our ability to develop and bring to market new products based on our proprietary technology. Accordingly, we devote substantial resources to research and development. We have assembled a scientific staff with a variety of complementary skills in several advanced research disciplines, including molecular biology, immunology and protein chemistry. In addition, we maintain consulting and advisory relationships with a number of prominent researchers.

During 2000, 2001 and 2002, Matritech spent approximately $2.3 million, $3.4 million and $3.8 million, respectively, on research, development and clinical affairs. Substantially all of these expenditures were related to the development of diagnostic products and conducting clinical trials.

Our expenditures and strategy for research and development are set out in greater detail in Item 7, Management's Discussion and Analysis, Research and Development.

Recent Developments

On March 31, 2003, we completed a private placement of 7.5% Convertible Debentures (the "Convertible Debentures") in an aggregate subscription amount equal to $5 million and accompanying Warrants for an aggregate of 784,314 shares of our common stock, including a Warrant for 98,039 shares issued to a placement agent in connection with this transaction (the "Private Placement"). The Convertible Debentures are convertible into shares of our common stock at a conversion price initially equal to $2.55, but which will be adjusted downward (subject to certain limited exceptions) upon any dilutive issuances of our securities to an amount equal to 112% of the price at which such dilutive issuance is made, resulting in the potential for issuance of additional shares of our common stock upon conversion of the Convertible Debentures. The Convertible Debentures bear interest at the rate of 7.5% per annum, payable quarterly, and permit us, in certain circumstances, to make such interest payments in shares of common stock based on a 5% discount to the valuation of the common stock. The Convertible Debentures are redeemable in monthly installments equal to $1/26^{th}$ of the aggregate subscription amounts paid for such Convertible Debentures, such monthly payments to commence on the first of the month after the 11 month anniversary of the closing date. The monthly redemption payments, subject to certain conditions, may also be made in shares of common stock based on a 10% discount to valuation. The Warrants are immediately excercisable for a period of five years at an initial exercise price of $2.278. The exercise price of the Warrants will initially be adjustable down to the issuance price of any subsequent dilutive issuances (subject to certain limited exceptions), and after the Convertible

Debentures are no longer outstanding, the exercise price of the Warrants will be adjustable based on a weighted-average basis upon any such subsequent dilutive issuance.

The aggregate number of shares of common stock issuable upon exercise of the Warrants and conversion of the Convertible Debentures, including as a result of any anti-dilution adjustments, and in connection with any payment of interest on or redemption of such Convertible Debentures, is capped at an aggregate of 6,426,127 shares unless shareholder approval is subsequently obtained. In addition, in the event shareholder approval is obtained, our stock price meets certain levels and there is an effective registration statement covering the shares of common stock underlying the Convertible Debentures and Warrants issued in connection with the first closing, a second closing may be held with the same purchasers for the issuance of additional Convertible Debentures in an aggregate subscription amount of $3 million and additional Warrants for an amount of shares equal to 35% of the number of shares for which such additional Convertible Debentures are initially convertible. Under the terms of the Private Placement we are required to file a registration statement covering the shares of our common stock underlying the Convertible Debentures and Warrants within 30 days of closing.

The Convertible Debentures may become immediately due and payable at a premium of 120% of the outstanding principal amount plus accrued interest and damages in the event of default by us of certain covenants and also obligate us to pay damages and interest upon certain events. Events of default under the Convertible Debentures include, among other things, failure to remain listed on any of the Nasdaq SmallCap Market, New York Stock Exchange, American Stock Exchange or the Nasdaq National Market, sale or disposition of our assets in excess of 33% of our total assets, failure to timely deliver stock certificates upon conversion, and default on our existing or future liabilities in excess of $150,000. In addition, the terms of the Private Placement prohibit us from entering into obligations that are senior to the Convertible Debentures and place certain restrictions on our ability to raise additional capital through equity issuances, including a prohibition on such activity (with certain limited exceptions) for a period of 90 days from the effective date of the registration statement filed with respect to the shares underlying the Convertible Debentures and Warrants, and an ability to match any additional funds raised on the same terms. See Factors That May Affect Future Results — *"We recently completed a private placement for the issuance of $5 million of 7.5% Convertible Debentures (the "Convertible Debentures") and accompanying 5-Year Warrants (the "Warrants") which may have a significant dilutive impact on the ownership interest of our existing stockholders," "We have substantially increased our indebtedness," "If we are unsuccessful in obtaining needed additional capital on an on-going basis, we may be unable to conduct our business as planned, to pursue desirable markets for our current products or to develop and market new products," and "We cannot assure you that we will continue to meet the NASDAQ listing requirements and failure to maintain a listing for more than ten trading days would place us in default under the Convertible Debentures."*

Available Information

We are subject to the informational requirements of the Securities Exchange Act, and in accordance with those requirements file reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy the reports, proxy statements and other information that we file with the Commission under the informational requirements of the Securities Exchange Act at the Commission's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call 1-800-SEC-0330 for information about the Commission's Public Reference Room. The Commission also maintains a Web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Commission. The address of the Commission's Web site is http: //www.sec.gov. Our Web site is http: //www.matritech.com. Information contained on our Web site is not a part of this report.

Item 2. ***Properties.***

Our corporate headquarters in Newton, Massachusetts which houses our research and development and manufacturing facilities comprise approximately 22,500 square feet. Our lease is for a term of five years and expires on December 31, 2005, with the right to renew for an additional five-year period at the then market rate. The annual base rent for each year of the present term is $405,000. These facilities are adequate to meet

our expected growth for at least the next two years and would not require any substantial modification or expansion if we were to start manufacturing any additional products or components used in our products. Additionally, we lease approximately 5,700 square feet of sales office space in Freiburg, Germany. The German lease is for a term of five years and expires on January 31, 2006. The annual base rent for each year of the term is approximately $50,000. These facilities are adequate to meet our expected growth for at least the next year.

Item 3. ***Legal Proceedings.***

We are not currently a party to any material pending legal proceeding.

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 2002.

PART II

Item 5. ***Market For Registrant's Common Equity and Related Stockholder Matters.***

Since January 27, 2003, our common stock has been traded on The NASDAQ SmallCap Market under the symbol: "NMPS." Prior to January 27, 2003, our common stock was traded on the NASDAQ National Market. The following table sets forth the range of quarterly high and low bid price information for the common stock as reported by the NASDAQ National Market.

	High	Low
Fiscal 2001		
First Quarter	$6.250	$2.750
Second Quarter	4.140	2.750
Third Quarter	3.330	0.900
Fourth Quarter	3.720	1.000
Fiscal 2002		
First Quarter	$3.150	$2.040
Second Quarter	3.250	2.000
Third Quarter	2.900	1.350
Fourth Quarter	2.350	1.460

As of March 1, 2003, there were approximately 400 shareholders of record. We believe that shares of our common stock held in bank, money management, institution and brokerage house "nominee" names may account for an estimated 10,000 additional beneficial holders.

We have never paid cash dividends on our common stock. We currently intend to retain any earnings to finance future growth and therefore do not anticipate paying any cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders(1)	2,533,865(3)	$3.38	2,983,320(4)
Equity compensation plans not approved by security holders(2)	200,000	$2.50	—
Total	2,733,865	$3.32	2,983,320

(1) Includes the 1988 Stock Plan, 1992 Stock Plan, Amended and Restated 1992 Non-Employee Director Stock Plan, 1992 Employee Stock Purchase Plan, 2002 Stock Option and Incentive Plan, 2002 Non-Employee Director Stock Option Plan and the 2002 Employee Stock Purchase Plan.

(2) Consists of warrants to purchase 200,000 shares of common stock at a price of $2.50 per share. These warrants were issued in 2000 to a placement agent in connection with a stock offering and are exercisable until July 2005.

(3) Excludes purchase rights accruing under the 2002 Employee Stock Purchase Plan, which has a stockholder-approved reserve of 225,000 shares and 221,000 shares were available for purchase rights under the Plan as of December 31, 2002.

(4) Consists of shares available for future issuance under the 2002 Stock Option and Incentive Plan, 2002 Non-Employee Director Stock Option Plan and the 2002 Employee Stock Purchase Plan.

Recent Sales of Unregistered Securities

During the fiscal year ended December 31, 2002, we issued the following securities that were not registered under the Securities Act of 1933, as amended (the "Securities Act"):

In March 2002, we completed a private placement of 538,437 units, at a purchase price of $8.00 per unit. Each unit consists of four shares of common stock and a warrant to purchase one share of common stock at a price of $3.00 per share. These warrants were exercisable until November 30, 2002 and were callable by us if certain conditions are satisfied. We received net proceeds of approximately $4,140,000 after deducting transaction expenses. None of these warrants have been exercised.

In November 2002, we entered into an exclusive worldwide license and exclusive supply agreement with Sysmex Corporation ("Sysmex"). Under the agreement, Sysmex purchased 783,208 shares of our common stock at a price of $2.55 per share.

In December 2002, we completed a private placement of 222,077 units, at a purchase price of $5.31 per unit. Each unit consists of three shares of common stock and a warrant to purchase one share of common stock at a price of per share. These warrants are exercisable until December 9, 2005 and are callable by us if certain conditions are satisfied. We received net proceeds of approximately $1,155,000. None of these warrants have been exercised.

The offer and sale of securities in the transaction described above was exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act and Regulation D promulgated thereunder, as a transaction by an issuer not involving any public offering. The recipients of securities in this transaction represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in this transaction.

Item 6. ***Selected Financial Data.***

The selected financial data presented below for each year in the five-year period ended December 31, 2002, have been derived from our consolidated financial statements. This data should be read in conjunction with the financial statements, related notes, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information included elsewhere in this Form 10-K.

	1998	1999	2000	2001	2002
Statements of Operations Data:					
Revenue:					
Product sales and collaboration fees	$ 967,759	$ 622,808	$ 1,245,611	$ 2,340,940	$ 3,280,131
Expenses:					
Cost of product sales	749,436	603,349	983,466	1,705,908	2,149,115
Research, development and clinical	3,260,932	2,543,456	2,295,097	3,362,024	3,805,435
Selling, general and administrative	4,922,114	3,803,252	5,130,124	6,151,330	5,657,908
Total operating expenses	8,932,482	6,950,057	8,408,687	11,219,262	11,612,458
Loss from operations	7,964,723	6,327,249	7,163,076	8,878,322	8,332,327
Interest income	457,678	224,658	345,644	169,665	75,164
Interest expense	28,479	21,625	18,822	22,170	21,111
Net loss	$(7,535,524)	$(6,124,216)	$(6,836,254)	$(8,730,827)	$(8,278,274)
Basic/diluted net loss per common share(1)	$ (0.40)	$ (0.29)	$ (0.28)	$ (0.33)	$ (0.27)
Weighted average number of common shares outstanding(1)	18,608,784	21,126,422	24,802,015	26,319,329	30,490,071

	1998	1999	2000	2001	2002
Balance Sheet Data:					
Cash and cash equivalents	$ 4,146,821	$ 5,612,194	$ 4,661,005	$ 4,819,733	$ 4,172,013
Working capital	3,787,709	5,341,336	4,587,611	4,337,372	3,663,781
Total assets	5,511,825	6,902,575	6,595,468	6,612,260	6,818,173
Accumulated deficit	(41,151,016)	(47,275,232)	(54,111,486)	(62,842,313)	(71,120,587)
Total stockholders' equity	$ 4,399,981	$ 5,943,460	$ 5,568,008	$ 5,221,862	$ 3,838,985

(1) Basic and diluted net loss per share are the same for all periods presented. See Note 1 of Notes to Consolidated Financial Statements.

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations.***

This Annual Report, other reports and communications to security holders, as well as oral statements made by our officers or agents may contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may relate to, among other things, our future revenues, operating income and the plans and objectives of management. In particular, certain statements contained in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in "Factors That May Affect Future Results" constitute forward-looking statements. Actual events or results may differ materially from those stated in any forward-looking statement. Factors that may cause such differences are discussed below and in our other reports filed with the Securities and Exchange Commission (the "Commission").

Overview

We were incorporated in 1987 to develop, manufacture and market innovative cancer diagnostic products based on our proprietary NMP technology. We have been unprofitable since inception and expect to incur significant operating losses for at least the next several years. For the period from inception to December 31, 2002 we incurred a cumulative net loss of approximately $71.1 million.

The results of operations for the years ended December 31, 2001 and 2002 include the activities of our European subsidiary, Matritech GmbH. The results of operations for the year ended December 31, 2000 include the activities of Matritech GmbH, from June 28, 2000 (the date of acquisition) to December 31, 2000. Matritech GmbH distributes our products and third-party products in Europe.

We are engaged in the research, production and marketing of cancer diagnostic products. Our primary research focus is on the identification of proteins in the body which are associated with or created by cancerous processes and which, when measured, can provide useful medical information to physicians. In the last five years, our research has focused on discovering these substances using low-throughput research mass spectrometry. Because low-throughput research mass spectrometry technology was determined to be inadequately controllable and reproducible and too costly to create commercially viable products or services, in the last two years our research has been focused on applying high-throughput mass spectrometry methods to measure the proteins characterized as clinical candidates during discovery research and to improve the controls and reproducibility of our mass spec technology.

To develop products which will provide physicians medically useful information, we can develop our technology in three different ways: Lab Test Kits, Point-of-Care Test Devices and Proprietary Laboratory Procedures. For technological and marketing reasons, we have decided initially to launch our newer technologies — NMP35, NMP48 and NMP66 — as Proprietary Laboratory Procedures using high throughput mass spectrometry technology.

Agreements

In 2001, we entered into an eight-year, non-exclusive product supply and marketing agreement with DPC enabling DPC to develop and market an automated version of our NMP22 Lab Test Kit. Under this agreement we receive royalty payments which are recognized when earned. In all such agreements, the determination of when royalties are earned is based upon the receipt of data from the licensees in accordance with the related license agreement supporting the amount of and basis for such royalty payments to us.

In March 2002, we entered into a supply and distribution agreement with MBL granting MBL the exclusive right in Japan to sell the NMP22 BladderChek Device. MBL is responsible for conducting clinical trials and securing the necessary regulatory approvals in Japan. Under the terms of this agreement MBL paid us a non-refundable license fee which is being recognized as revenue over the eight-year term of the agreement.

In September 2002, we entered into a distribution agreement with Cytogen, granting Cytogen the exclusive right to market and sell the NMP22 BladderChek Device in the United States to the urology and oncology marketplace. Under the terms of the agreement, Cytogen paid a non-refundable license fee which is being recognized as revenue over the five-year term of the agreement.

In November 2002, we entered into an exclusive license and supply agreement with Sysmex, which granted them the use of NMP179 technology for automated non-slide-based laboratory instruments. Under the terms of the agreement, Sysmex purchased shares of our common stock at a premium. A premium of approximately $500,000 has been ascribed to the value of the license and is being recognized as revenue over the fourteen-year term of the related patents. This agreement also contains future royalty, milestone and research and development payments. We will recognize any future royalty and milestone payments over the remaining life of the related patents.

In March 2003, we entered into a collaboration and commercialization agreement with Mitsubishi Kagaku Medical, Inc., a division of Mitsubishi Chemical, whereby we will collaborate to develop and validate

a Proprietary Lab Procedure for NMP66 suitable for implementation in one or more commercial laboratories in Japan. Under the terms of this agreement, Mitsubishi will pay Matritech an upfront fee as well as several milestone payments. These payments will be recognized over the term of the agreement.

Results of Operations

Year Ended December 31, 2002 Compared with Year Ended December 31, 2001

Total revenue increased to $3,280,000 from $2,341,000 for the years ended December 31, 2002 and 2001, respectively. The revenue earned in the 2002 period consisted of $3,094,000 of product sales and $186,000 of revenue from various alliances and amortization of prepaid marketing fees. The revenue earned in the 2001 period consisted entirely of product sales. Sales of our NMP22 bladder cancer product line totaled approximately $1,180,000 and $664,000 for the years ended December 31, 2002 and 2001, respectively. This increase is primarily due to increased sales of the point-of-care NMP22 BladderChek Device. The sales growth is being driven by the expansion of our distribution partner base with significant distributors being added during the year. During 2002, we shipped approximately $344,000 of the NMP22 BladderChek Device to distributors for which we did not have sufficient history to estimate returns. Accordingly, these amounts are included in deferred revenue at December 31, 2002, and will be recognized as revenue when the distributor reports to us that it has either shipped or disposed of the devices (indicated that the return period has lapsed). Product sales of the allergy products distributed by Matritech GmbH totaled approximately $1,877,000 and $1,600,000 for the years ended December 31, 2002 and 2001, respectively.

We recognize alliance revenue and prepaid marketing fees over the lives of the respective contracts. Deferred revenue related to various alliances and prepaid marketing fees increased to $867,000 at December 31, 2002 from $30,000 at December 31, 2001. This increase is primarily due to a new collaborative license and development agreement with a business partner which contains a non-refundable license fee of approximately $500,000. This payment is being recognized as revenue over the 14 year life of the license agreement. We also entered into several other agreements with distributors which contain upfront nonrefundable payments totaling $350,000. These payments are being recognized as revenue of the life of the arrangements which range from 5 to 8 years.

Cost of product sales increased to $2,149,000 from $1,706,000 for the years ended December 31, 2002 and 2001, respectively. As a percentage of product sales, cost of sales decreased to 69% from 73% for the years ended December 31, 2002 and 2001, respectively. The decrease in cost of sales on a percentage basis is largely the result of increased sales of the point-of-care NMP22 BladderChek Device which carries higher margins than other products.

Research, development, clinical and regulatory expenses increased to $3,805,000 from $3,362,000 for the years ended December 31, 2002 and 2001, respectively. Clinical site payments and supplies costs increased a total of $196,000 due to the increased number of active projects, salary-related costs increased $175,000 due to increased headcount and patent-related legal fees increased $103,000.

Selling, general and administrative expenses decreased to $5,658,000 from $6,151,000 for the years ended December 31, 2002 and 2001, respectively. The changes were primarily due to the following: a $213,000 increase in marketing and promotion costs, a $181,000 increase in personnel costs due to increased headcount and a $119,000 increase in travel costs, which were offset by the absence of $1,020,000 of noncash compensation expense in 2002 and the absence of goodwill amortization of $89,000.

Interest and other income was $75,000 for the year ended December 31, 2002 and $170,000 for the year ended December 31, 2001. The decrease was due to a lower average cash balance for investment along with lower investment yields.

Year Ended December 31, 2001 Compared with Year Ended December 31, 2000

Product sales increased to $2,341,000 from $1,246,000 for the years ended December 31, 2001 and 2000, respectively. This increase was primarily due to the inclusion of a full year of Matritech GmbH results in 2001, an increase in Matritech GmbH's European sales of distributed products of $974,000, and an increase in

research-use product sales in the United States of $65,000. Sales of our NMP22 bladder cancer product line totaled approximately $664,000 and $609,000 for the years ended December 31, 2001 and 2000, respectively. Product sales of the allergy products distributed by Matritech GmbH totaled approximately $1,600,000 and $626,000 for the years ended December 31, 2001 and 2000, respectively.

Cost of product sales increased to $1,706,000 from $983,000 for the years ended December 31, 2001 and 2000, respectively. As a percentage of product sales, cost of sales decreased to 73% from 79% for the years ended December 31, 2001 and 2000, respectively. The decrease in cost of sales as a percentage of sales is due to the inclusion of a full year of Matritech GmbH's sales of third-party products in 2001 which carry higher margins than the microtiter plate format NMP22 Lab Test Kit developed and manufactured by Matritech. Matritech product margins are negatively affected by costs related to excess capacity maintained by the Company to support planned future sales increases.

Research, development, clinical and regulatory expenses increased to $3,362,000 from $2,295,000 for the years ended December 31, 2001 and 2000, respectively. Clinical consulting costs and site payments increased a total of $653,000 due to the increased number of active projects. Payroll-related expenses and recruiting costs increased $84,000 and $67,000, respectively, due to increased headcount. The allocated portion of rent and utilities increased $87,000 under the amended lease agreement. Other increases include $55,000 for contract research related to our NMP22 BladderChek Device, $39,000 for lab supplies expense and $61,000 for temporary help.

Selling, general and administrative expenses increased to $6,151,000 from $5,130,000 for the years ended December 31, 2001 and 2000, respectively. The increase was primarily due to the following: a $652,000 increase in Matritech GmbH's operational expense as a full year is included in 2001 compared to only two quarters in 2000, a $213,000 increase in personnel costs due to higher headcount, increased amortization of goodwill and deferred compensation in 2001 of $192,000 and $178,000 increase in outside legal costs related to new alliance and partnership arrangements. These increases were offset by a $278,000 reduction in consulting costs due to a market study conducted by the Company in 2000.

Interest and other income was $170,000 for the year ended December 31, 2001 and $346,000 for the year ended December 31, 2000. The decrease was primarily due to a lower investment yield in 2001 as compared to 2000.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private and public offerings of our securities and through funded development and marketing agreements. At December 31, 2002, we had cash and cash equivalents of $4,172,000, working capital of $3,664,000, and an accumulated deficit of $(71,121,000). Based on our current rate of cash utilization, our cash at December 31, 2002 is expected to last through June 2003. However, we believe that our existing cash resources, the Private Placement we completed in March 2003, product sales, corporate partnerships and other developments and changes in our operations will be sufficient to satisfy our capital needs through 2003.

We are currently seeking to raise additional capital and will consider various financing alternatives, including equity or debt financings and corporate partnering arrangements. However, we may not be able to raise needed capital on terms that are acceptable to us, or at all. If we raise funds on unfavorable terms, we may provide rights and preferences to new investors which are not available to current shareholders. Any future equity financings will dilute the ownership interest of our existing investors and may have an adverse impact on the price of our common stock. If we do not receive additional financing or do not receive an adequate amount of additional financing, we will be required to curtail our expenses by reducing research and/or marketing or to take other steps that could hurt our future performance, including but not limited to, the premature sale of some or all of our assets or product lines on undesirable terms, merger with or acquisition by another company on unsatisfactory terms or the cessation of operations. Any of the foregoing steps will have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that capital will be available on terms acceptable to us, if at all.

Our operating activities used cash of approximately $7,200,000, $6,886,000 and $5,710,000 for the years ended December 31, 2002, 2001 and 2000, respectively, primarily to fund our operating loss. The increase in net cash used in operating activities for the year ended December 31, 2002 was primarily due to an increase in the net loss of $568,000 exclusive of a noncash expense of $1,021,000 related to investor relation warrants issued in 2000, an increase in accounts receivable due to higher product shipments offset by an increase in deferred revenue. For the year ended December 31, 2002, Days Sales Outstanding (DSO) was approximately 82 days versus approximately 42 days for the year ended December 31, 2001. Approximately 25 days in the 2002 period is the result of deferring revenue on shipments of the point-of-care NMP22 BladderChek Device. The remaining increase from the 2001 to 2002 period is primarily the result of increased sales volume at the end of the quarter in the 2002 period.

Our investing activities used cash of approximately $564,000, $97,000 and $306,000 in the years ended December 31, 2002, 2001 and 2000, respectively, primarily for the purchase of laboratory equipment, and in the 2000 period, for amounts paid in connection with the purchase of Matritech GmbH. We acquired net fixed assets of $202,000 in the acquisition of Matritech GmbH. We expect to use approximately $250,000 in 2003 for purchases of property and equipment.

Our financing activities provided cash of approximately $7,146,000, $7,128,000 and $5,073,000 in the years ended December 31, 2002, 2001 and 2000, respectively. The activity in the 2002 period resulted primarily from proceeds from the sale of common stock and warrants and proceeds from a note payable offset by payments on notes payable. The activity in the 2001 and 2000 periods resulted primarily from proceeds received from the sale of common stock under an equity financing agreement as well as proceeds received from the exercise of common stock warrants, net of payments on notes payable.

In connection with the acquisition of Matritech GmbH, we assumed certain debt obligations. At December 31, 2002, these obligations consist of a $67,000 loan from a bank, a $42,000 third-party demand note and $3,000 worth of automobile loans. The bank loan bears interest at 5.2%, is due in monthly installments of $4,000 and is secured by trade receivables and inventory. The demand note will be repaid by us and we will be reimbursed by a key Matritech GmbH employee. We have recorded a corresponding asset for this employee receivable. The automobile loans bear interest between 6.99% and 7.50% and are due in monthly installments of $600.

In 2000, Matritech GmbH entered into a 5-year extension of the distribution agreement with Hitachi which contains minimum annual purchase commitments. These commitments are negotiated annually for the following year. The 2003 minimum purchase commitment totals $95,000.

In June 2000, we signed an amendment to the original 1995 lease agreement for our space in Massachusetts which extended the lease term for an additional five years, ending December 31, 2005, and a five-year option for the period commencing January 1, 2006. The amendment provides for a change in the monthly rent amount and the security deposit to conform to the then market rates; the remainder of the lease terms, however, is substantially unchanged.

Our future commitments are as follows:

	Total	2003	2004	2005	2006
Facility and equipment leases	$1,571,000	$543,000	$519,000	$500,000	$ 9,000
Maturities of debt obligations	476,000	160,000	133,000	113,000	70,000
Purchase commitments	95,000	95,000	—	—	—
Total	$2,142,000	$798,000	$652,000	$613,000	$79,000

In July 2000, we filed a Form S-3 shelf registration statement with the Commission for the issuance of up to 2.45 million shares of our common stock. In August 2000, we entered into a common stock purchase agreement covering the sale of up to $30 million (a maximum of 2.45 million shares) of our common stock with Acqua Wellington North American Equities Fund, Ltd. (“Acqua”). During the term of the agreement

Acqua purchased 1,386,477 shares, with net proceeds to us of $5,013,000. The Acqua agreement terminated on October 22, 2001.

In December 2001, we sold an aggregate of 1,063,523 shares of common stock for prices ranging from $2.15 to $2.74 per share. These shares were sold under our Registration Statement on Form S-3 dated July 28, 2000. Proceeds from this sale were $2,246,000 after deducting transaction expenses.

In December 2001, we completed a private placement of 113,969 units, at a purchase price of $9.44 per unit. Each unit consists of four shares of common stock and a warrant to purchase one share of common stock at a price of $2.75 per share. These warrants are exercisable over two years and are callable by us if certain conditions are satisfied. We received net proceeds of $1,061,000 after deducting transaction expenses. In 2002, warrants to purchase 4,000 shares of common stock were exercised.

In March 2002, we completed a private placement of 538,437 units, at a purchase price of $8.00 per unit. Each unit consists of four shares of common stock and a warrant to purchase one share of common stock at a price of $3.00 per share. These warrants were exercisable until November 30, 2002 and were callable by us if certain conditions were satisfied. We received net proceeds of approximately $4,140,000 after deducting transaction expenses. None of these warrants have been exercised.

In July 2002, we entered into a term note for $410,000 with Citizens Bank of Massachusetts to finance an equipment purchase. The term note is payable over four years, bears interest at 1% plus the bank's prime rate and contains a covenant which requires us to maintain a cash balance of $250,000 at all times. This note is collateralized by the capital equipment. If the ratio of our cash and cash equivalents to total liabilities (excluding deferred revenue) is 115% or less, the bank has the right to exchange the equipment as collateral for a certificate of deposit in the amount of $410,000. We were in compliance with all debt covenants at December 31, 2002.

In November 2002, we entered into an exclusive worldwide license and exclusive supply agreement with Sysmex Corporation ("Sysmex"). Under the agreement, Sysmex purchased 783,208 shares of our common stock at a price of $2.55 per share A premium of approximately $500,000 has been ascribed to the value of the license and is being recognized as revenue over the fourteen-year term of the related patents.

In December 2002, we completed a private placement of 222,077 units, at a purchase price of $5.31 per unit. Each unit consists of three shares of common stock and a warrant to purchase one share of common stock at a price of $2.30 per share. These warrants are exercisable until December 9, 2005 and are callable by us if certain conditions are satisfied. We received net proceeds of approximately $1,155,000. None of these warrants have been exercised.

In March 2003, we completed a private placement of $5 million of 7.5% Convertible Debentures and Warrants to purchase 784,313 shares of Common Stock at an initial exercise price of $2.278 and including a Warrant for 98,039 shares issued to a placement agent in connection with the transaction. The Convertible Debentures are convertible into shares of our common stock and interest and redemption payments may, subject to certain circumstances, be made in shares of common stock at a discount to valuation. The Warrants are exercisable until March 31, 2008. We received net proceeds of approximately $4.5 million. A second closing may be held for an additional aggregate subscription amount of $3 million based on the share price of our common stock reaching a certain level, but only if shareholder approval has already been obtained and there is an effective registration statement covering the shares of common stock underlying the Convertible Debentures and Warrants issued in connection with the first closing. See Recent Developments and Factors That May Affect Future Results — *"We recently completed a private placement for the issuance of $5 million of 7.5% Convertible Debentures (the "Convertible Debentures") and accompanying 5-Year Warrants (the "Warrants") which may have a significant dilutive impact on the ownership interest of our existing stockholders," "We have substantially increased our indebtedness," "If we are unsuccessful in obtaining needed additional capital on an on-going basis, we may be unable to conduct our business as planned, to pursue desirable markets for our current products or to develop and market new products," and "We cannot assure you that we will continue to meet the NASDAQ listing requirements and failure to maintain a listing for more than ten trading days would place us in default under the Convertible Debentures."*

Our future capital requirements will depend on many factors, including, but not limited to: continued scientific progress in our research and development programs; the magnitude of our research and development programs; progress with clinical trials for our diagnostic products; the magnitude of product sales; the time involved in obtaining regulatory approvals; the costs involved in filing, prosecuting and enforcing patent claims; the competing technological and market developments; and the ability of the Company to establish additional development and marketing arrangements to provide funding for research and development and to conduct clinical trials, obtain regulatory approvals, and manufacture and market certain of our products.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions in certain circumstances that affect amounts reported in the accompanying consolidated financial statements and related footnotes. In preparing these financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality and assuming that we will continue as a going concern. We do not believe it is likely that materially different amounts would be reported related to the accounting policies described below. However, application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates.

Revenue Recognition

We recognize revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* ("SAB 101"). Revenue is recognized when the following criteria have been met:

1. Persuasive evidence of an arrangement exists
2. Delivery has occurred and risk of loss has passed
3. The seller's price to the buyer is fixed or determinable
4. Collectibility is reasonably assured

When determining whether risk of loss has transferred to customers on product sales, we evaluate both the contractual terms and conditions of our sales agreements as well as our business practices. Business practices such as agreeing to product exchanges may indicate the existence of an implied right to return the product even if there are no such contractual provisions for product returns. We treat such practices, whether contractual or implied, as conveying a right of return and will establish provisions for returns when reasonable and reliable estimates can be made. In accordance with SAB 101, where we do not have sufficient history to make reasonable and reliable estimates of returns, revenue associated with such practices is deferred until the return period lapses or a reasonable estimate can be made. This deferred revenue will be recognized as revenue when the distributor reports to us that it has either shipped or disposed of the units (indicating that the return period has lapsed).

Contract and license fee revenue is primarily generated through collaborative license and development agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones, payments for product manufacturing and royalties on net product sales. Revenue arrangements where multiple products or services are sold together under one contract are evaluated to determine if each element represents a separate earnings process. In the event that an element of such multiple element arrangement does not represent a separate earnings process, revenue from this element is recognized over the term of the related contract.

Where we have continuing performance obligations under the terms of a collaborative arrangement, non-refundable license fees are recognized as revenue over the period we complete our performance obligations. Revenues from milestone payments related to arrangements under which we have no continuing performance

obligations are recognized upon achievement of the related milestone. Revenues from milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations.

Payments received from collaborative partners for research and development services performed by us are recognized as revenue on a straight line basis (unless evidence indicates an alternative earnings pattern can be demonstrated) over the term of the arrangement or the expected service period, whichever is longer. Revenue from royalty payments is recognized when earned, upon the receipt of data from the licensees in accordance with the related license agreement supporting the amount of and basis for such royalty payments to us.

Valuation Allowances

Inventory. We value our inventory account balances at lower of cost or net realizable value. Management analyzes inventory levels quarterly and reviews inventory account balances and compares such amounts with sales forecasts and projections, historical revenue trends and shelf life of items in inventory. This analysis involves management estimates of future cash flows which are highly judgmental and may differ from actual cash flows. Inventory with a life in excess of its shelf life is disposed of and the related costs are written off. If actual market conditions are less favorable than those projected by management, additional inventory writedowns may be required.

Accounts Receivable. Management periodically reviews outstanding balances in accounts receivable to determine future collections. Based on our historical experience, current business conditions and expected future collections, management established an allowance for uncollectible accounts. In the event circumstances change to affect the assumptions underlying this allowance, we might be required to take additional write-offs of our accounts receivable balances.

Impairment of Long-Lived Assets and Goodwill. Our policy regarding long-lived assets is to evaluate the recoverability or usefulness of these assets when the facts and circumstances suggest that these assets may be impaired. This analysis relies on a number of factors, including changes in strategic direction, business plans, regulatory developments, economic and budget projections, technological improvements, and operating results. The test of recoverability or usefulness is a comparison of the asset value to the undiscounted cash flow of its expected cumulative net operating cash flow over the asset's remaining useful life. Any write-downs would be treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized. To date, we have had recurring operating losses and the recoverability of our long-lived assets is contingent upon executing our business plan that includes, among other factors, significantly increasing sales. If we are unable to execute our business plan, we may be required to write down the value of our long-lived assets in future periods.

Effective January 1, 2002, we adopted Statement of Financial Accounting Standards ("SFAS") No. 142, *Goodwill and Other Intangible Assets* ("SFAS 142"). Under SFAS No. 142, amortization of goodwill ceased and we assess the realizability of this asset annually and whenever events or changes in circumstances indicate it may be impaired. Such events or circumstances generally include the occurrence of operating losses or a significant decline in earnings associated with one or more of our reporting units. We estimate the fair value of our reporting unit by using forecasts of discounted future cash flows. When impairment is indicated, any excess of carrying value over fair value is recorded as a loss.

We performed an initial test for impairment upon adoption of SFAS No. 142 at January 1, 2002, and determined that goodwill was not impaired. We completed an annual test for impairment at December 31, 2002, and determined that goodwill was not impaired.

Pro forma results for 2001 and 2000, as if SFAS No. 142 had been adopted at the beginning of 2000, are as follows:

	2000	2001
Reported net loss	$(6,836,254)	$(8,730,827)
Add back: Goodwill amortization	49,021	86,817
Adjusted net loss	$(6,787,233)	$(8,644,010)

Recent Accounting Pronouncements

In April 2002, the Financial Accounting Standards Board ("FASB") issued SFAS 145, *Rescission of FASB Statement No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections.* SFAS 145 rescinds FASB Statement No. 4, *Reporting Gains and Losses from Extinguishment of Debt,* and an amendment of that Statement, FASB Statement No. 64, *Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements.* SFAS 145 also rescinds FASB Statement No. 44, *Accounting for Intangible Assets of Motor Carriers.* SFAS 145 amends FASB Statement No. 13, *Accounting for Leases,* to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. This Statement also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions of SFAS 145 are effective for financial statements issued on or after May 15, 2002. The adoption of SFAS 145 did not have a material effect on our financial statements.

In July 2002, the FASB issued SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities.* SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized at its fair market value when the liability is incurred, rather than at the date of an entity's commitment to an exit plan. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have a material effect on our financial statements.

In December 2002, the FASB issued SFAS 148, *Accounting for Stock-Based Compensation-Transition and Disclosure — An Amendment of FAS No. 123.* SFAS 148 amends SFAS 123, *Accounting for Stock-Based Compensation,* to provide alternative methods of transition for those companies who voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of FAS 123 to require prominent disclosures in both the annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The transition and annual disclosure provision of FAS 148 are effective for fiscal years ending after December 15, 2002. We have not adopted the fair value method of accounting for stock-based compensation, and will continue to apply APB 25 for our stock-based compensation plans. We have incorporated the disclosure requirements of SFAS 148 at December 31, 2002, which require a tabular pro forma presentation of net income had FAS 123 been adopted by us in the "Summary of Significant Accounting Policies" footnote of the financial statements.

In November 2002, FASB Emerging Issues Task Force reached consensus with respect to Issue 00-21 ("EITF 00-21"), *Accounting for Revenue Arrangements with Multiple Deliverables.* EITF 00-21 addresses the accounting for multiple-element revenue arrangements. Specifically, EITF 00-21 addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how arrangement consideration should be measured and allocated to the separate units of accounting. This EITF is effective for the revenue arrangements entered into in fiscal periods beginning after June 15, 2003. At the present time, this EITF is not expected to have material impact on our financial position or results of operations.

In November 2002, the FASB issued FASB Interpretation No. 45 ("FIN 45"), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an*

interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34. FIN 45 elaborates on the disclosures to be made by a guarantor in our interim and annual financial statements about our obligations under certain guarantees that it has issued. It requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value for the obligation undertaken in issuing the guarantee. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective for financial statement periods ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on our consolidated financial statements. See Note 5, "Commitments and Contingencies," to our consolidated financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), *Consolidation of Variable Interest Entities, an interpretation of ARB No. 51*. FIN 46 requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. Variable interest entities that effectively disperse risk will not be consolidated unless a single party holds an interest or combination of interests that effectively recombines risks that were previously dispersed. FIN 46 also requires enhanced disclosure requirements related to variable interest entities. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 is not expected to have a material effect on our financial statements.

Research and Development

We are engaged in the research, production and marketing of cancer diagnostic products. All of our research and development expenditures, whether conducted by our own staff or by external scientists on our behalf and at our expense, are recorded as expenses as incurred and amounted to approximately $40 million dollars for the period since our inception in October of 1987 through December 31, 2002. Research and development expenses include the salaries and related overhead of our research personnel, laboratory supplies, payments to third parties to help us execute clinical trials, depreciation of research related equipment, legal expenses related to filing and prosecuting patents, other direct expenses and an allocation of our occupancy and related expenses based on the square footage occupied by our research and development staff and their laboratories.

Our research and development scientists typically are assigned to lead one project at a time but may also provide support for other projects. In addition, our various programs share a substantial amount of our common fixed costs such as facility depreciation, utilities and maintenance. All of our research and development programs are similar in nature as they are based on our common protein discovery technology and a significant finding in any one cancer type may provide a similar benefit across all programs. Accordingly, we do not track our research and development costs by individual research and development programs.

Discovery Research

Our primary research focus is on the identification of proteins in the body which are associated with or created by cancerous processes and which, when measured, can provide useful medical information to physicians. Since 1998 our research has focused on discovering these substances using low-throughput research mass spectrometry. Because the cost of research mass spectrometry technology was determined to be too high to create commercially viable products or services, in the last two years our research has been focused on applying high-throughput mass spectrometry methods to measure the proteins characterized as clinical candidates during discovery research and to improving the controls and reproducibility of our mass spec technology. Since the development of core test methods applicable to all cancer types has been a major activity of our staff, we have not tried to track spending by product or to allocate our total research costs to individual products.

Product and Service Development

To develop products which will provide physicians medically useful information, we can develop our technology in three different ways: Lab Test Kits, Point-of-Care Test Devices and Proprietary Laboratory Procedures. For technological and marketing reasons, we have decided initially to launch our newer technologies – NMP35, NMP48 and NMP66 – as Proprietary Laboratory Procedures using high throughput mass spectrometry technology. Since Proprietary Lab Services must be adapted to the skills and technology of a clinical laboratory partner ("lab partner"), we cannot be certain that a lab partner will find our current methods economical and reproducible in their laboratory processing environment. Furthermore, the ability of this technology to generate useful medical information cannot be assessed until we have transferred it to our lab partner and such partner has conducted a successful clinical trial. We do not intend to launch development of a service for NMP35 until at least one of the others has been successfully launched. See Factors That May Affect Future Results — *If we are unable to develop and market viable future products, our stock price may drop.* It is our plan to complete agreements with lab partners to develop a Proprietary Lab Service for NMP66 and NMP48 in 2003 and to implement a Proprietary Laboratory Procedure that works for either NMP48 or NMP66 during 2003 and to implement the other in 2004.

We also intend to develop Lab Test Kits and Point-of-Care Test Devices based upon our new technologies. While we have successfully configured NMP22 in these formats, there are always uncertainties involved in successfully creating products which perform reproducibly in every laboratory. Because our newer technologies employ different proteins and because they are measured in blood not in urine, we plan not only to apply several of the techniques used in developing NMP22 products but also to employ additional outside resources to complete the development of these products successfully. See Factors That May Affect Future Results — *If we are unable to develop and market viable future products, our stock price may drop.* We have a goal to complete development of a Lab Test Kit and a Point-of-Care Test Device for one of the new products in 2005 and for the other in 2006. We do not intend to begin development of a product for NMP35 until at least one of the others has been successfully completed.

Product development can also involve activities which resemble discovery research because it may be necessary to identify a fraction of the target protein (such as an antibody binding site) or to separate two similar proteins (or two forms of the same protein) in order to complete this stage. Therefore, the risks of discovery may extend into product development in completing a service or a product which delivers useful information to physicians.

Clinical Trials

After a product or service has been developed, the information it generates must be validated in one or more clinical trials. These activities are designed to confirm the most appropriate and useful ways to use the data generated by our products and services to help physicians diagnose and manage disease. As indicated by our NMP22 products, different clinical applications have different FDA approvals required. While NMP22 has demonstrated an ability to generate information useful in more than one indication, the demonstrated success in one indication will not necessarily ensure success in another. The differences in the proteins themselves combined with the variability in the disease and the performance of other diagnostic technologies make this process subject to numerous uncertainties which can only be overcome by large, successful clinical trial studies. For each product or service, we expect to develop a claim for aiding in the diagnosis of the disease for patients who have no prior history of the disease and for monitoring the course of the disease. The order in which these claims are developed may be different for each product.

The table below summarizes our development programs, including stage of development and current FDA status.

Protein	Form of Technology	Clinical Application	Stage of Development	FDA Status
NMP22 Bladder	Lab Test Kit	Monitoring	Commercialized	Approved
NMP22 Bladder	Lab Test Kit	Diagnosis	Commercialized	Approved
NMP22 Bladder	POC Test Device	Monitoring	Commercialized	Approved
NMP22 Bladder	POC Test Device	Diagnosis	Approvable subject to FDA inspection	Approvable
NMP179 Cervical	Non-Slide-Based System	Identifying High Risk Cases	Licensee Sysmex is conducting further product development	*
NMP48 Prostate	Proprietary Lab Service	To Be Determined	Product/Service Development	**
NMP48 Prostate	Lab Test Kit	To Be Determined	Product/Service Development	*
NMP48 Prostate	POC Test Device	To Be Determined	Product/Service Development	*
NMP66 Breast	Proprietary Lab Service	To Be Determined	Clinical Service Development with Mitsubishi	**
NMP66 Breast	Lab Test Kit	To Be Determined	Product/Service Development	*
NMP66 Breast	POC Test Device	To Be Determined	Product/Service Development	*
NMP35 Colon	All	To Be Determined	Discovery Research Completed	* **

* If submitted for a screening or diagnosis clinical application, FDA will require Premarket Approval ("PMA"). If submitted as a monitoring test, FDA may only require Premarket Clearance ("510-k").

** If offered (as intended) as a service, no FDA submission is likely to be required. If the service includes a reagent such as a antibody provided by a party other than the laboratory conducting the test, the FDA requires an Analyte Specific Reagent notification.

Spending on Research and Development Projects. Total research and development spending in 2002 was approximately $3.8 million dollars. We expect research and development expenditures to be less than $7 million dollars over the next two years and to be devoted to our various programs as discussed below.

NMP22 — Bladder. Expenditures on the various NMP22-based products are virtually complete. Except for sponsoring additional clinical trials to demonstrate different ways to use the information generated by the products, we do not expect to incur any significant additional R&D spending on any of these products.

NMP179 — Cervical. Discovery research on this product was completed prior to 2000 and our expenditures in 2002 were principally for technical support of the licensing activity. In 2002 we licensed the worldwide rights for non-slide-based applications to Sysmex, Inc. as discussed more thoroughly in Item 1. Substantially all future costs to support additional research and development of this product are expected to be paid for by Sysmex. If we incur any additional costs in connection with this program, we expect such costs to be paid in connection with an effort to license this technology to a company with a slide-based cervical cancer detection system.

NMP48, NMP66 & NMP35. Over the next two years, research and development funds will be spent principally to develop both products and services for NMP48 and NMP66 and to improve the controls, reproducibility and costs of our mass spec research technology. Depending on the ongoing results of our programs we will make decisions on how to proceed and will consider options including but not limited to terminating certain activities, licensing the technology to third parties or selling the technology to third parties. As a result of these uncertainties surrounding these projects we cannot reasonably estimate the likelihood of reaching the goals set forth in the table above. The nature, timing, costs and efforts to reach those goals, and the amount or timing of the net cash inflows of our individual programs are not possible to predict.

Factors That May Affect Future Results

Our future financial and operational results are subject to a number of material risks and uncertainties that may affect such results or conditions, including:

We recently completed a private placement for the issuance of $5 million of 7.5% Convertible Debentures (the "Convertible Debentures") and accompanying 5-Year Warrants (the "Warrants") which may have a significant dilutive impact on the ownership interest of our existing stockholders. On March 31, 2003, we completed a private placement of Convertible Debentures in an aggregate subscription amount equal to $5 million and accompanying Warrants for an aggregate of 784,314 shares of our common stock, including a Warrant for 98,039 shares issued to a placement agent in connection with the transaction (the "Private Placement"). The Convertible Debentures are convertible into shares of our common stock at a conversion price initially equal to $2.55, but which will be adjusted downward (subject to certain limited exceptions) upon any dilutive issuances of our securities to an amount equal to 112% of the price at which such dilutive issuance is made, resulting in the potential for issuance of additional shares of our common stock upon conversion of the Convertible Debentures. The Convertible Debentures bear interest at the rate of 7.5% per annum, payable quarterly, and permit us, in certain circumstances, to make such interest payments in shares of common stock based on a 5% discount to the valuation of the common stock. The Convertible Debentures are redeemable in monthly installments equal to 1/26th of the aggregate subscription amounts paid for such Convertible Debentures, such monthly payments to commence upon the first of the month after the 11 month anniversary of the closing date. The monthly redemption payments, subject to certain conditions, may also be made in shares of common stock based on a 10% discount to valuation. The Warrants are immediately excercisable for a period of five years at an initial exercise price of $2.278. The exercise price of the Warrants will initially be adjustable down to the issuance price of any subsequent dilutive issuances (subject to certain limited exceptions), and after the Convertible Debentures are no longer outstanding, the exercise price of the Warrants will be adjustable based on a weighted-average basis upon any such subsequent dilutive issuance.

The aggregate number of shares of common stock issuable upon exercise of the Warrants and conversion of the Convertible Debentures, including as a result of any anti-dilution adjustments, and in connection with any payment of interest on or redemption of such Convertible Debentures, is capped at an aggregate of 6,426,127 shares unless shareholder approval is subsequently obtained. In addition, in the event shareholder approval is obtained, our stock price meets certain levels and there is an effective registration statement covering the shares of common stock underlying the Convertible Debentures and Warrants issued in connection with the first closing, a second closing may be held with the same purchasers for the issuance of additional 7.5% Convertible Debentures in an aggregate subscription amount of $3 million and additional Warrants for an amount of shares equal to 35% of the number of shares for which such additional Convertible Debentures are initially convertible. Under the terms of the Private Placement we are required to file a registration statement covering the shares of our common stock underlying the Convertible Debentures and Warrants within 30 days of closing.

We have substantially increased our indebtedness. As a result of the Private Placement, we have substantially increased our indebtedness. The existing Convertible Debentures are for an aggregate principal amount of $5 million and the terms of the Private Placement provide for the issuance of up to an additional $3 million in aggregate principal amount of Convertible Debentures upon certain conditions. Although the Convertible Debentures provide that interest and redemption payments may in certain circumstances be made in shares of common stock instead of cash, we cannot guarantee that such circumstances will exist and in the

event they do not, such payments will need to be made in cash. The Convertible Debentures may become immediately due and payable at a premium of 120% of the outstanding principal amount plus accrued interest and damages in the event of default by us of certain covenants and also obligate us to pay damages and interest upon certain events. We cannot guarantee that we will be able to meet our obligations under the Convertible Debentures and that we will have sufficient funds to repay such Convertible Debentures in the event of redemption or an event of default. In addition, the level of our indebtedness, among other things could:

- make it difficult for us to make payment on our debt and other obligations;
- make it difficult for us to obtain future financing;
- require dedication of significant amounts of cash flow from operations to service our indebtedness and reduce our cash flow available for other purposes;
- require us to take measures that might hurt our future performance in order to satisfy our debt obligations; and
- make us more vulnerable in the event of a downturn in our business.

If we are unsuccessful in obtaining needed additional capital on an on-going basis, we may be unable to conduct our business as planned, to pursue desirable markets for our current products or to develop and market new products. We will need additional funding to continue to market our NMP22 Lab Test Kit for bladder cancer and our NMP22 BladderChek Device for bladder cancer, to conduct research and development, to conduct clinical trials and to manufacture and market our products as we currently contemplate. We are currently seeking to raise additional capital and will consider various financing alternatives, including equity or debt financings and corporate partnering arrangements. However, we may not be able to raise needed capital on terms that are acceptable to us, or at all. Our recently completed Private Placement prohibits us from entering into obligations that are senior to the Convertible Debentures and places certain restrictions on our ability to raise additional capital through equity issuances, including a prohibition on such activity (with certain limited exceptions) for a period of 90 days from the effective date of the registration statement filed with respect to the shares underlying the Convertible Debentures and Warrants, and an ability for the Private Placement investors to match any additional funds raised on the same terms. These terms may severely limit our ability to obtain additional financing or do so on favorable terms. If we raise funds on unfavorable terms, we may provide rights and preferences to new investors which are not available to current shareholders. If we do not receive additional financing or do not receive an adequate amount of additional financing, we may be unable to meet our payment obligations under the Convertible Debentures or we may be required to curtail our expenses by reducing research and/or marketing or to take other steps that could hurt our future performance, including but not limited to, the premature sale of some or all of our assets or product lines on undesirable terms, merger with or acquisition by another company on unsatisfactory terms or the cessation of operations. Any future equity financings will dilute the ownership interest of our existing investors and may have an adverse impact on the price of our common stock.

Because our stock price may be volatile, the shares you hold may lose their value rapidly. The market price of our common stock has been, and may continue to be, highly volatile. This price has ranged between $3.25 and $1.25 in the fifty-two week period prior to March 3, 2003. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology sector, which have often been unrelated to the operating performance of particular companies. Factors such as announcements of technological innovations or new products by our competitors or disappointing results by third parties, as well as market conditions in our industry, may significantly impact the market price of our common stock. For example, in the past our stock price has been affected by announcements of clinical results, clinical or technical breakthroughs or earnings by other biotechnology companies unrelated to our performance or us. Our stock price has also been affected by announcements of developments at Matritech. For example, our stock price has, in the past, reacted to announcements regarding a delay of our regulatory approval process for a new product, fluctuating sales results and decreasing balances of funds in the corporate treasury. Thus, as a result of events at Matritech or in our industry, shares of Matritech stock could lose their value rapidly. In addition, sales of a substantial number of shares of our common stock by stockholders could adversely affect

the market price of our shares. In fiscal year 2002, our shares had an average daily trading volume of approximately 71,000 shares. Bulk sales in a short period of time could cause the market price for our shares to decline.

We cannot assure you that we will continue to meet the NASDAQ listing requirements and failure to maintain a listing for more than ten trading days would place us in default under the Convertible Debentures. Our common stock is currently listed on the NASDAQ SmallCap Market. For continued listing of our common stock on the NASDAQ SmallCap Market, we must, among other things, maintain one of the following: 1) at least $2.5 million in stockholder's equity or, 2) net income in the most recently completed fiscal year of at least $500,000 or failing that, $500,000 in two of the last three years, or 3) have a market value of listed securities of $35 million. We must also maintain a minimum bid price for our common stock of $1.00, maintain a market value of our publicly held shares of $1 million, maintain a public float of at least 500,000 shares, have at least two market makers in our shares, and have at least 300 round lot shareholders. As of our most recently completed fiscal year end on December 31, 2002, our stockholder's equity was $3.8 million, we were not profitable and so did not have a positive net income and the market value of our listed securities held on March 3, 2003, was $59.4 million. In addition, as of March 3, 2003, our share price was in excess of a dollar per share, we had approximately 31.6 million shares held by non-affiliates with a market value of $58.5 million, we had approximately 32 million shares outstanding, had 12 market makers in our shares as of March 3, 2003 and had over 340 round lot shareholders. Although we satisfied the NASDAQ SmallCap Market continued listing standards as of the dates shown above, we cannot assure you that we will continue to do so in the future. If we fail to meet these criteria, our shares may be delisted from the NASDAQ SmallCap Market. If we were delisted from the NASDAQ SmallCap Market and were able to continue as a company it is our expectation that trading, if any, would then be conducted on the over-the-counter market or on an electronic bulletin board established for securities that do not meet the NASDAQ SmallCap Market listing requirements.

If trading in our stock is conducted on the over-the-counter market or on an electronic bulletin board, it could have an adverse affect on the market price of our shares and you will find it more difficult to buy and sell shares of our stock or to obtain accurate quotations as to the price of our stock. In addition, if our shares are no longer on the NASDAQ SmallCap Market, they may be subject to a rule that imposes additional sales practice requirements on broker-dealers who sell our shares to persons other than established customers and accredited investors. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. Consequently, delisting, if it occurred, might reduce the ability of broker-dealers to sell our shares and your ability to sell your shares.

In addition, failure of our common stock to be listed on at least one of the NASDAQ SmallCap Market, the NASDAQ National Market, the New York Stock Exchange or the American Stock Exchange for a period of more than ten trading days may trigger an event of default under the Convertible Debentures. An event of default would result in our having to pay 120% of the remaining principal plus accrued interest and damages. Any change in the listing of our common stock could significantly impair our ability to raise capital in the public markets should we desire to do so in the future.

The operations of our European subsidiary involve currency exchange and other risks. In June 2000, we completed the acquisition of Matritech GmbH. Matritech GmbH, our European subsidiary, accounted for approximately 74% of our sales for the fiscal year ended December 31, 2002. Accounts of our European subsidiary are maintained in Euros and are translated into U.S. Dollars. To the extent that foreign currency exchange rates fluctuate in the future, we may be exposed to continued financial risk. The financial statements of Matritech GmbH are translated in accordance with SFAS No. 52, Foreign Currency Translation. The functional currency of our foreign subsidiary is the local currency (Euro), and accordingly, all assets and liabilities of the foreign subsidiary are translated using the exchange rate at the balance sheet date except for intercompany receivables which are of long-term-investment nature, and capital accounts which are translated at historical rates. Revenues and expenses are translated at average rates during the period. Adjustments

resulting from the translation from the financial statements of the Matritech GmbH into U.S. Dollars are excluded from the determination of net income and are accumulated in a separate component of stockholders' equity. Foreign currency transaction gains and losses are reported in the accompanying consolidated statements of operations and are immaterial to the results of operations. In addition, we have integrated the operations of this subsidiary we still must coordinate geographically separate organizations, manage personnel with disparate business backgrounds and conduct business in a different regulatory and corporate culture. It remains to be seen whether the use of this subsidiary to spearhead the marketing effort of our products in Europe will be successful.

If we are unable to develop and market viable future products our stock price may drop. We believe that the market value of our stock is based in part on an expectation of future revenue-producing products. Other than the NMP22 products and other diagnostic products distributed by our European subsidiary, Matritech GmbH, all of our products are under development and are not expected to generate generally available commercial products for some time, if at all. If we are unable to successfully develop and commercialize other products, the future prospects for our business, sales and profits will be materially impaired. In addition, we may incur substantially greater costs than we currently expect in an attempt to overcome the obstacles preventing successful development.

These development programs involve the use of advanced technical methods that require both a high degree of skill and judgment in their application. We have encountered unexpected technical difficulties and may encounter additional ones in the course of the development process that we may not be able to overcome or may only overcome if we expend additional funds and time. For example, in 1997 we elected to terminate development of a blood-based Lab Test Kit for PC1, a candidate marker for prostate cancer. Despite encouraging initial results from an earlier low throughput research testing method, we were unable to develop such a kit for use in testing prostate cancer patients even when we employed 1997 state-of-the-art detection methods. We subsequently announced that a different protein (NMP48), discovered using research mass spec methods, would be the primary candidate in our prostate cancer program. More recently, we and others have observed that the testing methodologies of low throughput research mass spectrometry are not readily reproducible or transferable to high throughput mass spectrometry. This has required us to try a number of different changes in our procedures to improve controls, reproducibility and costs in order to measure these proteins using a high throughput mass spec. Such changes in our technology and in our procedures may lead us to products or services which do not perform or do not perform as well as the results reported using our discovery research procedure.

Investors should not expect products which reach commercialization will perform as well as preliminary discovery research results in the small numbers of samples reported by us. The variability and risks we face in our development programs, including but not limited to, obtaining proper specimens from patients and healthy individuals, testing a much larger cohort of individuals than can be accomplished in early discovery, preparing the specimens properly for testing, developing an economic and reproducible test method for the substance to be measured and testing the final product in a clinical setting, will lead to product performance which is very unlikely to be as accurate as the results reported from the discovery phase. Furthermore there is inherent biologic variability which only becomes evident when larger numbers of patients are tested, which also influences the variability of clinical test results. Therefore, the most important empirical data to be used in evaluating our product development programs are the results of clinical trials of commercial products such as those reported since 1996 for products based on NMP22.

With regard to a Proprietary Lab Service, we may complete our product development efforts to our satisfaction, but we may not obtain the agreement and approval from our clinical lab partner that the technology works adequately in their laboratory environment or that it has the clinical performance and information value that they originally expected. Because Proprietary Laboratory Procedures utilize technologies which are, by their nature, more sensitive and more operator dependent than the technologies involved in products such as Lab Test Kits and Point-of-Care Test Devices, these risks are increased in this area. Furthermore, we have no demonstrated success in developing Proprietary Laboratory Procedures as we have in developing Lab Test Kits and Point-of-Care Test Devices.

We may successfully complete technical development for one or all of our product development programs, but we may fail to develop a commercially successful product for a number of other reasons. We may not obtain the required regulatory approvals for their use. The economic value of our technology may be too low or its production cost may be too high because the marketplace value of our products or any other diagnostic technology is based on the clinical utility of the information generated, not on the fundamental biochemistry of the technology or on its performance in discovery research. Therefore, while we are basing our research programs on the data we have generated during discovery research, our physician customers will base their long-term purchase decisions on the clinical information they obtain and whether such information helps them make medical decisions. As discussed above, the data generated by our FDA clinical trials and other third party clinical trials, not the data reported during the discovery phase, are the principal data physicians will use to appraise clinical value. In addition, it should also be understood that the perceived value of this clinical information (even if generated by an FDA-approved test) is likely to differ from physician to physician. Our success in the market for the diagnostic products we develop will also depend on our ability to educate physicians, patients, insurers and our distributors on the clinical utility of our new products. Even if we successfully educate the market, a competing product may prevent us from gaining wide market acceptance for our products.

We continue to incur operating losses and if we are unable to achieve profitability our stock price may drop. We have incurred operating losses since we began operations in 1987. These losses have resulted principally from costs incurred in research and development and from selling, general and administrative costs associated with our development. These costs have averaged $8.8 million per year for the past three fiscal years ending December 31, 2002. Our costs have exceeded our revenues, which in the past three fiscal years, ending December 31, 2002, have averaged approximately $2.3 million per year. Our revenues to date have been generated primarily from sales of our NMP22 Test Kit, our NMP22 BladderChek Device and other diagnostic products, our development agreements, government grants and interest income. We will continue to incur operating losses until gross profits from our product sales cover period operating costs. Our ability to be profitable depends in part on our ability to successfully market our existing products and obtain required regulatory approvals to broaden those markets.

If our distributors do not successfully sell our current products, our sales revenue will suffer. We anticipate that in the near-term our success will be substantially dependent on the success of the NMP22 Test Kit, the NMP22 BladderChek Device and the products sold and distributed by our European subsidiary. We have derived a significant portion of our NMP22 sales revenue in the past from distribution agreements with distributors. Since 1994 Konica Corporation has had an exclusive right to sell our NMP22 Test Kit in Japan. Since 1998 Fisher Healthcare has had a co-exclusive right with us to sell our NMP22 Test Kit to hospitals and commercial laboratories in the United States. More recently, U.S. Summit Company has been granted the right to distribute our product in South East Asia and the People's Republic of China. During the third quarter of 2002, we entered into an exclusive relationship with Cytogen Corporation for the marketing and distribution of our NMP22 BladderChek Device to urologists and oncologists in the United States. In Europe in the third and fourth quarters of 2002, Matritech GmbH entered into agreements with a number of distributors outside of Germany.

Because we generally do not deal directly with customers when selling through distributors, we depend on the ability of the distributors to develop demand for our products, to market actively, to forecast demand accurately and to maintain appropriate levels of inventory. We have minimal control over our distributors, and these distributors are under no obligation to purchase a set quantity of our products (although in some cases the agreement may be terminable by us if the distributor does not make certain minimum purchases). The failure or delay by a distributor in selling our products or any material breach of their agreements with us could significantly reduce our revenues. We may be unable to enter into additional distribution relationships on favorable terms, if at all. To launch the NMP22 BladderChek Device in the United States, we have hired a five-person sales force to support sales to urologists and, where appropriate, to general practitioners and to support the marketing efforts of our U.S. distributor, and our German subsidiary, Matritech GmbH sells our products in Europe. Our internal marketing and sales resources are not presently capable of assuming all of our distributor's responsibilities. To the extent we attempt to use our internal marketing resources in territories

where we have lost, do not have, or do not intend to use third-party distributors, we may have to develop a larger marketing and sales force with the appropriate technical expertise and distribution capability. This effort will take a considerable amount of time, may not meet with success and may incur excessive expense.

We face intense competition and our technology may become obsolete. Although we are not aware of any other company using nuclear matrix protein technology to develop diagnostic or therapeutic products, competition in the development and marketing of cancer diagnostics and therapeutics, using a variety of technologies, is intense. Many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engage in the research and development of clinical cancer diagnostic products. Many of these organizations have greater financial, manufacturing, marketing and human resources than we do.

We expect that our Lab Test Kits and our Point-of-Care Test Devices will compete with existing FDA-approved clinical tests, including tests known as BTA, UroVysion and ImmunoCyt bladder cancer tests, which have been approved for monitoring bladder cancer; a test known as CEA, which is used primarily for monitoring colorectal and breast cancers; a test known as CA19.9, which is used primarily for monitoring colorectal and gastric cancers; a test known as PSA, which is used primarily for monitoring and screening prostate cancer; and tests known as TRUQUANT® BR RIA, CA15.3 and CA27.29 which are used for monitoring breast cancer. We are also aware of a number of companies that have announced that they are engaged in developing cancer diagnostic products based upon oncogene technology. Our diagnostic products will also compete with more invasive or expensive procedures such as minimally invasive surgery, bone scans, magnetic resonance imaging and other *in vivo* imaging techniques. In addition, other companies may introduce competing diagnostic products based on other technologies that may adversely affect our competitive position. As a result, our products may become obsolete or non-competitive.

If our suppliers or assemblers cancel their agreements with us, it may be difficult for us to find replacements. We currently assemble our NMP22 Lab Test Kits in our Newton facility and we rely on subcontractors for certain components and processes. A contract manufacturer produces our NMP22 BladderChek Device. We do not have alternative suppliers for units of the NMP22 BladderChek Device or for certain key components and processes used in our NMP22 tests. If the units or components from these suppliers or the services of these assemblers should become unavailable for any reason, including failure to comply with FDA regulations, we would seek alternative sources of supply or assembly. Our suppliers may or may not have undergone inspection by the FDA to ascertain compliance. In order to maintain the FDA acceptance of our manufacturing process, we would have to show that these alternative sources of supply are equivalent to our current sources. Although we attempt to maintain an adequate level of inventory to provide for these and other contingencies, if our manufacturing processes are disrupted as a result of a shortage of key components, a revalidation of new components or the failure of an assembler to meet our requirements, we may be unable to meet our commitments to customers. Our failure or delay in meeting our commitments could cause sales to decrease, market share to be lost permanently, and could result in significant expenses to obtain alternative sources of supply or assembly with the necessary facilities and know-how.

Our operating results may fluctuate. Our future operating results may vary significantly from quarter to quarter or from year to year depending on a number of factors including:

- the timing and size of orders from our customers and payments from and sales by our distributors;
- the rate and size of our expenditures to expand our domestic and international sales and distribution networks;
- the timing and likelihood of FDA approvals for additional uses of the NMP22 BladderChek Device or our other products as they become available;
- the establishment of agreements with distributors in markets where we have not previously had a presence;
- acceptance by physicians and clinical laboratories of our products;

- the extent of reimbursement for the cost of our products from government health administration authorities, private health insurers and other third-party payors,
- the introduction of new products by us; and
- the market acceptance of our products.

Our current planned expense levels are based in part upon expectations as to future revenue. Consequently, profits may vary significantly from quarter to quarter or year to year based on the timing of revenue. Revenue or profits in any period will not necessarily be indicative of results in subsequent periods.

We may need licenses for our point-of-care tests. We have developed a point-of-care product which use test strips composed of an absorbent material that will soak up urine from a small reservoir at one end of the container housing the test strip and expose the urine to chemicals and antibodies arranged on the surface or imbedded in the test strip. After a short period of time and after a reaction with our proprietary antibodies, a test result will appear in a window located on the container housing the test strip. We are investigating whether the manufacture, use, sale, or import of point-of-care products which include this test strip technology in certain jurisdictions may require us to obtain patent licenses from third parties and, if appropriate, we will attempt to obtain such licenses. We may not be able to obtain patent licenses, where appropriate, to permit us to make, use, sell, or import such products in the United States or in certain other jurisdictions. In the event we are unable to obtain a required license, we will have to suspend sale of the point-of-care product until the expiration of the relevant patents or until we are able to arrive at a design solution that uses a different technology.

If we are unable to manufacture the product volumes we need, we will be unable to achieve profitability. We have been manufacturing and assembling our test kits for limited commercial sales since 1995 but have not yet manufactured the large product volumes necessary for us to achieve profitability. We may encounter difficulties in scaling up production of new products, if necessary, including problems involving:

- production yields;
- quality control and assurance;
- component supply; and
- shortages of qualified personnel.

These problems could make it very difficult to produce sufficient product to satisfy customer needs and could result in customer dissatisfaction. We may not be able to achieve reliable, high-volume manufacturing at a commercially reasonable cost. In addition, numerous governmental authorities extensively regulate our manufacturing operations. Failure to satisfy our manufacturing needs could result in decreased sales, loss of market share and potential loss of certain distribution rights.

Healthcare reform measures and third-party reimbursement policies could limit the per-product revenues for our products. Our ability to commercialize our planned products successfully will depend in part on the extent to which reimbursement for the cost of our products will be available from government health administration authorities, private health insurers and other third-party payors. In the case of private insurers, the reimbursement of any medical device, either approved for investigational use only, or for research use, is at the sole discretion of the patient's individual carrier. Even if a procedure has been previously approved for reimbursement, the insurance carrier may decide not to continue to reimburse the procedure. Further, even if in the future we do successfully sell our products to managed care providers, it is possible that these sales will involve significant pricing pressure on our products and keep our per-product revenues low. Healthcare reform is an area of continuing attention and a priority of many governmental officials. Certain reform proposals, if adopted, could impose limitations on the prices we will be able to charge for our products or the amount of reimbursement available for our products from governmental agencies or third-party payors. While we cannot predict whether any of these legislative or regulatory proposals will be adopted or the effect that these proposals may have on our business, the announcement or adoption of these proposals could hurt our business by reducing demand for our products and could hurt our stock price because of investor reactions.

Government regulation could make the development and sale of our products costly and difficult. The FDA and, in some instances, foreign governments, extensively regulate the medical devices that we market and manufacture. The NMP22 Test Kit was first approved for sale in the United States by the FDA in 1996, in Japan by the Koseisho in 1998 and in the People's Republic of China by the State Drug Administration in 1999. In July 2002, we received approval from the FDA to market our NMP22 BladderChek Device in the United States for monitoring patients with a history of bladder cancer. We have submitted an application to the FDA for approval to market our NMP22 BladderChek Device in the United States as an aid in diagnosis of patients at risk for bladder cancer and have been notified that our application is approvable subject to inspection of the manufacturing facilities. The FDA regulates the clinical testing, manufacture, labeling, distribution and promotion of medical devices in the United States. If we fail to comply with the FDA's requirements, including Good Manufacturing Practices, as this term is defined by the FDA, we may face a number of consequences, including:

- fines;
- injunctions;
- civil penalties;
- recall or seizure of products;
- total or partial suspension of production;
- failure of the government to grant premarket clearance or premarket approval for devices;
- withdrawal of marketing approvals; and
- criminal prosecution.

The FDA also has the authority to request the repair, replacement or refund of the cost of any device that we manufacture or distribute.

Any products that we or our suppliers manufacture or distribute in accordance with FDA approvals are subject to pervasive and continuing regulation by the FDA, including:

- device manufacturers and distributors are required to comply with record keeping requirements and to report adverse experiences with the use of the device;
- device manufacturers are required to register their establishments and list their devices with the FDA and are subject to periodic inspections by the FDA and certain state agencies; and
- devices are required to be manufactured in accordance with Good Manufacturing Practices, as this term is defined by the FDA, regulations which impose certain procedural and documentation requirements on us with respect to manufacturing and quality assurance activities.

Labeling and promotional activities are subject to scrutiny in the United States by the FDA and, in certain instances, by the Federal Trade Commission. For example, the NMP22 Test Kit has received FDA approval and may be promoted by us only as aid in management of patients with bladder cancer or as a diagnostic aid for use for previously undiagnosed individuals who have symptoms of or are at risk for bladder cancer. The FDA actively enforces regulations prohibiting the promotion of devices for unapproved uses and the promotion of devices for which premarket approval has not been obtained. Consequently, we cannot currently promote the NMP22 Test Kit for any unapproved use. If we or our suppliers fail to comply with these manufacturing or promotional requirements, we may face regulatory enforcement action by the FDA that would prevent us or our suppliers from manufacturing or selling our products, hurt our ability to conduct testing necessary to obtain market approval for these products and reduce our potential sales revenues.

We are also subject to a variety of state laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those states or localities. Manufacturers are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire

hazard control, and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with these laws and regulations now or in the future, which could increase future losses or reduce future profitability.

If we lose our proprietary technology advantage, we could be overwhelmed by competitors. We rely on a combination of patent, trade secret and trademark laws, nondisclosure and other contractual provisions and technical measures to protect the proprietary rights in our current and planned products. These protections may be inadequate, and our competitors may independently develop technologies that are substantially equivalent or superior to our technology. Patent law relating to the scope of claims in the biotechnology field is still evolving and, therefore, the degree of future protection for our proprietary rights is uncertain. In addition, the laws of certain countries in which our products are, or may be, licensed or sold do not protect our products and intellectual property rights to the same extent as the laws of the United States.

We believe that the use of the patents for nuclear matrix protein technology owned by us or licensed to us, and the use of our trademarks and other proprietary rights, do not infringe upon the proprietary rights of third parties. However, we may not prevail in any challenge of third-party intellectual property rights, and third parties may successfully assert infringement claims against us in the future. In addition, we may be unable to acquire licenses to any of these proprietary rights of third parties on reasonable terms.

If we are unable to retain our key personnel, we may be unable to achieve our developmental objectives. Our success depends, in large part, upon our ability to attract and retain a highly qualified scientific and management team. The loss of key personnel or the failure to recruit the necessary additional personnel needed, certain of which must possess specific scientific qualifications, for a qualified team on acceptable terms might impede the achievement of developmental objectives. We face competition for qualified personnel from other companies, research and academic institutions, government entities and other organizations.

If we are sued for product-related liabilities, the cost could be prohibitive to us. The testing, marketing and sale of human healthcare products entail an inherent exposure to product liability, and third parties may successfully assert product liability claims against us. Although we currently have insurance covering our products, we may not be able to maintain this insurance at acceptable costs in the future, if at all. In addition, our insurance may not be sufficient to cover large claims. Significant product liability claims could result in large and unexpected expenses as well as a costly distraction of management resources and potential negative publicity and reduced demand for our product.

Our activities involve the use of hazardous materials, and we may be held liable for any accidental injury from these hazardous materials. Our research and development activities involve the controlled use of hazardous materials, including carcinogenic compounds. Although we believe that our safety procedures for handling and disposing of our hazardous materials comply with the standards prescribed by federal, state and local laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for damages that result, and significant and unexpected costs including costs relating to liabilities and clean-up, costs from increased insurance premiums or inability to obtain adequate insurance at a reasonable price and costs from loss of operations during clean-up.

Conviction of Arthur Andersen LLP. Prior to July 17, 2002, Arthur Andersen LLP (''Arthur Andersen'') served as the Company's independent auditors. On March 14, 2002, Arthur Andersen was indicted on federal obstruction of justice charges arising from the government's investigation of Enron Corporation and on June 15, 2002, Arthur Andersen was found guilty. Arthur Andersen informed the SEC that it would cease practicing before the SEC by August 31, 2002, unless the SEC determined that another date was appropriate. On July 17, 2002, the Company dismissed Arthur Andersen and retained PricewaterhouseCoopers LLP as its independent auditors for its current fiscal year ended December 31, 2002. SEC rules require the Company to present historical audited financial statements in various SEC filings, such as registration statements, along with Arthur Andersen's consent to the Company's inclusion of Arthur Andersen's audit report in those filings. Since the Company's former engagement partner and audit manager have left Arthur Andersen and in light of the announced cessation of Arthur Andersen's SEC practice, the Company will not be able to obtain the consent of Arthur Andersen to the inclusion of Arthur Andersen's audit report in the Company's relevant

current and future filings. The SEC recently has provided regulatory relief designed to allow companies that file reports with the SEC to dispense with the requirement to file a consent of Arthur Andersen in certain circumstances, but purchasers of securities sold under the Company's registration statements, which were not filed with the consent of Arthur Andersen to the inclusion of Arthur Andersen's audit report will not be able to sue Arthur Andersen pursuant to Section 11(a)(4) of the Securities Act of 1933 and therefore the purchasers' right of recovery under that section may be limited as a result of the lack of the Company's ability to obtain Arthur Andersen's consent.

Item 7a. ***Quantitative and Qualitative Disclosures About Market Risk.***

Investment Portfolio. We own financial instruments that are sensitive to market and interest rate risks as part of our investment portfolio. The investment portfolio is used to preserve our capital until it is required to fund operations including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. Our investment policy prohibits investing in derivatives and we stringently adhere to this policy; the policy also limits the amount of credit exposure to any one issue, issuer, and type of instrument. See Note 1 of Notes to Consolidated Financial Statements – "Operations and Significant Accounting Policies."

Foreign Exchange. The financial statements of Matritech GmbH are translated in accordance with SFAS No. 52, *Foreign Currency Translation*. The functional currency of our foreign subsidiary is the local currency (Euro), and accordingly, all assets and liabilities of the foreign subsidiary are translated using the exchange rate at the balance sheet date except for intercompany receivables which are of long-term-investment nature, and capital accounts which are translated at historical rates. Revenues and expenses are translated at average rates during the period. Adjustments resulting from the translation from the financial statements of the Matritech GmbH into U.S. Dollars are excluded from the determination of net income and are accumulated in a separate component of stockholders' equity. Foreign currency transaction gains and losses are reported in the accompanying consolidated statements of operations and are immaterial to the results of operations. We had sales denominated in foreign currency of approximately $2,443,000, $1,729,000 and $667,000 denominated in foreign currency for the periods ended December 31, 2002, 2001 and 2000, respectively. The year ended December 31, 2000 includes the results from Matritech GmbH from June 28 (the date of acquisition).

Item 8. ***Consolidated Financial Statements and Supplementary Data.***

The information required by this item is contained in the financial statements set forth in Item 14(a) under the caption "Financial Statements" as a part of this report.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.***

On July 17, 2002, the Audit Committee of our Board of Directors, upon the authority delegated to it by the Board of Directors, dismissed Arthur Andersen LLP ("Arthur Andersen") as our independent public accountants, and engaged the services of PricewaterhouseCoopers LLP ("PWC") as our independent public accountants for the year ending December 31, 2002.

The reports of Arthur Andersen on our consolidated financial statements for the years ended December 31, 2001 and December 31, 2000 did not contain any adverse opinion or disclaimer of opinion, nor was any such audit report qualified or modified as to uncertainty, audit scope or accounting principles. We and Arthur Andersen have not, in connection with the audit of our financial statements for each of the prior two years ended December 31, 2001 and December 31, 2000 or for the interim period prior to and including July 17, 2002, had any disagreement on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to Arthur Andersen's satisfaction, would have caused Arthur Andersen to make reference to the subject matter of the disagreement in connection with its reports. During years ended December 31, 2001 and December 31, 2000, and through the interim period prior to and including July 17, 2002, none of the reportable events as described under Item 304(a)(1)(v) of Regulation S-K have occurred. We have provided a copy of the foregoing disclosures to Arthur Andersen and have requested that it furnish us with a letter addressed to the Securities and Exchange Commission (the "Commission") stating whether or not it agrees with the above statements. A copy of this letter was filed with the Commission on July 17, 2002. To date, Arthur Andersen has not provided us with a response.

PART III

Item 10. ***Directors and Executive Officers of the Registrant.***

Directors

The information concerning directors of Matritech required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2002 under the headings "Occupations of Directors and Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance."

Executive Officers

The information concerning executive officers of Matritech required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2002 under the headings "Occupations of Directors and Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance."

Item 11. ***Executive Compensation.***

Executive Compensation

The following table summarizes the compensation paid or accrued by the Company for services rendered to the Corporation for the fiscal years ended December 31, 2002, 2001, and 2000 to (i) Mr. Chubb, the Company's Chairman and Chief Executive Officer, and (ii) Mr. Corbet, Dr. Domurad, Dr. Ip, and Mr. Quigley, the next four most highly compensated executive officers of the Company as of December 31, 2002 (the "Named Officers"). The Company did not grant any restricted stock awards or stock appreciation rights ("SARs") and did not make any long-term incentive plan payouts during fiscal 2002, 2001 or 2000:

Summary Compensation Table

Name and Principal Position	Year	Annual Compensation		Long-Term Compensation Awards	
		Salary ($)	Bonus ($)	Securities Underlying Options(#)	All Other Compensation ($)(1)
Stephen D. Chubb	2002	$238,915	$24,990	212,750	$413
Chairman, Director and	2001	238,915	35,700	12,526	413
Chief Executive Officer	2000	229,315	36,915	11,153	413
David L. Corbet	2002	$200,769	$17,500	158,929	$144
Director, President and	2001	200,769	25,000	8,772	144
Chief Operating Officer	2000	196,450	26,349	7,960	413
Melodie R. Domurad	2002	$167,114	$25,229	112,872	$144
Vice President, Clinical and	2001	162,454	24,000	48,421	96
Regulatory Affairs	2000	128,077	16,371	4,946	94
Stephen H. Ip	2002	$166,927	$40,000	120,408	$413
Vice President,	2001	160,154	20,375	7,149	221
Corporate Development	2000	152,769	14,898	4,501	221
John E. Quigley, Jr.	2002	$144,803	$20,182	110,297	$ 96
Vice President,	2001	69,228	9,310	103,267	40
Sales and Marketing					

(1) Compensation represents term life insurance premiums paid by the Company

Options

The following table provides information about options granted during the fiscal year ended December 31, 2002 under the 1992 Plan and 2002 Plan to the Named Officers:

Option Grants In Last Fiscal Year(1)

Individual Grants(2)(3) Name	Number of Securities Underlying Options Granted(#)	Percent of Total Options Granted to Employees in Fiscal Year(%)(5)	Exercise Price ($/Share)	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(4)	
					5%($)	10%($)
Stephen D. Chubb	200,000	15.84%	$2.22	2-26-12	$279,229	$707,622
	12,750	1.01	1.96	12-31-12	15,716	39,828
David L. Corbet	150,000	11.88	2.22	2-26-12	209,422	530,716
	8,929	.71	1.96	12-31-12	11,006	27,892
Melodie R. Domurad	100,000	7.92	2.22	2-26-12	139,615	353,811
	12,872	1.02	1.96	12-31-12	15,866	40,209
Stephen H. Ip	100,000	7.92	2.22	2-26-12	139,615	353,811
	20,408	1.62	1.96	12-31-12	25,156	63,749
John E. Quigley, Jr.	100,000	7.92	2.22	2-26-12	139,615	353,811
	10,297	.82	1.96	12-31-12	12,692	32,165

(1) The Company did not grant any SARs in 2002.

(2) Stock options were granted under the 1992 Plan and 2002 Plan at an exercise price equal to the fair market value of the Company's common stock on the date of grant.

(3) The options have a term of ten years from the date of grant and become exercisable as to 25% of the shares covered on each of the first four anniversaries of the date of grant.

(4) Amounts reported in these columns represent amounts that may be realized upon exercise of the options immediately prior to the expiration of their term assuming the specified compounded rates of appreciation (5% and 10%) on the Company's common stock over the term of the options. These numbers are calculated based on rules promulgated by the Securities and Exchange Commission and do not reflect the Company's estimate of future stock price growth. Actual gains, if any, on stock option exercises and common stock holdings are dependent on the timing of such exercise and the future performance of the Company's common stock. There can be no assurance that the rates of appreciation assumed in this table can be achieved or that the amounts reflected will be received by the individuals.

(5) A total of 1,262,280 options were granted to employees in 2002 under the 1992 and 2002 Plans.

The following table sets forth information regarding stock option exercises in the last fiscal year and exercisable and unexercisable stock options held as of December 31, 2002 by each of the Named Officers. Amounts described in the following table under the heading "Value Realized" were calculated based on the difference between the fair market value of the Company's common stock on the date of the exercise and the exercise price of the options in accordance with the regulations promulgated under the Securities Exchange Act of 1934, as amended, and do not necessarily reflect amounts received by the Named Officers. Amounts described in the following table under the heading "Value of Unexercised In-the-Money Options at December 31, 2002" are based upon the fair market value of the Company's common stock as of December 31, 2002, the last trading day for the fiscal year ended December 31, 2002, which was $2.08 per

share as quoted on the NASDAQ National Market less the applicable exercise price, multiplied by the number of shares underlying the options. The Company has never granted any SARs.

Aggregated Option Exercises In Last Fiscal Year And Fiscal Year-End Option Values

Name	Shares Acquired on Exercise (#)	Value Realized ($)	Number of Securities Underlying Unexercised Options at December 31, 2002 (#) Exercisable/ Unexercisable	Value of Unexercised In-the-Money Options at December 31, 2002 ($) Exercisable/ Unexercisable
Stephen D. Chubb	—	—	281,172/230,050	$11,072/1,530
David L. Corbet	—	—	272,072/235,259	28,344/1,071
Melodie R. Domurad	—	—	32,642/153,819	4,934/2,470
Stephen H. Ip	—	—	80,274/133,024	93,000/31,000
John E. Quigley, Jr.	—	—	25,817/127,407	—/1,236

Compensation of Directors

The Board of Directors voted on June 14, 2002 to provide non-employee directors with a cash payment of $2,500 per Board of Directors meeting attended and $500 per meeting attended of a Committee of the Board of Directors. Non-employee Directors also receive options to purchase common stock of the Company pursuant to the 2002 Director Plan and the 2002 Plan. The 2002 Director Plan includes two types of option grants: (a) each non-employee director who first became or becomes a member of the Board of Directors on or after June 14, 2002 is automatically granted on the date of such election, without further action by the Board, an option (an "Initial Option") to purchase 10,000 shares of the Company's common stock which vests over a four-year period and (b) annually, each non-employee director is automatically granted, as of the date of the Annual Meeting of Stockholders in such year, an option (an "Annual Option") to purchase 10,000 shares of common stock which vests over a one-year period. Any non-employee who becomes a director after the Annual Meeting of Stockholders in any year shall be entitled to receive, in addition to the Initial Option, a fraction of the Annual Option equal to (x) divided by twelve (12), where (x) equals the number of complete months remaining until the first anniversary of the preceding Annual Meeting of Stockholders. In addition, certain directors have received options to purchase common stock of the Company pursuant to the 2002 Plan. Under the 2002 Director Plan, Annual Option grants were made to each of Messrs. Rubinfien, Thompson, Zadel and Ms. Kurland to purchase 10,000 shares of the Company's common stock all of which vest over one-year periods. Upon rejoining the Board in September 2002, Mr. Sandberg received a grant of an option to purchase 10,000 shares, which vests over four years and annual grant for 7,500 shares, which vests over a one-year period under the 2002 Director Plan. All options granted pursuant to the 2002 Director Plan and the 2002 Plan have an exercise price equal to the fair market value of the Company's common stock on the date of grant and expire ten years after the date of grant. Directors are also reimbursed for their expenses incurred in attending meetings of the Board of Directors and committee.

Directors who are employees of the Company receive no additional compensation for service on the Board of Directors or its committees.

Compensation Committee Report

The Compensation Committee of the Board of Directors (the "Compensation Committee") is currently composed of David Rubinfien and T. Stephen Thompson, none of whom is currently an officer or employee of the Company.

The functions of the Compensation Committee are to establish salaries and incentive compensation for the Company's executive officers and to administer the Company's stock option and stock purchase plans.

The Company's executive compensation programs are designed (i) to attract and retain experienced and well qualified executives capable of leading the Company to meet its business objectives, and (ii) to motivate them to enhance long-term stockholder value. In setting the compensation level for executive officers, the Compensation Committee is guided by the following considerations:

- Compensation levels should be competitive with compensation generally being paid to executives in the biotechnology industries to ensure the Company's ability to attract and retain superior executives;
- Each individual executive officer's compensation should reflect the performance of the Company as a whole, the performance of the officer's business unit, if applicable, and the performance of the executive officer; and
- A significant portion of executive officer compensation should be paid in the form of equity-based incentives to link closely stockholder and executive interests and to encourage stock ownership by executive officers.

An executive's total compensation package includes a salary and cash bonus determined by the Compensation Committee, long-term incentive compensation in the form of stock options and various benefits, including a 401(k) retirement plan and medical insurance plans that are available to all employees of the Company. Salaries of the Company's Chief Executive Officer and the next four most highly compensated executives during fiscal 2002 are listed in the "Summary Compensation Table". The Compensation Committee reviews executive salaries at least once per year and, while it is not required to do so, it may in its discretion adjust these salaries. The Compensation Committee attempts to keep the Company's compensation programs competitive by comparing them with those of other local and national companies in the industry. The Compensation Committee also attempts to balance the compensation level for an individual executive against his or her specific job requirements, including the individual's influence on obtaining corporate objectives.

Cash Compensation. The Compensation Committee sets the annual salaries for individual executives by reviewing the salaries historically paid at the Company, the salaries paid by the Company's competitors to persons holding comparable positions and compensation studies prepared by independent third parties. The Compensation Committee determines any increases in annual salaries and bonuses based on a comparison of the executive's actual performance against his or her performance objectives, as well as on various subjective factors. The performance objectives for each executive depend on his or her area of responsibility and may include achievement of the performance objectives in the areas of product commercialization, clinical trials, corporate partnering, and financings, as well as other financial objectives. Among the subjective factors considered by the Compensation Committee is the executive's ability to provide leadership, to develop the Company's business, to promote the Company's image with its customers and stockholders and to manage the Company's continuing growth. The Compensation Committee also solicits and considers performance reviews and recommendations from senior management in establishing compensation levels for all but the Chief Executive Officer.

Equity Compensation. The Company's equity compensation program is designed to (i) provide long-term incentives to executive officers, (ii) tie compensation to creating long-term shareholder value, (iii) encourage executive officers to remain with the Company and to promote the Company's business, and (iv) provide executives with the opportunity to obtain significant, long-term stock ownership in the Company's common stock.

The Compensation Committee has granted options to executive officers as the long-term incentive component of the executive officers' total compensation package. The Compensation Committee generally grants options that become exercisable over a four-year period as a means of encouraging executives to remain with the Company and to promote its success. In fiscal 2002, the Compensation Committee only awarded the Company's executives stock options with exercise prices equal to the market price of the common stock on the date of grant. As a result, executives will benefit from these stock option grants only to the extent that the price of the Company's common stock increases and the Company's stockholders have also benefited.

In deciding whether to grant options and in determining the number of shares to be subject to such options, the Compensation Committee generally reviews the option holdings of each of the executive officers, including the number of unvested options and the then-current value of such unvested options. The number of options granted to certain of the most highly compensated executive officers of the Company in fiscal 2002 is set forth in the table captioned "Option Grants in Last Fiscal Year". The total options held by each of these executives at December 31, 2002 is set forth in the table captioned "Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values".

CEO Compensation. With respect to the compensation of the Company's Chief Executive Officer, Mr. Chubb's salary was $238,915 in 2002. In addition, Mr. Chubb was granted a cash bonus in the amount of $24,990 in 2002, which was paid in January 2003. On February 26, 2002 and December 31, 2002, he received options under the Company's 2002 Plan to purchase up to 200,000 and 12,750 shares respectively of the Company's common stock at exercise prices of $2.22 and $1.96 respectively per share. The February options become exercisable as to 25% of the shares covered on each of February 26, 2003, 2004, 2005 and 2006. The December options become exercisable as to 25% of the shares covered on each of December 31, 2003, 2004, 2005 and 2006. All options granted to Mr. Chubb during 2002 expire ten years from the date of grant and have exercise prices equal to 100% of the fair market value of the Company's common stock as of the date of grant. In arriving at the level of compensation for Mr. Chubb, the Compensation Committee attempted to measure Mr. Chubb's contribution to the progress made by the Company during 2002 toward the achievement of the Company's principal objectives, but the Compensation Committee does not find it practicable to quantify or assign relative weight to the factors on which the Chief Executive Officer's compensation is based. In determining Mr. Chubb's salary for fiscal year 2003 at a meeting on January 7, 2003, the Compensation Committee considered the Company's financial, strategic and clinical objectives for fiscal year 2002 and concluded that Mr. Chubb's salary be increased by 5.5%.

Tax Deductibility of Executive Compensation. Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code"), generally prevents publicly-held corporations from deducting, for federal income tax purposes, compensation in excess of $1 million paid to certain executives. This deduction limitation does not apply, however, to compensation that constitutes "qualified performance-based compensation" within the meaning of Section 162(m) of the Code and the regulations promulgated thereunder. The Compensation Committee has considered the limitations on deductions imposed by Section 162(m) of the Code and it is the Compensation Committee's present intention that, for so long as it is consistent with its overall compensation objectives, substantially all tax deductions attributable to executive compensation will not be subject to the deduction limitations of Section 162(m) of the Code.

Respectfully submitted,

David Rubinfien
T. Stephen Thompson

Item 12. ***Security Ownership of Certain Beneficial Owners and Management.***

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2002, under the heading "Securities Ownership of Management and Principal Stockholders."

Item 13. ***Certain Relationships and Related Transactions.***

The information, if any, required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission within 120 days after the close of our fiscal year ended December 31, 2002, under the heading "Certain Relationships and Related Transactions."

Item 14. ***Controls and Procedures***

Within the 90 days prior to the date of this report, the Chief Executive Officer and Chief Financial Officer performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures are effective in ensuring the reporting of material information required to be included in our periodic filings with the Securities and Exchange Commission.

There were no significant changes in our internal controls or in other factors that could significantly affect these internal controls subsequent to the date of the most recent evaluation.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules, and Reports on Form 8-K.***

(a) 1. Consolidated Financial Statements.
Reports of Independent Accountants.
Consolidated Balance Sheets as of December 31, 2001 and 2002.
Consolidated Statements of Operations for the Years Ended December 31, 2000, 2001 and 2002.
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2000, 2001 and 2002.
Consolidated Statements of Cash Flows for the Years Ended December 31, 2000, 2001 and 2002.
Notes to Consolidated Financial Statements.

2. All schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

3. List of Exhibits

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant (originally filed as Exhibits 3, 4.1 to our Registration Statement No. 33-46158 on Form S-1 and re-filed in electronic form as Exhibit 3.1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
3.2	Amended and Restated By-Laws of the Registrant (originally filed as Exhibits 3.2, 4.1 to our Registration Statement No. 33-46158 on Form S-1 and re-filed in electronic form as Exhibit 3.2 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
3.3	Certificate of Amendment dated June 16, 1994, of Amended and Restated Certificate of Incorporation of the Registrant (originally filed as Exhibit 3.2 of our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 19995 and re-filed in electronic form as Exhibit 3.3 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
3.4	Certificate of Amendment dated June 5, 1995, of Amended and Restated Certificate of Incorporation of the Registrant (originally filed as Exhibit 3.3 of our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1995 and re-filed in electronic form as Exhibit 3.4 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
4.1	Description of Capital Stock contained in the Registrant's Amended and Restated Certificate of Incorporation, filed as Exhibits 3.1, 3.3 and 3.4.
4.2	Form of Warrant Agreement and Certificate between the Company and certain designees of Sunrise Securities Corp. (filed as Exhibit 4.2 to our Form 8-K, filed on June 4, 1997 and incorporated herein by reference).
4.3	Form of Common Stock and Warrant Purchase Agreement between the Company and several investors (filed as Exhibit 4.1 to our Form 8-K, filed on November 22, 1999 and incorporated herein by reference).
4.4	Form of Warrant Agreement issued by the Company to the several investors (filed as Exhibit 4.2 to our Form 8-K, filed on November 22, 1999 and incorporated herein by reference).

Exhibit Number	Description of Exhibit
4.5	Purchase Agreement dated June 28, 2000, by and among Petra Urban, on behalf of Franz Maier, Eva Heidt and Joachim Hevler, the shareholders of ADL, and Stephan Schmidt, on behalf of the Company (filed as Exhibit 4.1 to our Form 8-K, filed on July 10, 2000 and incorporated herein by reference).
4.6	Form of Common Stock and Warrant Purchase Agreement (including form of Warrant) between the Company and Several Investors (filed as Exhibit 4.1 to our 8-K, filed on January 4, 2002 and incorporated herein by reference).
4.7	Form of Common Stock and Warrant Purchase Agreement between the Company and each of the Purchasers (filed as Exhibit 4.1 to our 8-K, filed on December 9, 2002 and incorporated herein by reference).
10.1@††	License Agreement between the Company and the Massachusetts Institute of Technology dated December 14, 1987, as amended March 15, 1988, December 20, 1989 and March 4, 1992 (originally filed as Exhibit 10.1 to our Registration Statement No. 33-46158 on Form S-1 and re-filed in electronic form as Exhibit 10.1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.2#	1988 Stock Plan (originally filed as Exhibit 10.8 to our Registration Statement No. 33-46158 on Form S-1 and re-filed in electronic form as Exhibit 10.2 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.3#	1992 Stock Plan as amended June 16, 2000 (filed as Exhibit 4.6 to our Registration Statement No. 333-51116 on Form S-8, filed on December 1, 2000 and incorporated herein by reference).
10.4#	Amended and Restated 1992 Non-Employee Director Stock Plan as amended June 16, 2000 (filed as Exhibit 4.7 to our Registration Statement No. 333-51116 on Form S-8, filed on December 1, 2000 and incorporated herein by reference).
10.5#	1992 Employee Stock Purchase Plan (originally filed as Exhibit 10.11 to our Registration Statement No. 33-46158 on Form S-1 and re-filed in electronic form as Exhibit 10.5 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.6	Form of Indemnity Agreement with directors (originally filed as Exhibit 10.14 to our Registration Statement No. 33-46158 on Form S-1 and re-filed in electronic form as Exhibit 10.6 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.7	Fourth Amendment dated March 18, 1993 to License Agreement between the Company and the Massachusetts Institute of Technology dated December 14, 1987, as amended (originally filed as Exhibit 10.9 to our Annual Report on Form 10-K for the fiscal year ended December 31, 1997 and re-filed in electronic form as Exhibit 10.7 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.8	Fifth Amendment dated April 14, 1994 to License Agreement between the Company and the Massachusetts Institute of Technology dated December 14, 1987, as amended (originally filed as Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended March 31, 1994 and re-filed in electronic form Exhibit 10.8 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).

Exhibit Number	Description of Exhibit
10.9@††	Exclusive Distribution Agreement between the Company and Konica Corporation dated as of November 9, 1994 (originally filed as Exhibit 10.26 to our Annual Report on Form 10-K for the fiscal year ended December 31, 1994 and re-filed in electronic form as Exhibit 10.9 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.10	First Amendment to Agreement of Lease between the Company and One Nevada Realty Trust dated June 22, 2000 (filed as exhibit 10.10 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2000 and incorporated herein by reference).
10.11	Sixth Amendment dated March 1, 1996 to License Agreement between the Company and the Massachusetts Institute of Technology dated December 14, 1987, as amended (originally filed as Exhibit 10.26 to our Annual Report on Form 10-K for the fiscal year ended December 31, 1995 and re-filed in electronic form as Exhibit 10.11 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.12	Senior Loan and Security Agreement No. 0096 between the Company and Phoenix Leasing, Incorporated dated August 29, 1997 including form of Senior Secured Promissory Note between the Company and Phoenix Leasing, Incorporated (filed as Exhibit 10.20 to our Annual Report on Form 10-K for the fiscal year ended December 31, 1997 and incorporated herein by reference).
10.13@	Distributorship Agreement by and between the Company and Curtin Matheson Scientific, a division of Fisher Scientific Company, L.L.C. dated March 19, 1998 (filed as Exhibit 10.21 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1997 and incorporated herein by reference).
10.14	Investor Relations Warrant Agreement dated July 14, 2000, by and among the Company and the individuals set forth on Exhibit A thereto (filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2000 and incorporated herein by reference).
10.15	Bank Loan between Matritech GmbH and Sparkasse Freiburg, dated May 7, 1999 (filed as exhibit 10.17 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2000 and incorporated herein by reference).
10.16††	Distributorship Agreement by and between Matritech GmbH and Hitachi Chemical Diagnostics, Inc., dated October 1, 2000 (filed as exhibit 10.18 to our Annual Report on Form 10-K for the year ended December 31, 2000 and incorporated herein by reference).
10.17	Distribution Agreement between Matritech, Inc. and Timm Medical Technologies, Inc., dated January 17, 2001 (filed as exhibit 10.19 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2001 and incorporated herein by reference).
10.18#	2002 Stock Option and Incentive Plan (filed as Appendix B to our Definitive Proxy Statement, filed April 22, 2002 on Form 14A and incorporated herein by reference).
10.19#	2002 Non-Employee Director Stock Option Plan (filed as Appendix C to our Definitive Proxy Statement, filed April 22, 2002 on Form 14A and incorporated herein by reference).
10.20#	2002 Employee Stock Purchase Plan (filed as Appendix D to our Definitive Proxy Statement filed April 22, 2002 on Form 14A and incorporated herein by reference).
10.21††**	Distribution Agreement between Matritech, Inc and Cytogen Corporation, dated October 18, 2002.
10.22††**	Exclusive License and Supply Agreement between Matritech, Inc. and Sysmex Corporation, dated November 20, 2002.
99.1**	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.

Exhibit Number	Description of Exhibit
99.2**	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.
23**	Consent of PricewaterhouseCoopers LLP.

@ Confidential Treatment Granted for portions thereof

** Filed herewith

# Indicates management contract or compensatory plan or arrangement required to be filed as an exhibit to this Form 10-K pursuant to Item 14(c) of this report.

†† Confidential Treatment has been requested as to omitted portions pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended. A complete copy of this agreement is being filed separately with the SEC.

(b) Reports on Form 8-K.

i) On October 31, 2002, the Company filed a Current Report on Form 8-K dated as of October 28, 2002 including Item 5.

Item 5 reported the following other event: On October 29, 2002 the Company announced that Richard A. Sandberg was elected as the Company's Chief Financial Officer by the Board of Directors at a meeting held on October 28, 2002, succeeding John Doherty.

ii) On November 21, 2002, the Company filed a Current Report on Form 8-K dated as of November 20, 2002 including Item 5.

Item 5 reported the following other event: The Company entered into an exclusive worldwide license and exclusive supply agreement with Sysmex Corporation to develop an automated Pap smear test.

iii) On December 9, 2002, the Company filed a Current Report on Form 8-K dated as of December 9, 2002 including Items 5 and 7.

Item 5 reported the following other event: The Company completed a private placement of an aggregate of 222,077 units, at a purchase price equal to $5.31 per unit, and with each unit consisting of three shares of Common Stock and a warrant to purchase one share of Common Stock exercisable at $2.30 per share on or before December 9, 2005. Item 7 included a Form of Common Stock and Warrant Purchase Agreement between the Company and each of the investors.

(c) Exhibits. The Company hereby files as exhibits to this Form 10-K those exhibits listed in Item 14(a)(3), above.

(d) Financial Statement Schedules. The Company hereby files as financial statement schedules to this Form 10-K those financial statement schedules listed in Item 14(a)(2), above.

SIGNATURES

Pursuant to the requirements of 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, in the City of Newton, Commonwealth of Massachusetts, on the 31st day of March, 2003.

Matritech, Inc.

By: /s/ STEPHEN D. CHUBB

Stephen D. Chubb
Director, Chairman 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.

Signature	Title	Date
/s/ STEPHEN D. CHUBB Stephen D. Chubb	Director, Chairman, and Chief Executive Officer (Principal Executive Officer)	March 31, 2003
/s/ DAVID L. CORBET David L. Corbet	Director, President and Chief Operating Officer	March 31, 2003
/s/ RICHARD A. SANDBERG Richard A. Sandberg	Director, Vice President, Chief Financial Officer and Treasurer (Principal Accounting and Financial Officer)	March 31, 2003
/s/ JUDITH KURLAND Judith Kurland	Director	March 31, 2003
/s/ DAVID RUBINFIEN David Rubinfien	Director	March 31, 2003
/s/ T. STEPHEN THOMPSON T. Stephen Thompson	Director	March 31, 2003
/s/ C. WILLIAM ZADEL C. William Zadel	Director	March 31, 2003

CERTIFICATIONS

I, Stephen D. Chubb, certify that:

1. I have reviewed this Annual Report on Form 10-K of Matritech, Inc. (the "registrant"):

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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-14 and 15d-14) for the registrant and have:

a. designed such disclosure controls and procedures 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 annual report is being prepared;

b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ Stephen D. Chubb

Stephen D. Chubb
Chief Executive Officer

Date: March 31, 2003

CERTIFICATIONS

I, Richard A. Sandberg, certify that:

1. I have reviewed this Annual Report on Form 10-K of Matritech, Inc. (the "registrant"):

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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-14 and 15d-14) for the registrant and have:

a. designed such disclosure controls and procedures 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 annual report is being prepared;

b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ Richard A. Sandberg

Richard A. Sandberg
Chief Financial Officer

Date: March 31, 2003

MATRITECH, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

THE FOLLOWING REPORT IS A COPY OF A REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP AND HAS NOT BEEN REISSSUED BY ARTHUR ANDERSEN LLP.

AS DISCUSSED IN NOTE 1, MATRITECH, INC. HAS RESTATED ITS FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2001, AND DECEMBER 30, 2000, TO INCLUDE THE TRANSITIONAL DISCLOSURES REQUIRED BY STATEMENT OF FINANCIAL ACCOUNTING STANDARDS NO. 142, "GOODWILL AND OTHER INTANGIBLE ASSETS," THE REVISION TO THE 2001 AND 2000 FINANCIAL STATEMENTS RELATED TO THIS TRANSITIONAL DISCLOSURES WAS REPORTED ON BY PRICEWATERHOUSECOOPERS LLP, AS STATED IN THEIR REPORT APPEARING HEREIN.

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Matritech, Inc.:

We have audited the accompanying consolidated balance sheets of Matritech, Inc. (a Delaware corporation) and subsidiary as of December 31, 2000 and 2001, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Matritech, Inc. and subsidiary as of December 31, 2000 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ARTHUR ANDERSEN LLP

Boston, Massachusetts
March 4, 2002

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

In our opinion, the accompanying consolidated balance sheet as of December 31, 2002 and the related consolidated statement of operations, statement of cash flows and statement of stockholders' equity for the year then ended present fairly, in all material respects, the financial position of Matritech Inc., and its subsidiary, as of December 31, 2002, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit 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 audit provides a reasonable basis for our opinion. The financial statements of the Company as of December 31, 2001 and for each of the two years in the period ended December 31, 2001, prior to the revisions discussed in Note 1(l), were audited by other independent accountants who have ceased operations. Those independent accountants expressed an unqualified opinion on those financial statements in their report dated March 4, 2002.

As disclosed in Note 1(l) to the consolidated financial statements, the Company changed the manner in which it accounts for goodwill and other intangible assets upon adoption of Statement of Financial Accounting Standards No. 142, "Goodwill and other Intangible Assets" on January 1, 2002.

As discussed above, the financial statements of Matritech Inc. as of December 31, 2001, and for each of the two years in the period ended December 31, 2001 were audited by other independent accountants who have ceased operations. As described in Note 1(l), these financial statements have been revised to include the transitional disclosures required by Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets", which was adopted by the Company on January 1, 2002. We audited the transitional disclosures for 2001 and 2000 described in Note 1(l). However, we were not engaged to audit, review, or apply any procedures to the 2001 and 2000 financial statements of the Company other than with respect to such adjustments and transitional disclosures and, accordingly, we do not express an opinion or any other form of assurance on the 2001 and 2000 financial statements taken as a whole.

/s/ PRICEWATERHOUSECOOPERS LLP

Boston, Massachusetts
March 31, 2003

MATRITECH, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2001	December 31, 2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,819,733	$ 4,172,013
Accounts receivable less allowance of $32,433 in 2001 and $23,591 in 2002	291,902	719,039
Inventories, net	337,087	497,913
Prepaid expenses and other current assets	176,748	173,812
Total current assets	5,625,470	5,562,777
Property and equipment, at cost:		
Laboratory equipment	1,898,125	2,287,360
Office equipment	273,148	321,901
Laboratory furniture	62,739	62,739
Leasehold improvements	88,865	88,865
Automobiles	33,205	39,130
	2,356,082	2,799,995
Less — Accumulated depreciation and amortization	1,636,365	1,837,048
	719,717	962,947
Goodwill	132,615	132,615
Other assets	88,961	114,337
Receivable from related party	45,497	45,497
	$ 6,612,260	$ 6,818,173
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of notes payable	$ 46,366	$ 159,741
Accounts payable	491,993	433,080
Accrued expenses	720,201	843,392
Deferred revenue	29,538	462,783
Total current liabilities	1,288,098	1,898,996
Notes payable, less current maturities	102,300	316,433
Deferred revenue	—	763,759
Total liabilities	1,390,398	2,979,188
Commitments and Contingencies (Note 5)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $1.00 par value		
Authorized—4,000,000 shares		
Issued and outstanding—no shares	—	—
Common stock, $0.01 par value		
Authorized—60,000,000 shares		
Issued and outstanding—28,332,073 shares in 2001 and 32,128,243 shares in 2002	283,321	321,282
Additional paid-in capital	67,882,572	74,694,619
Deferred compensation	(107,146)	(35,710)
Accumulated other comprehensive income (loss)	5,428	(20,619)
Accumulated deficit	(62,842,313)	(71,120,587)
Total stockholders' equity	5,221,862	3,838,985
	$ 6,612,260	$ 6,818,173

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

MATRITECH, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2000	2001	2002
REVENUE:			
Product sales	$ 1,245,611	$ 2,340,940	$ 3,093,729
Alliance and collaboration revenue	—	—	186,402
Total revenue	1,245,611	2,340,940	3,280,131
EXPENSES:			
Cost of product sales	983,466	1,705,908	2,149,115
Research, development and clinical expense	2,295,097	3,362,024	3,805,435
Selling, general and administrative expense	5,130,124	6,151,330	5,657,908
Total operating expenses	8,408,687	11,219,262	11,612,458
Loss from operations	(7,163,076)	(8,878,322)	(8,332,327)
Interest income	345,644	169,665	75,164
Interest expense	18,822	22,170	21,111
Net loss	$(6,836,254)	$(8,730,827)	$(8,278,274)
Basic and diluted net loss per common share	$ (0.28)	$ (0.33)	$ (0.27)
Basic and diluted weighted average number of common shares outstanding	24,802,015	26,319,329	30,490,071

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

MATRITECH, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income/(Loss)	Accumulated Deficit	Total Stockholders' Equity
	Number of shares	Par Value					
Balance, December 31, 1999	23,552,984	$235,530	$52,983,162	—	—	$(47,275,232)	$5,943,460
Net loss	—	—	—	—	—	(6,836,254)	(6,836,254)
Cumulative translation adjustment	—	—	—	—	$ (9,021)	—	(9,021)
Total comprehensive loss	—	—	—	—	—	—	(6,845,275)
Sale of common stock, net of issuance costs of $64,051	281,082	2,811	1,473,138	—	—	—	1,475,949
Exercise of common stock options	188,204	1,882	448,131	—	—	—	450,013
Exercise of common stock warrants	1,465,264	14,653	3,378,306	—	—	—	3,392,959
Issuance of common stock under employee stock purchase plan	3,000	30	4,470	—	—	—	4,500
Issuance of common stock to consultant	13,595	136	89,864	—	—	—	90,000
Compensation related to issuance of common stock warrants	—	—	1,020,684	—	—	—	1,020,684
Deferred compensation shares	37,153	371	213,929	$(214,300)	—	—	—
Amortization of deferred compensation shares	—	—	—	35,718	—	—	35,718
Balance, December 31, 2000	25,541,282	$255,413	$59,611,684	$(178,582)	$ (9,021)	$(54,111,486)	$5,568,008
Net loss	—	—	—	—	—	(8,730,827)	(8,730,827)
Cumulative translation adjustment	—	—	—	—	14,449	—	14,449
Total comprehensive loss	—	—	—	—	—	—	(8,716,378)
Sale of common stock and warrants, net of issuance costs of $193,893	2,658,739	26,587	6,967,580	—	—	—	6,994,167
Exercise of common stock options	60,494	605	92,426	—	—	—	93,031
Exercise of common stock warrants	50,000	500	124,500	—	—	—	125,000
Issuance of common stock under employee stock purchase plan	11,558	116	34,998	—	—	—	35,114
Shares issued to former ADL shareholders (Note 3)	10,000	100	30,700	—	—	—	30,800
Compensation related to issuance of common stock warrants	—	—	1,020,684	—	—	—	1,020,684
Amortization of deferred compensation shares	—	—	—	71,436	—	—	71,436
Balance, December 31, 2001	28,332,073	$283,321	$67,882,572	$(107,146)	$ 5,428	$(62,842,313)	$5,221,862
Net loss	—	—	—	—	—	(8,278,274)	(8,278,274)
Cumulative translation adjustment	—	—	—	—	(26,047)	—	(26,047)
Total comprehensive loss	—	—	—	—	—	—	(8,304,321)
Sale of common stock and warrants, net of issuance costs of $191,803	2,992,279	29,922	5,265,000	—	—	—	5,294,922
Sale of common stock, net of issuance costs of $6,304	783,208	7,832	1,489,622	—	—	—	1,497,454
Exercise of common stock options	6,850	69	9,521	—	—	—	9,590
Exercise of common stock warrants	4,000	40	10,960	—	—	—	11,000
Issuance of common stock under employee stock purchase plan	9,833	98	23,356	—	—	—	23,454
Amortization of deferred compensation	—	—	—	71,436	—	—	71,436
Compensation related to common stock warrants	—	—	13,588	—	—	—	13,588
Balance, December 31, 2002	32,128,243	$321,282	$74,694,619	$ (35,710)	$(20,619)	$(71,120,587)	$3,838,985

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

MATRITECH, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2000	2001	2002
Cash Flows from Operating Activities:			
Net loss	$(6,836,254)	$(8,730,827)	$(8,278,274)
Adjustments to reconcile net loss to net cash used in operating Activities:			
Depreciation and amortization	205,804	266,408	279,940
Amortization of deferred compensation	35,718	71,436	71,436
Expense related to issuance of common stock to former ADL shareholders (Note 3)	—	30,800	—
Expense related to issuance of common stock warrants to consultant	1,020,684	1,020,684	13,588
Expense related to issuance of common stock to consultant	90,000	—	—
Changes in assets and liabilities:			
Accounts receivable	108,280	(40,965)	(406,678)
Inventories	77,892	(2,560)	(160,826)
Prepaid expenses and other current assets	(56,329)	16,434	2,936
Other assets	—	—	(25,376)
Accounts payable	(185,698)	126,182	(58,913)
Accrued expenses	(168,320)	334,688	165,246
Deferred revenue	(1,454)	21,105	1,197,004
Net cash used in operating activities	(5,709,677)	(6,886,615)	(7,199,917)
Cash Flows from Investing Activities:			
Purchases of property and equipment	(135,945)	(117,966)	(563,500)
(Increase) decrease in other assets	(68,779)	20,585	—
Cash paid for acquisition costs in purchase of ADL, net of cash acquired (Note 3)	(100,813)	—	—
Net cash used in investing activities	(305,537)	(97,381)	(563,500)
Cash Flows from Financing Activities:			
Payments on notes payable	(250,375)	(119,037)	(100,548)
Proceeds from notes payable			410,000
Proceeds from sale of common stock and warrants	1,475,949	6,994,167	6,792,376
Proceeds from exercise of common stock warrants	3,392,959	125,000	11,000
Proceeds from exercise of common stock options	450,013	93,031	9,590
Proceeds from issuance of common stock under employee stock purchase plan	4,500	35,114	23,454
Net cash provided by financing activities	5,073,046	7,128,275	7,145,872
Effect of foreign exchange on cash and cash equivalents	(9,021)	14,449	(30,175)
Increase (Decrease) in cash and cash equivalents	(951,189)	158,728	(647,720)
Cash and cash equivalents, beginning of year	5,612,194	4,661,005	4,819,733
Cash and cash equivalents, end of year	$ 4,661,005	$ 4,819,733	$ 4,172,013
Supplemental Cash Flow Information:			
Cash paid during the year for interest	$ 18,822	$ 22,170	$ 21,111
In connection with the acquisition of ADL, the following transactions occurred:			
Fair value of assets acquired	$ 532,545		
Goodwill	268,453		
Cash paid for acquisition costs, net of cash acquired	(100,813)		
Liabilities assumed	$ 700,185		
Issuance of common stock for services to be provided	$ 214,300		

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

(1) Operations and Significant Accounting Policies

Matritech, Inc. was incorporated on October 29, 1987, to develop, produce and distribute products for the diagnosis and potential treatment of cancer based on its proprietary nuclear matrix protein technology. This technology was licensed to us by the Massachusetts Institute of Technology ("MIT").

We are devoting substantially all of our efforts toward product research and development, raising capital, securing partners and marketing products. We are subject to risks common to companies in similar stages of development, including history of operating losses and anticipated future losses, fluctuation in operating results, uncertainties associated with future performance, near-term dependence on a limited number of products, uncertainties around bringing new products to market, reliance on sole suppliers, dependence on key individuals, competition from substitute products and larger companies, the development of commercially usable products and the need to obtain adequate additional financing necessary to fund its operations and the development of its future products.

We are currently seeking to raise additional capital and will consider various financing alternatives, including equity or debt financings and corporate partnering arrangements. However, we may not be able to raise needed capital on terms that are acceptable to us, or at all. If we raise funds on unfavorable terms, we may provide rights and preferences to new investors which are not available to current shareholders. If we do not receive additional financing or do not receive an adequate amount of additional financing, we will be required to curtail our expenses by reducing research and/or marketing or to take other steps that could hurt our future performance, including but not limited to, the premature sale of some or all of our assets or product lines on undesirable terms, merger with or acquisition by another company on unsatisfactory terms or the cessation of operations. Any future equity financings will dilute the ownership interest of our existing investors and may have an adverse impact on the price of our common stock. Any of the foregoing steps will have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that capital will be available on terms acceptable to us, if at all.

On June 28, 2000, we acquired all of the outstanding shares of capital stock of ADL GmbH, Gesellschaft fur Allergie, Diagnostika und Laborkonzepte ("ADL"), now called Matritech GmbH ("Matritech GmbH"), a European distributor of diagnostic testing products, including our NMP22 Test Kit for bladder cancer (see Note 3). The consolidated financial statements include the accounts our wholly-owned subsidiary, Matritech GmbH since the date of acquisition. All significant intercompany balances and transactions have been eliminated at consolidation level.

(a) Principles of Consolidation

The consolidated financial statements include the accounts of us and our wholly-owned subsidiary. All significant intercompany balances and transactions have been eliminated at consolidation level.

(b) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

(c) Revenue Recognition

We recognize revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 101 Revenue Recognition in Financial Statements ("SAB 101"). Revenue is recognized when the following criteria have been met:

1. Persuasive evidence of an arrangement exists
2. Delivery has occurred and risk of loss has passed
3. The seller's price to the buyer is fixed or determinable
4. Collectibility is reasonably assured

When determining whether risk of loss has transferred to customers on product sales, we evaluate both the contractual terms and conditions of our sales agreements as well as our business practices. Business practices such as agreeing to product exchanges may indicate the existence of an implied right to return the product even if there are no such contractual provisions for product returns. We treat such practices, whether contractual or implied, as conveying a right of return and will establish provisions for returns when reasonable and reliable estimates can be made. In accordance with SAB 101, where we do not have sufficient history to make reasonable and reliable estimates of returns, revenue associated with such practices is deferred until the return period lapses or a reasonable estimate can be made. This deferred revenue will be recognized as revenue when the distributor reports to us that it has either shipped or disposed of the units (indicating that the return period has lapsed).

Contract and license fee revenue is primarily generated through collaborative license and development agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones, payments for product manufacturing and royalties on net product sales. Revenue arrangements where multiple products or services are sold together under one contract are evaluated to determine if each element represents a separate earnings process. In the event that an element of such multiple element arrangement does not represent a separate earnings process, revenue from this element is recognized over the term of the related contract.

Where we have continuing performance obligations under the terms of a collaborative arrangement, non-refundable license fees are recognized as revenue over the period we complete our performance obligations. Revenues from milestone payments related to arrangements under which we have no continuing performance obligations are recognized upon achievement of the related milestone. Revenues from milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations.

Payments received from collaborative partners for research and development services performed by us are recognized as revenue on a straight line basis (unless evidence indicates an alternative earnings pattern can be demonstrated) over the term of the arrangement or the expected service period, whichever is longer. Revenue from royalty payments is recognized when earned, upon the receipt of data from the licensees in accordance with the related license agreement supporting the amount of and basis for such royalty payments to us.

Deferred revenue consists of the following:

	December 31, 2001	December 31, 2002
Non-refundable fees	$29,538	$ 866,676
Deferred product revenue	—	359,866
	$29,538	$1,226,542

(d) Cash and Cash Equivalents

We consider all highly liquid investments with original maturities of 90 days or less to be cash equivalents. We follow the provisions of Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities", in accounting for our marketable securities. Securities held at December 31, 2001, include only cash and cash equivalents, which consist of auction market preferred stocks and money market accounts that are classified as held-to-maturity securities. Securities held at December 31, 2002, include only cash and cash equivalents, which consist of auction market preferred stocks, a $410,000 certificate of deposit and money market accounts that are classified as held-to-maturity securities.

(e) Inventories

Inventories are stated at the lower of cost (determined on a first-in first-out basis) or market and consist of the following:

	December 31, 2001	December 31, 2002
Raw materials	$147,234	$160,862
Work-in-process	3,804	3,667
Finished goods	186,049	270,205
Consignment inventory	—	63,179
	$337,087	$497,913

(f) Depreciation

We provide for depreciation using accelerated and straight-line methods by charges to operations in amounts that allocate the cost of property and equipment over their estimated useful lives as follows:

Asset Classification	Useful Life
Laboratory equipment	4 to 10 years
Office equipment	3-5 years
Laboratory furniture	5 years
Leasehold improvements	Life of lease
Automobiles	5 years

(g) Concentration of Credit Risk and Significant Customers

Financial instruments that potentially expose us to concentrations of credit risk consist primarily of cash and cash equivalents and trade accounts receivable. We limit credit risk in cash and cash equivalents by investing only in short-term, investment grade securities with financial institutions of high credit standing We

do not require collateral from our customers. To reduce risk, we routinely assess the financial strength of its customers and, as a consequence, believe that our trade accounts receivable credit risk exposure is limited.

We received revenue of greater than 10% of total product sales and collaboration fees from the following customers during the following periods:

	A	B	F
Year ended December 31, 2000	13%	18%	—
Year ended December 31, 2001	—	11%	14%
Year ended December 31, 2002	—	—	12%

We had accounts receivable balances greater than 10% of total accounts receivable from the following customers as of December 31, 2001 and 2002:

	A	B	D	F	G
As of December 31,					
2001	13%	17%	15%	14%	—
2002	—	—	—	—	39%

(h) Disclosure of Fair Value of Financial Instruments

Our financial instruments consist mainly of cash and cash equivalents, accounts receivable, accounts payable and notes payable. The carrying amounts of our financial instruments approximate their estimated fair values at December 31, 2001 and 2002. The estimated fair values have been determined through information obtained from market sources and management estimates.

(i) Net Loss per Common Share

We compute earnings per share in accordance with SFAS No. 128, "Earnings per Share". Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the year. Diluted loss per share is the same as basic loss per share as the effects of our potential common stock are antidilutive. Potential common stock consists of stock options and warrants as well as 22,914 and 12,262 contingently issuable shares of common stock held in escrow in connection with the Matritech GmbH acquisition at December 31, 2001 and 2002, respectively. The number of antidilutive common stock equivalents excluded from the computation of diluted loss per share were 1,556,440, 1,801,079 and 3,078,173 for the years ended December 31, 2000, 2001 and 2002, respectively.

(j) Comprehensive Income(Loss)

We adopted SFAS No. 130, "Reporting Comprehensive Income", which requires that all items recognized under accounting standards as components of comprehensive income or loss (e.g., foreign currency translation adjustments and unrealized gains and losses on certain marketable securities) be reported in the annual financial statements. The composition of accumulated other comprehensive loss is as follows:

	2000	2001	2002
Reported net income (loss)	$(6,836,254)	$(8,730,827)	$(8,278,274)
Other comprehensive income (loss)			
Foreign currency translation adjustments	(9,021)	14,449	(26,047)
Comprehensive income (loss)	$(6,845,275)	$(8,716,378)	$(8,304,321)

(k) Foreign Currency Translation

The financial statements of the Matritech GmbH are translated in accordance with SFAS No. 52, *Foreign Currency Translation*. The functional currency of our foreign subsidiary is the local currency (Euro), and accordingly, all assets and liabilities of the foreign subsidiary are translated using the exchange rate at the balance sheet date except for intercompany receivables which are of long-term-investment nature, and capital accounts which are translated at historical rates. Revenues and expenses are translated at average rates during the period. Adjustments resulting from the translation from the financial statements of the Matritech GmbH into U.S. Dollars are excluded from the determination of net income and are accumulated in accumulated other comprehensive income within stockholders' equity. Foreign currency transaction gains and losses are reported in the accompanying consolidated statements of operations and are immaterial to the results of operations.

(l) Goodwill and Long-lived Assets

Effective January 1, 2002, we adopted SFAS No. 142, *Goodwill and Other Intangible Assets* ("SFAS 142"). This statement requires that goodwill and certain other intangibles no longer be amortized, but instead tested for impairment at least annually. We have completed the impairment test as required by SFAS 142 and, based on the results of this analysis, no impairment of goodwill was identified. We did not record amortization expense relating to our goodwill during the year ended December 31, 2002. Goodwill amortization was $86,817 and $49,021 for the years ended December 31, 2001 and 2000, respectively. A reconciliation of previously reported net income and earnings per share to the amounts adjusted for the exclusion of goodwill amortization follows:

	2000	2001	2002
Reported net loss	$(6,836,254)	$(8,730,827)	$(8,278,274)
Add back: Goodwill amortization	49,021	86,817	—
Adjusted net loss	$(6,787,233)	$(8,644,010)	$(8,278,274)
Basic and diluted loss per share:			
Reported net loss	$ (0.28)	$ (0.33)	$ (0.27)
Goodwill amortization	.01	—	—
Adjusted net loss	$ (0.27)	$ (0.33)	$ (0.27)

Our policy regarding long-lived assets is to evaluate the recoverability or usefulness of these assets when the facts and circumstances suggest that these assets may be impaired. This analysis relies on a number of factors, including changes in strategic direction, business plans, regulatory developments, economic and budget projections, technological improvements, and operating results. The test of recoverability or usefulness is a comparison of the asset value to the undiscounted cash flow of its expected cumulative net operating cash flow over the asset's remaining useful life. Any write-downs would be treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized. To date, we have had recurring operating losses and the recoverability of our long-lived assets is contingent upon executing our business plan that includes, among other factors, significantly increasing sales. If we are unable to execute our business plan, we may be required to write down the value of our long-lived assets in future periods.

(m) Research and Development Costs

Research and development costs, which are comprised of costs incurred in performing research and development activities including wages and associated employee benefits, clinical trial costs, contract services, and facilities and overhead costs, are expensed as incurred.

(n) Stock-Based Compensation

We have elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25") and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation,* ("SFAS No. 123"). Under APB 25, when the exercise price of options granted under these plans equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. In accordance with Emerging Issues Task Force ("EITF") 96-18, we record compensation expense equal to the fair value of options granted to non-employees over the vesting period, which is generally the period of service.

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

	2000 (unaudited)	2001 (unaudited)	2002
Net loss attributable to common stockholders	$(6,836,254)	$(8,730,827)	$(8,278,274)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all rewards	(1,015,622)	(508,378)	(913,037)
Pro forma net loss	$(7,851,876)	$(9,239,205)	$(9,191,311)
Amounts per common share:			
Basic and diluted — as reported	$ (0.28)	$ (0.33)	$ (0.27)
Basic and diluted — pro forma	$ (0.32)	$ (0.35)	$ (0.30)

The weighted-average per share fair value of grants during 2000, 2001, and 2002 was $3.19, $2.09, and $1.93, respectively.

The fair value of stock options and common shares issued pursuant to the stock option and stock purchase plans at the date of grant were estimated using the Black-Scholes model with the following weighted-average assumptions:

	2000	2001	2002
Risk-free interest rate	5.28% - 6.33%	4.56 - 5.41%	1.35 - 3.28%
Expected dividend yield	—	—	—
Expected life	7 years	7 years	7 years
Expected volatility	65%	65%	110%

The effects on 2000, 2001 and 2002 pro form net loss and net loss per share of expensing the estimated fair value of stock options and common shares issued pursuant to the stock option and stock purchase plans are not necessarily representative of the effects on reported results of operations for future years as options vest over several years and we intend to grant varying levels of stock options in future periods.

(o) Recent Accounting Pronouncements

In April 2002, the FASB issued SFAS 145, *Rescission of FASB Statement No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections.* SFAS 145 rescinds FASB Statement No. 4, *Reporting Gains and Losses from Extinguishment of Debt,* and an amendment of that Statement, FASB Statement No. 64, *Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements.* SFAS 145 also rescinds FASB Statement No. 44, *Accounting for Intangible Assets of Motor Carriers.* SFAS 145 amends FASB Statement No. 13, *Accounting for Leases,* to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects

that are similar to sale-leaseback transactions. This Statement also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions of SFAS 145 are effective for financial statements issued on or after May 15, 2002. The adoption of SFAS 145 did not have a material effect on our financial statements.

In July 2002, the FASB issued SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities.* SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized at its fair market value when the liability is incurred, rather than at the date of an entity's commitment to an exit plan. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have a material effect on our financial statements.

In December 2002, the FASB issued SFAS 148, *Accounting for Stock-Based Compensation-Transition and Disclosure — An Amendment of FAS No. 123.* SFAS 148 amends SFAS 123, *Accounting for Stock-Based Compensation,* to provide alternative methods of transition for those companies who voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of FAS 123 to require prominent disclosures in both the annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The transition and annual disclosure provision of FAS 148 are effective for fiscal years ending after December 15, 2002. We have not adopted the fair value method of accounting for stock-based compensation, and will continue to apply APB 25 for our stock-based compensation plans. We have incorporated the disclosure requirements of SFAS 148 at December 31, 2002, which require a tabular pro forma presentation of net income had FAS 123 been adopted by us in the "Summary of Significant Accounting Policies" footnote of the financial statements.

In November 2002, FASB Emerging Issues Task Force reached consensus with respect to Issue 00-21 ("EITF 00-21"), *Accounting for Revenue Arrangements with Multiple Deliverables.* EITF 00-21 addresses the accounting for multiple-element revenue arrangements. Specifically, EITF 00-21 addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how arrangement consideration should be measured and allocated to the separate units of accounting. This EITF is effective for the revenue arrangements entered into in fiscal periods beginning after June 15, 2003. At the present time, this EITF is not expected to have material impact on our financial position or results of operations.

In November 2002, the FASB issued FASB Interpretation No. 45 ("FIN 45"), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34.* FIN 45 elaborates on the disclosures to be made by a guarantor in our interim and annual financial statements about our obligations under certain guarantees that it has issued. It requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value for the obligation undertaken in issuing the guarantee. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective for financial statement periods ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on our consolidated financial statements. See Note 5, "Commitments and Contingencies," to our consolidated financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), *Consolidation of Variable Interest Entities, an interpretation of ARB No. 51.* FIN 46 requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. Variable interest entities that effectively disperse risk will not be consolidated unless a single party holds an interest or combination of interests that effectively recombines risks that were previously dispersed. FIN 46 also requires enhanced disclosure requirements related to variable interest entities. FIN 46

applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 is not expected to have a material effect on our financial statements.

(2) Agreements

In March 2001, we entered into an eight-year, non-exclusive product supply and marketing agreement with DPC enabling DPC to develop and market an automated version of our NMP22 Lab Test Kit. Under this agreement we receive royalty payments which are recognized when earned. In all such agreements, the determination of when royalties are earned is based upon the receipt of data from the licensees in accordance with the related license agreement supporting the amount of and basis for such royalty payments to us.

In March 2002, we entered into a supply and distribution agreement with MBL granting MBL the exclusive right in Japan to sell the NMP22 BladderChek Device. MBL is responsible for conducting clinical trials and securing the necessary regulatory approvals in Japan. Under the terms of this agreement MBL paid us a non-refundable license fee which is being recognized as revenue over the eight-year term of the agreement.

In September 2002, we entered into a distribution agreement with Cytogen, granting Cytogen the exclusive right to market and sell the NMP22 BladderChek Device to the urology and oncology market in the United States. Under the terms of the agreement, Cytogen paid a non-refundable license fee which is being recognized as revenue over the five-year term of the agreement.

In November 2002, we entered into an exclusive license and supply agreement with Sysmex, which granted them the use of NMP179 technology for automated non-slide-based laboratory instruments. Under the terms of the agreement, Sysmex purchased shares of our common stock at a premium. A premium of approximately $500,000 has been ascribed to the value of the license and is being recognized as revenue over the fourteen-year term of the related patents. This agreement also contains future royalty, milestone and research and development payments. We will recognize any future royalty and milestone payments over the remaining life of the related patents.

(3) Acquisition of ADL

On June 28, 2000, we acquired all of the outstanding shares of capital stock of ADL, now called Matritech GmbH, a European distributor of diagnostic testing products, including our NMP22 Test Kit for bladder cancer. Matritech GmbH is located in Freiburg, Germany. Pursuant to Accounting Principles Board ("APB") Opinion No. 16*, Business Combinations,* this acquisition was accounted for as a purchase, and accordingly the results of operations of Matritech GmbH from June 28, 2000 forward are included in our consolidated statement of operations.

The aggregate purchase price of approximately $801,000 consisted of assumed liabilities of $700,000 and acquisition costs of $101,000, net of cash acquired. The purchase price was allocated based upon the fair values of the tangible and intangible assets acquired. Total tangible assets acquired were approximately $533,000 comprised of current assets of $311,000, net fixed assets of $201,000 and other assets of $21,000. Goodwill of $268,000 was recorded in connection with the acquisition. In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets,* the remaining $133,000 of goodwill as of December 31, 2001 will cease to be amortized and will be reviewed annually for impairment.

In connection with the acquisition, we issued 37,153 shares of our common stock to the former shareholders of ADL. These shares are restricted subject to continued employment of the ADL shareholders.

This issuance of shares was valued at $214,300, and is being recorded ratably as compensation over the three-year employment period. In 2001, 10,000 shares of common stock were issued to the former shareholders of ADL in accordance with their employment agreements. We recorded compensation expense based on the fair market value of the common stock on the date of these grants, totaling $30,800.

Pro Forma Results of Operations (Unaudited)

The following unaudited pro forma combined results of operations is calculated by assuming that the ADL acquisition was completed on January 1, 1999. These proforma results represent the historical operating results of ADL prior to its date of acquisition, combined with those of the Company with appropriate adjustments. These pro forma results are not necessarily indicative of operating results that would have occurred if the ADL acquisition had been operated by current management during the periods presented.

	Year Ended December 31, 2000
Total revenue	$ 1,935,121
Net loss	$(7,069,385)
Net loss per share — basic and diluted	$ (.29)

(4) Income Taxes

A reconciliation of the federal statutory rate to our effective tax rate is as follows:

	December 31,		
	2000	2001	2002
Income tax provision at federal statutory rate	(34.0)%	(34.0)%	(34.0)%
Increase in tax resulting from State tax provision, net of Federal benefit	(6.0)	(6.0)	(6.0)
Increase in valuation allowance	40.0	40.0	40.0
Effective tax rate	0%	0%	0%

We follow the provisions of SFAS No. 109, Accounting *for Income Taxes*. Under the provisions of SFAS No. 109, we recognized a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences between the carrying values of assets and liabilities for financial reporting purposes and their tax basis and carry forwards to the extent they are realizable. A valuation reserve is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. Accordingly, a valuation reserve has been established for the full amount of the deferred tax asset. Of the total valuation allowance, approximately $352,000 relates to stock option compensation deductions. The tax benefit associated with the stock option compensation deductions will be credited to equity when and if realized.

At December 31, 2002, we had federal and state tax NOL carryforwards of approximately $53,631,000 and $30,088,000, which begin to expire in 2003. Approximately, $3,925,000 of state NOLs expired in 2002. We also have a NOL from our operation in Germany of approximately $1,289,000, which carries forward indefinitely. At December 31, 2002, we had federal and state research and experimentation credit carryforwards of approximately $1,414,000 and $1,065,000, which begin to expire in 2004, respectively. Based upon the Internal Revenue Code Section 382, changes in our ownership, could limit the utilization of our tax attributes.

Our net deferred tax asset consists of the following:

	December 31,	
	2001	2002
Net operating loss carryforwards	$ 18,526,000	$ 20,611,000
Capitalized research and development expenses	5,057,000	5,774,000
Tax credits	2,311,000	2,117,000
Deferred revenue		494,000
Other temporary differences	(429,000)	(95,000)
Deferred tax asset	25,465,000	28,901,000
Valuation allowance	(25,465,000)	(28,901,000)
Net deferred tax asset	$ —	$ —

A full valuation allowance has been provided due to the uncertainty surrounding the realization of the deferred tax asset.

(5) Commitments and Contingencies

We lease office and laboratory facilities and certain equipment under operating leases that expire through 2006. Total commitments are due as follows:

2003	$ 543,000
2004	519,000
2005	500,000
2006	9,000
Total	$1,571,000

Rent expense, including facility and equipment rentals, for the years ended December 31, 2000, 2001 and 2002 was approximately $341,000, $509,000 and $540,000 respectively.

In 2000, Matritech GmbH entered into a 5-year extension of the distribution agreement with Hitachi which contains minimum annual purchase commitments. These commitments are negotiated annually for the following year. The 2003 minimum purchase commitment totals $95,000.

Guarantees

As permitted under Delaware law, we have agreements whereby we indemnify our officers and directors for certain events or occurrences while the officer or director is, or was, serving at our request in such capacity. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited; however, we have a Director and Officer insurance policy that limits our exposure and enables us to recover a portion of any future amounts paid. As a result of our insurance policy coverage, we believe the estimated fair value of these indemnification agreements is minimal. All of these indemnification agreements were grandfathered under the provisions of FIN No. 45 as they were in effect prior to December 31, 2002. Accordingly, we have no liabilities recorded for these agreements as of December 31, 2002.

We enter into standard indemnification agreements in our ordinary course of business. Pursuant to these agreements, we indemnify, hold harmless, and agree to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally our business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect

to our products. The term of these indemnification agreements vary. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the estimated fair value of these agreements is minimal. All of these indemnification agreements were grandfathered under the provisions of FIN No. 45 as they were in effect prior to December 31, 2002. Accordingly, we have no liabilities recorded for these agreements as of December 31, 2002.

(6) Notes Payable

We had a term note with Phoenix Leasing Incorporated for equipment purchases. The term note is payable over 48 months, bears interest at 11.75%, is secured by the underlying equipment and requires a final lump sum payment (which may be paid over the course of 10 months upon election by us) upon the conclusion of the term of the note. The monthly payments on this note were paid off in October 2001. We elected to make a lump sum payment and sold one of the pieces of equipment in satisfaction of the final lump sum payment.

In connection with the acquisition of ADL, we assumed certain debt obligations. At December 31, 2002, these obligations consist of a $67,000 loan from a bank, a $42,000 third-party demand note and $3,000 worth of automobile loans. The bank loan bears interest at 5.2%, is due in monthly installments of $4,000 and is secured by trade receivables and inventory. The demand note will be repaid by us and we will be reimbursed by a key Matritech GmbH employee. We have recorded a corresponding asset for this employee receivable. The automobile loans bear interest between 6.99% and 7.50% and are due in monthly installments of $600.

In July 2002, we entered into a term note for $410,000 with Citizens Bank of Massachusetts to finance an equipment purchase. The term note is payable over four years, bears interest at 1% plus the bank's prime rate (4.25% at December 31, 2002) and contains a covenant which requires us to maintain a cash balance of $250,000 at all times. This note is collateralized by the capital equipment. If the ratio of our cash and cash equivalents to total liabilities (excluding deferred revenue) is 115% or less, the bank has the right to exchange the equipment as collateral for a certificate of deposit in the amount of $410,000. We were in compliance with all debt covenants at December 31, 2002.

Maturities of debt obligations are as follows:

2003	$159,741
2004	133,169
2005	112,986
2006	70,278
Total	$476,174

(7) Stockholders' Equity

(a) Sale of Common Stock

In April 1999, we completed a private placement of 3,094,965 shares of our common stock resulting in net proceeds of $3,910,000 after deducting transaction expenses. In November 1999, we completed another private placement of 1,801,340 shares of common stock at $2 per share resulting in proceeds of $3,546,000 after deducting transaction expenses. In connection with the second private placement, we issued to the investors warrants to purchase 900,670 shares of common stock at $2.20 per share. All such warrants were exercised during 2000, providing proceeds to us of $1,981,000.

In August 2000, we entered into a common stock purchase agreement covering the sale of up to $30 million (a maximum of 2.45 million shares) of our common stock with Acqua Wellington North

American Equities Fund, Ltd. ("Acqua"). During 2000, Acqua purchased 281,082 shares, with net proceeds to us of $1,476,000. During 2001, Acqua purchased 1,105,395 shares, with net proceeds to us of $3,537,000. This agreement terminated on October 22, 2001.

On various closing dates throughout December 2001, we sold an aggregate of 1,063,523 shares of common stock for prices ranging from $2.15 to $2.74 per share. These shares were sold under our Registration Statement on Form S-3 dated July 28, 2000. Proceeds from this sale were $2,246,000 after deducting transaction expenses. In December 2001, we completed a private placement of 113,969 units, at a purchase price of $9.44 per unit. Each unit consists of four shares of common stock and a warrant to purchase one share of common stock at a price of $2.75 per share. These warrants were exercisable for the two-year period ending December 2003 and were callable by us if certain conditions are satisfied. We received net proceeds of $1,061,000 after deducting transaction expenses. The values of the warrants and common stock in excess of par value have been reflected in additional paid-in-capital. In 2002, 4,000 of these warrants were exercised, providing proceeds to us of $11,000.

In March 2002, we completed a private placement of 538,437 units, at a purchase price of $8.00 per unit. Each unit consists of four shares of common stock and a warrant to purchase one share of common stock at a price of $3.00 per share. The warrants were exercisable until November 30, 2002 and were callable by us if certain conditions were satisfied. We received net proceeds of approximately $4,140,000 after deducting transaction expenses. None of these warrants have been exercised. The values of the warrants and common stock in excess of par value have been reflected in additional paid-in-capital.

In November 2002, we entered into an exclusive worldwide license and exclusive supply agreement with Sysmex Corporation ("Sysmex"). Under the agreement, Sysmex purchased 783,208 shares of our common stock at a price of $2.55 per share.

In December 2002, we completed a private placement of 222,077 units, at a purchase price of $5.31 per unit. Each unit consists of three shares of common stock and a warrant to purchase one share of common stock at a price of $2.30 per share. These warrants are exercisable until December 9, 2005 and are callable by us if certain conditions are satisfied. We received net proceeds of approximately $1,155,000. None of these warrants have been exercised. The values of the warrants and common stock in excess of par value have been reflected in additional paid-in-capital.

(b) Warrants

In April 1997, we issued a warrant to an investor relations consultant for the purchase of up to 150,000 shares of our common stock for a price of $6.50 per share expiring in April 2002. These warrants were valued at $500,000 in accordance with SFAS No. 123 and were expensed ratably over the one-year term of the agreement. We expensed $150,000 as a component of selling, general and administrative expense on the statement of operations for the year ended December 31, 1998. In 1999, these warrants were repriced to $2.50 per share and an additional $72,000 was recorded as a component of selling, general and administrative expenses in 1999 for the repricing. In 2000, all such warrants were exercised, providing proceeds to us of $375,000.

In May 1997, in connection with a private placement, we issued to the placement agent a warrant to purchase 245,761 shares of common stock at $5 per share. In 1999, these warrants were repriced to $2.50 per share and $87,000 was recorded as a component of selling, general and administrative expenses in 1999 for the repricing. In 2000, 214,594 of these warrants were exercised, providing proceeds to us of $536,000.

In July 2000, we issued a fully vested, nonforfeitable warrant to an investor relations consultant for the purchase of up to 450,000 shares of our common stock for a price of $2.50 per share expiring in July 2005. These warrants were valued at $2,041,368 in accordance with SFAS No. 123 and were expensed ratably over the one-year term of the agreement. We expensed $1,020,684 as a component of selling, general and

administrative expense on the accompanying statement of operations for the years ended December 31, 2000 and 2001. In December 2000 and January 2001, 200,000 and 50,000, respectively, of these warrants were exercised, providing proceeds to us of $500,000 and $125,000, respectively.

(c) Stock Option and Purchase Plans

We have granted incentive and nonqualified options under our 1988, 1992 and 2002 option plans and the 1992 and 2002 Directors' Plans. All option grants, prices and vesting periods are determined by the Board of Directors. Incentive stock options must be granted at a price not less than the fair market value on the date of grant. Options vest at various rates over periods of up to four years and expire ten years from the date of grant. The exercise price of incentive options granted to an option holder who owns stock possessing more than 10% of the voting power of the outstanding capital stock must be at least equal to 110% of the fair market value of the common stock on the date of grant.

There are 2,762,320 common shares available for future grants under existing option plans at December 31, 2002. The following table summarizes stock option activity:

	Number of Options	Option Price Per Share	Weighted Average Price Per Share
Options outstanding, December 31, 1999	1,433,255	0.84 - 13.13	4.47
Granted	124,206	1.16 - 7.88	4.54
Exercised	(188,204)	1.16 - 7.88	2.42
Terminated	(97,107)	1.16 - 13.13	7.10
Options outstanding, December 31, 2000	1,272,150	0.84 - 13.13	4.58
Granted	321,278	1.80 - 4.34	3.09
Exercised	(60,494)	1.34 - 2.44	2.38
Terminated	(94,375)	1.34 - 7.88	1.54
Options outstanding, December 31, 2001	1,438,559	0.84 - 13.13	4.52
Granted	1,319,780	1.86 - 2.54	2.21
Exercised	(6,850)	1.34 - 1.44	1.40
Terminated	(217,624)	1.16 - 7.88	3.95
Options outstanding, December 31, 2002	2,533,865	$0.84 - $13.13	$3.38
Options exercisable, December 31, 2002	1,074,243	$0.84 - $13.13	$4.81
Options exercisable, December 31, 2001	975,016	$0.84 - $13.13	$5.35
Options exercisable, December 31, 2000	827,348	$0.84 - $13.13	$5.76

Range of Exercise Price	Options Outstanding: Number Outstanding	Options Outstanding: Weighted Average Remaining Contractual Life (in Years)	Options Outstanding: Weighted Average Exercise Price	Options Exercisable: Number Exercisable	Options Exercisable: Weighted Average Exercise Price
$ 0.84 - $ 1.16	130,000	6.58	$ 0.91	105,000	$ 0.93
$ 1.34 - 2.00	284,218	7.31	$ 1.76	120,513	$ 1.55
$ 2.03 - 2.85	1,302,996	8.70	$ 2.29	198,425	$ 2.40
$ 3.17 - 4.34	351,263	7.55	$ 3.40	186,317	$ 3.49
$ 5.00 - 6.69	42,325	6.83	$ 6.28	40,925	$ 6.27
$ 7.88 - 10.63	393,063	4.00	$ 7.89	393,063	$ 7.89
$13.13	30,000	3.43	$13.13	30,000	$13.13
Total	2,533,865	7.45	$ 3.38	1,074,243	$ 4.81

We have reserved and may issue up to an aggregate of 225,000 shares of common stock under the Employee Stock Purchase Plans pursuant to which stock is sold at 85% of fair market value, as defined. At December 31, 2001 and 2002, we have accumulated payroll deductions of $27,017 and $17,150, respectively, for the issuance of 10,308 and 8,511 shares of common stock, respectively, which are issued in the following year to employees pursuant to the plan. At December 31, 2002, 221,000 shares are available for issuance under the plan.

(d) Reserved Shares

As of December 31, 2002 the following shares of common stock were reserved and available for future issuance:

Stock Option Plans	5,296,185
2002 Employee Stock Purchase Plan	221,000
Exercise of warrants outstanding	532,046
	6,049,231

(8) License Agreements

(a) MIT License Agreement

MIT has granted us a worldwide exclusive license to certain technology, which was extended when we obtained FDA approval of our first cancer diagnostic product in 1996, until the expiration of all patent rights in 2006. Pursuant to the license agreement, we pay royalties on the sales of products incorporating the licensed technology. We paid $12,510, $10,715 and $19,425 in royalties in the years ended December 31, 2000, 2001 and 2002.

(b) Hybritech License Agreement

In August 1994, we entered into a non-exclusive license agreement with Hybritech, Inc. for the manufacture and sale of certain patented technology for immunometric assays using monoclonal antibodies. We are required to pay a royalty equal to 8% of net sales of licensed products subject to the license in countries where Hybritech, Inc. has a valid patent in effect. The last Hybritech, Inc. patent expires in 2008. We paid $25,000 in royalties in each of the years ending December 31, 2000, 2001 and 2002, respectively.

(9) Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2001	December 31, 2002
Payroll and related costs	$416,410	$491,551
Professional fees	170,012	158,711
Other	133,779	193,130
	$720,201	$843,392

(10) Valuation and Qualifying Accounts

The following table sets forth activity in the Company's accounts receivable reserve account:

	Balance at Beginning of Year	Charges to Expense	Write-offs	Balance at End of Year
2000	$32,433	—	—	$32,433
2001	32,433	—	—	32,433
2002	32,433	—	$8,842	23,591

(11) Segment and Geographic Information

We apply SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, which establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS No. 131 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker or decision making group, in making decisions how to allocate resources and assess performance. Our chief decision maker, as defined under SFAS No. 131, is a combination of the Chief Executive Officer, the President and the Chief Financial Officer. To date, we have viewed our operations and manage our business as principally one segment, the sale of diagnostic products. As a result, the financial information disclosed herein, represents all of the material financial information related to the principal operating segment. All of our products were shipped from our facilities located in the United States or, since June 28, 2000, from our facilities in Freiburg, Germany. Product sales by destination are as follows:

	Revenue ($ in 000's)					
	2000		2001		2002	
	$	%	$	%	$	%
United States	$ 240	19%	$ 351	15%	$ 347	11%
Japan	156	13	163	7	215	7
Europe	707	57	1,729	74	2,443	79
Rest of world	143	11	98	4	89	3
Total	$1,246	100%	$2,341	100%	$3,094	100%

Our total net fixed assets in the United States and Germany are as follows:

Total Net Fixed Assets ($ in 000's)

	2000		2001		2002	
	$	%	$	%	$	%
United States	$604	77%	$573	80%	$864	90%
Germany	177	23	147	20	99	10
Total	$781	100%	$720	100%	$963	100%

(12) Supplemental Financial Disclosure

Unaudited ($ in 000's, except per share amounts)	Q1-02	Q2-02	Q3-02	Q4-02
Revenue	$ 799	$ 866	$ 784	$ 831
Operating loss	(2,104)	(1,997)	(2,129)	(2,102)
Net loss	(2,086)	(1,972)	(2,122)	(2,098)
Basic/diluted net loss per share	$ (0.07)	$ (0.06)	$ (0.07)	$ (0.07)
Unaudited ($ in 000's, except per share amounts)	**Q1-01**	**Q2-01**	**Q3-01**	**Q4-01**
Revenue	$ 597	$ 586	$ 512	$ 646
Operating loss	(2,255)	(2,366)	(1,943)	(2,314)
Net loss	(2,194)	(2,328)	(1,919)	(2,291)
Basic/diluted net loss per share	$ (0.09)	$ (0.09)	$ (0.07)	$ (0.08)

(13) Subsequent Events

In March 2003, we entered into a collaboration and commercialization agreement with Mitsubishi Kagaku Medical, Inc., a division of Mitsubishi Chemical, whereby we will collaborate to develop and validate a Proprietary Lab Procedure for NMP66 suitable for implementation in one or more commercial laboratories in Japan. Under the terms of this agreement, Mitsubishi will pay Matritech an upfront fee as well as several milestone payments. These payments will be recognized over the term of the agreement.

On March 31, 2003, we completed a private placement of 7.5% Convertible Debentures (the "Convertible Debentures") in an aggregate subscription amount equal to $5 million and accompanying Warrants for an aggregate of 784,314 shares of our common stock, including a Warrant for 98,039 shares issued to a placement agent in connection with this transaction (the "Private Placement"). The Convertible Debentures are convertible into shares of our common stock at a conversion price initially equal to $2.55, but which will be adjusted downward (subject to certain limited exceptions) upon any dilutive issuances of our securities to an amount equal to 112% of the price at which such dilutive issuance is made, resulting in the potential for issuance of additional shares of our common stock upon conversion of the Convertible Debentures. The Convertible Debentures bear interest at the rate of 7.5% per annum, payable quarterly, and permit us, in certain circumstances, to make such interest payments in shares of common stock based on a 5% discount to the valuation of the common stock. The Convertible Debentures are redeemable in monthly installments equal to 1/26th of the aggregate subscription amounts paid for such Convertible Debentures, such monthly payments to commence on the first of the month after the 11 month anniversary of the closing date. The monthly redemption payments, subject to certain conditions, may also be made in shares of common stock based on a 10% discount to valuation. The Warrants are immediately excercisable for a period of five years at an initial exercise price of $2.278. The exercise price of the Warrants will initially be adjustable down to the issuance price of any subsequent dilutive issuances (subject to certain limited exceptions), and after the

Convertible Debentures are no longer outstanding, the exercise price of the Warrants will be adjustable based on a weighted-average basis upon any such subsequent dilutive issuance.

The aggregate number of shares of common stock issuable upon exercise of the Warrants and conversion of the Convertible Debentures, including as a result of any anti-dilution adjustments, and in connection with any payment of interest on or redemption of such Convertible Debentures, is capped at an aggregate of 6,426,127 shares unless shareholder approval is subsequently obtained. In addition, in the event shareholder approval is obtained, our stock price meets certain levels and there is an effective registration statement covering the shares of common stock underlying the Convertible Debentures and Warrants issued in connection with the first closing, a second closing may be held with the same purchasers for the issuance of additional Convertible Debentures in an aggregate subscription amount of $3 million and additional Warrants for an amount of shares equal to 35% of the number of shares for which such additional Convertible Debentures are initially convertible. Under the terms of the Private Placement we are required to file a registration statement covering the shares of our common stock underlying the Convertible Debentures and Warrants within 30 days of closing.

The Convertible Debentures may become immediately due and payable at a premium of 120% of the outstanding principal amount plus accrued interest and damages in the event of default by us of certain covenants and also obligate us to pay damages and interest upon certain events. Events of default under the Convertible Debentures include, among other things, failure to remain listed on any of the Nasdaq SmallCap Market, New York Stock Exchange, American Stock Exchange or the Nasdaq National Market, sale or disposition of our assets in excess of 33% of our total assets, failure to timely deliver stock certificates upon conversion, and default on our existing or future liabilities in excess of $150,000. In addition, the terms of the Private Placement prohibit us from entering into obligations that are senior to the Convertible Debentures and place certain restrictions on our ability to raise additional capital through equity issuances, including a prohibition on such activity (with certain limited exceptions) for a period of 90 days from the effective date of the registration statement filed with respect to the shares underlying the Convertible Debentures and Warrants, and an ability to match any additional funds raised on the same terms.