# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

## FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

**(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, 2001.**

**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. ☐

Aggregate market value, as of March 1, 2002, of Common Stock held by non-affiliates of the registrant: $77,366,228 based on the last reported sale price on the Nasdaq Stock Market.

Number of shares of Common Stock outstanding on March 1, 2002: 30,221,183

**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, 2001. 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") develops, manufactures and markets innovative cancer diagnostic products based on its 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. The Company has demonstrated that there are differences in the types and amounts of NMPs found in cancerous and normal tissue and believes the detection of such differences in NMPs provides important diagnostic information about cellular abnormalities, including cancer. Using its proprietary NMP technology and expertise, the Company has developed non-invasive or minimally invasive cancer diagnostic tests for bladder and cervical cancer and is developing additional tests for breast, colon and prostate cancer. The Company's objective is to develop tests that will be more accurate than existing tests and will result in lower treatment costs and a higher standard of patient care than currently available tests.

*NMP22 Test Kit for Bladder Cancer.* The Company's first product based on its NMP technology, the NMP22®[1] Test Kit for bladder cancer, was cleared for sale in the United States by the U.S. Food and Drug Administration ("FDA") in 1996 as a prognostic indicator for the recurrence of bladder cancer. In 2000, the FDA cleared the NMP22 Test Kit for use in testing previously undiagnosed individuals who have symptoms of or are at risk for bladder cancer. In 1998, the Company and Fisher Scientific Company, L.L.C. ("Fisher") entered into a co-exclusive distribution agreement for the NMP22 Test Kit in the United States. In 1998, the NMP22 Test Kit for bladder cancer was approved for sale in Japan by the Japanese Ministry of Health and Welfare ("Koseisho") for use in screening previously-undiagnosed patients for bladder cancer. The Company has an exclusive distribution agreement for the NMP22 Test Kit in Japan with Konica Corporation ("Konica"). In 1999, the State Drug Administration in the People's Republic of China approved the NMP22 Test Kit for sale for the detection and management of bladder cancer. In 1999, the Company entered into a distribution agreement with General Biologicals for the distribution of the NMP22 Test Kit in connection with an annual screening program for bladder cancer in Taiwan. The NMP22 Test Kit has been commercially available in Europe since 1995 and is distributed through the Company's subsidiary, Matritech GmbH, and other distributors throughout Europe. The NMP22 Test Kit is currently being marketed in Asia and in many other countries worldwide. The Company has retained worldwide manufacturing rights for the NMP22 Test Kit as well as co-marketing rights with Fisher in the United States.

*NMP22 BladderChek™ Point-of-Care Test.* During 2001, the Company developed the NMP22 Test in a new, point-of-care format known as BladderChek. In January 2001, the Company 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 BladderChek test in the United States to urologists. In May 2001, the Company announced that it 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 BladderChek test in Southeast Asia. In October 2001, this agreement was expanded to include the People's Republic of China. In September 2001, the Company began collecting samples for an FDA clinical trial and intends to submit the results of this trial to the FDA to obtain clearance to sell the BladderChek test in the United States. In November 2001, the Company announced the start of international shipments of the BladderChek test. The product is being shipped to the Company's distribution subsidiary in Europe and to US Summit for distribution in Asia.

*NMP22 Bladder Cancer Test Automated Format.* In March 2001, the Company entered into an eight-year, non-exclusive product supply and marketing agreement with Diagnostic Products Corporation ("DPC")

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[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.

enabling DPC to develop and market an automated version of the Company's NMP22 test for bladder cancer. DPC will conduct clinical trials directed towards showing the substantial equivalence of this automated version to Matritech's FDA-approved NMP22 Test Kit for bladder cancer.

*Test for Cervical Cancer.* The Company has also identified an NMP associated with cervical cancer and cervical precancer and has developed a diagnostic test, NMP179, based on its proprietary NMP technology for use in conjunction with routine and follow-up cervical testing. Matritech's scientists have reported the results of three preclinical trials of the NMP179 test in which it identified women with cancer or precancerous conditions of the cervix. These studies, which were conducted in collaboration with several leading women's health centers in New England, confirm the accuracy of the NMP179 antibody in identifying women with and at elevated risk for cervical cancer. The Company is in discussions with manufacturers of automated clinical instruments to provide a system to automate the review of cervical specimens using NMP179. The Company also plans to test the automated system developed in conjunction with this partner or partners for the analysis of cells obtained during the Pap smear procedure. The timing of the launch of a product using the Company's cervical cancer test will depend upon concluding a satisfactory agreement with such a partner, if any, and upon completion of the work necessary to design and implement the system for clinical testing.

*Breast Cancer Product (NMP66™).* During 1998, Matritech scientists, using a mass spectrometer instrument, identified certain cancer markers in the blood of breast cancer patients that were not present in the blood of normal individuals. In 1999, the Company announced the results of its analysis of blood specimens from women with breast cancer and women thought to be free of the disease. Matritech scientists found specific proteins in the blood of women with breast cancer and by contrast, found no evidence of such proteins in the blood of women without breast cancer. The Company is investigating opportunities to offer NMP66 testing services by clinical laboratory partners. Matritech believes that the NMPs found in the blood of women with breast cancer and the Company's ability to detect these NMPs may enable it to develop a breast cancer testing service that is more accurate than the products that are presently available. In May 2001, the Company announced that it had begun patient recruitment for a multi-center, United States-based clinical study of its NMP66 blood test for the early detection of breast cancer. In June 2001, the Company announced the commencement of a parallel study in Germany for the NMP66 blood test. The Company has retained all rights, including marketing rights, on a worldwide basis for its breast cancer product under development. Discussions are underway for a development and testing service agreement with laboratory partners. Once an agreement is in place, the Company expects to complete its development of the testing method with the partner's scientists and start testing the clinical specimens shortly thereafter. The timing of the launch of a testing service using the Company's breast cancer test depends upon concluding a satisfactory agreement with such a partner and upon the completion with the partner of the development of a viable commercial test format.

*Prostate Cancer Product (NMP48™).* In 1999, the Company entered into a 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. Dr. Partin believes there is a clinical need to differentiate between aggressive and indolent forms of prostate cancer, thereby indicating the extent of treatment necessary. The Company's scientists have tested blood specimens from men with prostate cancer using mass spectrophotometric techniques similar to those used to discover cancer proteins for breast cancer. A previously published study reported by Dr. Partin and the Company reported elevated levels of NMP in the majority of men with life-threatening aggressive tumors. The protein was not found in men with normal prostate tissue and was absent or present at lower levels in indolent forms of prostate cancer, which is believed to be non life-threatening. In May 2001, the Company reported the results of a study that found a specific protein (NMP48) in the blood of patients with prostate cancer that was not present in the blood of healthy men. In December 2001, the Company reported additional research results which indicated that NMP48 correctly identified men with benign prostate disease as negative for prostate cancer. The Company intends to conduct additional specimen testing in collaboration with an automated instrument partner or clinical laboratory. Consequently, the timing of the launch of a product or testing service using the Company's NMP48 prostate cancer test will depend upon concluding a satisfactory agreement with such a partner, and upon completion of work necessary to design the test's automated format.

*Colon Cancer Product (NMP35™).* The Company has discovered blood-based proteins specific to colon cancer (NMP35) using its mass spectrophotometric discovery procedure. In 2000, Matritech reported that its scientists had identified NMP35 in the blood of patients with colon cancer, which were not present in the blood of individuals without cancer nor in the blood of patients with certain benign conditions of the lower digestive tract. Subsequent testing has revealed that NMP35 is also present in the blood of individuals with certain "high-risk" polyps of the colon and those with diverticulitis. The Company's clinical consultants have commented that the identification of high risk polyps could be a desirable feature for a colon cancer screening test and that the symptoms of diverticulitis would not be confused with colon cancer. Blood specimens for use in generating clinical data for a pre-market approval submission to the FDA have been collected, and the Company believes that these specimens are sufficient to substantiate a claim for the use of its NMP35 colon cancer test for the differential diagnosis of individuals exhibiting symptoms such as rectal bleeding. The Company intends to use these specimens to validate the performance of its NMP35 test. The Company intends to conduct the specimen testing in collaboration with an automated instrument partner or clinical laboratory. Consequently, the timing of the launch of a product or testing service using the Company's NMP35 colon cancer test will depend upon concluding a satisfactory agreement with such a partner, and upon development of a clinical test procedure with the partner.

*Other Diagnostic Products.* In 2000, the Company acquired ADL GmbH, now called Matritech GmbH, a European distributor of diagnostic testing products, including the Company's NMP22 Test Kit for bladder cancer. In addition, 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 and pursuant to which Matritech GmbH has 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.

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

**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, monitoring and evaluating prognosis. Screening tests and procedures, such as mammograms and Pap smears, are performed regularly on individuals who may have no evidence of ill health because the tests can reveal hidden, asymptomatic disease. These screening tests do not yield a final diagnosis. An actual diagnosis of cancer is usually made after microscopic examination of a tissue biopsy. 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. In the United States, blood-based cancer diagnostic assays have generally been approved by the FDA for monitoring patients with known disease. Only occasionally have these been approved for use in detecting cancer in previously undiagnosed individuals.

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 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.

Accurate *in vitro* diagnostic assays can reduce the need for more invasive or expensive procedures for detecting and managing cancer, such as surgery, biopsy, bone scans and *in vivo* imaging. There are only a limited number of FDA-approved *in vitro* cancer diagnostic tests currently available and the relatively low clinical sensitivity and specificity of these tests have limited their clinical utility. The Company believes that these tests suffer from inherent inaccuracies because they detect substances that are only indirectly correlated with the cancer. As a consequence of low clinical sensitivity, these tests yield false negatives and many patients with cancer are not diagnosed early enough to receive effective treatment, resulting in additional costs and morbidity. Conversely, low clinical specificity yields false positives resulting in unnecessary, expensive and painful follow-up procedures on individuals without malignant disease.

**NMP Technology**

The Company believes that its NMP technology permits the development of cost-effective *in vitro* assays that are more accurate than others currently available. 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, Matritech and independent scientists have demonstrated that there are differences in the types and amounts of NMPs found in cancerous and normal tissues and also among different types of normal cells. Independent academic investigators have also confirmed the Company's findings in papers published in scientific journals which reported NMPs specific to bone, kidney, prostate, breast and colon cancer tissues. Certain of these NMPs were shown to be present in 100% of the cancer tissue specimens examined, but were absent in all of the normal tissue specimens. The Company has examined numerous additional cancer tissue specimens with similar results. Matritech also has demonstrated that cell death, including cell death related to early tumor development, results in the release of NMPs into bodily fluids. As a result, elevated levels of certain NMPs may be found in the bodily fluids of cancer patients. The Company is not aware of any other cancer marker, or class of markers, which exhibit this level of clinical specificity and sensitivity.

The Company uses its proprietary technology and expertise to identify, isolate and extract NMPs from cancerous and normal tissues and blood. Following extraction, the Company's scientists characterize and sequence cancer-specific NMPs, which generally are absent, or present at low levels, in the urine, blood and cells of healthy individuals. The Company then develops proprietary antibodies to these NMPs and incorporates the antibodies into industry-standard diagnostic formats, such as blood-based immunoassays. During the past two years, the Company's scientists have used mass spectrometry to discover and identify proteins in the blood of cancer patients, which are absent from the blood of individuals without cancer. During this period, the Company has reported its identification of cancer-related proteins for breast, prostate and colon cancer.

The Company's core NMP technology is licensed from the Massachusetts Institute of Technology (''MIT''). Under the current terms of the Company's license from MIT, the Company's worldwide license is exclusive until the expiration of all claims contained in these patents in 2006. The Company has made additional advances in NMP technology and has filed its 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 fifteen additional United States patents relating to such advances.

**Matritech's Products and Products Under Development**

*NMP22 Test Kit for Bladder Cancer*

In 1996, Matritech's NMP22 Test Kit for bladder cancer was approved for sale in the United States by the FDA as a prognostic indicator for the recurrence of bladder cancer. The FDA's action was based upon data generated during an extensive clinical trial of the NMP22 Test Kit 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. In January 2000, the

FDA approved the expanded use of the Company's NMP22 Test Kit as an aid in identifying previously undiagnosed individuals who have symptoms of or are at risk for bladder cancer.

In 1998, the NMP22 Test Kit for bladder cancer was approved for sale in Japan by Koseisho for use in screening previously undiagnosed individuals. In 1999, the NMP22 Test Kit was also approved for sale in the People's Republic of China by the State Drug Administration for the detection and management of bladder cancer. The Company is currently marketing this product in the United States through its own sales efforts and a distributor, in Europe through its German subsidiary, Matritech GmbH, and in other major markets worldwide through distributors. Sales of the NMP22 Test Kit began in certain countries in Europe in 1995.

The Company believes that the use of the NMP22 Test Kit enables urologists to identify and manage bladder cancer patients with less invasive and less frequent procedures, thereby potentially reducing treatment costs while maintaining a high standard of patient care. If the level of the NMP22 marker in a bladder cancer patient is low (less than or equal to 10 units per milliliter) 10 or more days after surgery, there is a high probability that there will be no evidence of disease upon follow-up cystoscopic examination. Consequently, the urologist may decide to postpone the next cystoscopy in order to reduce the cost, anxiety and risk to the patient. Similarly, an NMP22 level of greater than 10 units per milliliter indicates a higher risk that the follow-up cystoscopic examination will indicate a recurrence of disease, enabling the urologist to make more aggressive patient management decisions. The Company believes that when the NMP22 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 hematuria (blood in the urine) is caused by bladder cancer or by a non-life-threatening condition. The Company believes that the NMP22 Test Kit has the potential to make a positive impact on the accurate and cost-effective detection and management of bladder cancer.

In 1998, the Company and Fisher entered into a co-exclusive distribution agreement for the NMP22 Test Kit in the United States. In 1998, the NMP Test Kit for bladder cancer was approved for sale in Japan by the Koseisho for use in screening previously undiagnosed patients for bladder cancer. The Company has an exclusive distribution agreement for the NMP22 Test Kit in Japan with Konica. In 1999, the State Drug Administration in the People's Republic of China approved the NMP22 Test Kit for sale for the detection and management of bladder cancer. In 1999, the Company entered into a distribution agreement with General Biologicals for the distribution of the NMP22 Test Kit in connection with an annual screening program for bladder cancer in Taiwan. The NMP22 Test Kit has been commercially available in Europe since 1995 and is distributed through the Company's subsidiary, Matritech GmbH, and other distributors throughout Europe. The NMP22 Test Kit is currently being marketed in Asia and in many other countries worldwide. The Company has retained worldwide manufacturing rights for the NMP22 Test Kit as well as co-marketing rights with Fisher in the United States.

***NMP22 BladderChek Point-of-Care Test***

During 2001, the Company developed the NMP22 Test in a new, point-of-care format known as BladderChek. In January 2001, the Company signed a six-year exclusive (subject to certain minimum purchase requirements) agreement with Timm providing for the distribution, upon FDA approval, of the BladderChek test in the United States to urologists. In September 2001, the Company began collecting samples for an FDA clinical trial and intends to submit the results of this trial to the FDA to obtain clearance to sell the BladderChek test in the United States. In May 2001, the Company announced that it had signed a six-year agreement with US Summit for the exclusive (subject to certain minimum purchase requirements) distribution of the BladderChek test in Southeast Asia. In October 2001, this agreement was expanded to include the People's Republic of China. In November 2001, the Company announced the commencement of international shipments of the BladderChek test. The product is being shipped to the Company's distribution subsidiary in Europe and to US Summit for distribution in Asia.

***Cervical Cancer Product (NMP179)***

Matritech's scientists have reported the results of three preclinical trials of its NMP179 Test for the identification of women with cancer or precancerous conditions of the cervix. These studies, which were

conducted in collaboration with several leading women's health centers in New England, confirm the efficacy of the NMP179 antibody in identifying women at elevated risk for cervical cancer. The Company is in the process of optimizing the format and procedures relating to the test in preparation for entering into a development and distribution agreement with automated clinical instrument partners. The Company plans to conduct FDA clinical trials with the partner or partners using their automated instrumentation in conjunction with NMP179 to identify women with cervical cancer and high risk precancer. Matritech has maintained its worldwide manufacturing and marketing rights to its cervical cancer product.

***Breast Cancer Product (NMP66)***

During 1998, Matritech scientists, using a mass spectrometer instrument, demonstrated the ability to detect certain breast cancer markers in the blood of cancer patients which were not present in the blood of normal individuals. In 1999, the Company announced the results of its analysis of blood specimens from 20 women with breast cancer and 20 women thought to be free of the disease. Matritech scientists found NMP66 in the blood of the women with breast cancer and by contrast, found no evidence of NMP66 in the blood of the women without breast cancer. In 2000, the Company reported that its scientists detected the presence of NMP66 in the blood of women with breast cancer which are absent in the blood of women without breast cancer as well as those with fibroadenoma, a benign breast disease. The Company is investigating opportunities to offer NMP66 testing services in conjunction with clinical laboratory partners. Matritech believes that the Company's ability to detect NMP66 in blood may enable it to develop a breast cancer blood-based assay more accurate than products presently available. The Company has retained all rights, including marketing rights, on a worldwide basis for its NMP66 breast cancer product under development.

***Prostate Cancer Product (NMP48)***

In 1999, the Company entered into a 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. Dr. Partin believes there is a clinical need to differentiate between aggressive and indolent forms of prostate cancer, thereby indicating the extent of treatment necessary. The Company's scientists have tested blood specimens from men with prostate cancer using mass spectrophotometric techniques similar to those used to discover cancer proteins for breast cancer. A previously published study reported by Dr. Partin and the Company reported elevated levels of NMP in the majority of men with life-threatening aggressive tumors. The protein was not found in men with normal prostate tissue and was absent or present at lower levels in indolent forms of prostate cancer, which is believed to be non life-threatening. In May 2001, the Company reported the results of a study that found a specific protein (NMP48) in the blood of patients with prostate cancer that was not present in the blood of healthy men. In December 2001, the Company reported additional research results which indicated that NMP48 correctly identified men with benign prostate disease as negative for prostate cancer. The Company intends to conduct the specimen testing in collaboration with an automated instrument partner or clinical laboratory. Consequently, the timing of the launch of a product or testing service using the Company's NMP48 prostate cancer test will depend upon concluding a satisfactory agreement with such a partner, and upon completion of work necessary to design the test's automated format.

***Colon Cancer Product (NMP35)***

The Company has also discovered a blood-based colon cancer marker, NMP35, identified using its mass spectrophotometric discovery procedure. Blood specimens for use in generating clinical data for a premarket approval submission to the FDA have been collected and the Company believes that these specimens are sufficient to substantiate a claim for the use of its colon cancer test kit for the differential diagnosis of individuals exhibiting symptoms such as rectal bleeding. The Company intends to use these specimens to validate the performance of NMP35. The Company intends to conduct the specimen testing in collaboration with an automated instrument partner or clinical laboratory. Consequently, the timing of the launch of a product or testing service using the Company's colon cancer test will depend upon concluding a satisfactory agreement with such a partner and upon completion of work with the partner necessary to design the test's

automated format. The Company has retained worldwide manufacturing and marketing rights for its colon cancer test. The Company is seeking clinical laboratories and automated instrument partners for this test.

**Marketing and Sales**

The Company has retained rights to sell all of its products in the United States. Matritech is selling its NMP22 Test Kit for bladder cancer in the United States to selected clinical laboratories, and in 1998 entered into a distribution agreement with Fisher granting Fisher the co-exclusive right with Matritech to distribute the NMP22 Test Kit to hospitals and commercial laboratories within the United States. The Company's German subsidiary, Matritech GmbH, which was acquired in 2000, along with additional distributors, sells the product in Europe. Matritech GmbH currently has four full-time sales representatives. In 1994 the Company entered into an agreement with Konica to distribute NMP22 in Japan. In the rest of the world, the Company sells the NMP22 Test Kit through distributors.

In May 2001, the Company announced that it had signed a six-year agreement with US Summit for the exclusive (subject to certain minimum purchase requirements) distribution of the BladderChek test in Southeast Asia. In October 2001, this agreement was expanded to include the People's Republic of China. In November 2001, the Company announced the start of international shipments of the BladderChek test. The product is being shipped to the Company's distribution subsidiary in Europe and to US Summit for distribution in Asia.

During the year ended December 31, 2001, the Company received approximately 7% and 11% of its revenue from Konica and Fisher, respectively. During the year ended December 31, 2000, the Company received approximately 13% and 18% of its revenue from Konica and Fisher, respectively. During the year ended December 31, 1999, the Company received approximately 30% and 49% of its revenue from Konica and Fisher, respectively.

During the years ended December 31, 1999, 2000 and 2001, 53%, 19% and 15%, respectively, of the Company's total product sales were from customers in the United States and 47%, 81% and 85%, respectively, were from customers in foreign countries. For the year ended December 31, 1999, product sales generated outside of the United States were primarily from Asia. Product sales generated outside the United States during the years ended December 31, 2000 and 2001, were primarily from Europe. See Note 9 of Notes to Consolidated Financial Statements — "Segment and Geographic Information."

**Foreign Operations**

In June 2000, the Company acquired all of the outstanding shares of capital stock of ADL GmbH, Gesellschaft für Allergie, Diagnostika und Laborkonzepte ("ADL"), now called Matritech GmbH, a European distributor of diagnostic testing products, including the Company's NMP22 Test Kit for bladder cancer. 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 the Company's consolidated statements of operations.

At December 31, 2001, approximately 9% of the Company's total assets were located at the German subsidiary, and approximately 74% of its revenue and 20% of its expenses, including cost of product sales, for fiscal year 2001 were related to this European operation.

**Third-Party Reimbursement**

The Company's ability to successfully commercialize its products will depend in part on the extent to which reimbursement for the cost of such products will be available from government health administration authorities, private health insurers and other third-party payors. The Company believes that FDA clearance of a diagnostic product facilitates third-party reimbursement, but there can be no assurance that reimbursement will be available for such products or, if available, that it will be adequate.

In the case of private insurance, the reimbursement of any medical device, whether approved, or for investigational use only or for research use, 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 is made by the carrier's medical director or review committee. This group will base their reimbursement decision on published clinical data and information by treating physicians. Even if a procedure has been approved for reimbursement, there are no assurances that the insurance carrier will continue to reimburse the procedure.

Health care reform is an area of continuing national attention and a priority of many governmental officials. Certain reform proposals, if adopted, could impose limitations on the prices the Company will be able to charge in the United States for its products or the amount of reimbursement available for the Company's products from governmental agencies or third-party payors.

**Manufacturing and Facilities**

The Company currently assembles its NMP22 Test Kits in a portion of its 22,500 square-foot facility in Newton, Massachusetts and relies on subcontractors for certain components and processes. The Company's lease is for a term of five years and expires on December 31, 2005. The Company has a first option to extend the lease for an additional five years at a base rent agreed upon with the lessor and consistent with market rates in 2005. The annual base rent for each year of the term is $405,000. The Company has retained all manufacturing rights for its products and products under development, except for certain rights that could be granted to Konica, the Company's NMP22 Test Kit distribution partner in Japan, if the Company fails to perform under its agreement with Konica.

The Company currently relies on sole suppliers for certain key components and assembly for its NMP22 tests. In the event that the components from such suppliers or the services of these assemblers should become unavailable for any reason, the Company would seek alternative sources of supply or assembly, which may entail making regulatory submissions and obtaining regulatory approvals from the FDA for such alternate suppliers. Although the Company attempts to maintain an adequate level of inventory to provide for these and other contingencies, should its 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 the Company's requirements, there can be no assurance that the Company would be able to meet its commitments to customers. The Company is 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 NMP technology. 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 those of the Company. Matritech expects that its 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 the Company and its marketing partners.

The Company expects that certain of its clinical tests will compete with existing FDA-approved clinical tests, including tests known as BTA and ImmunoCyt™ bladder cancer test, 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 PSA, which is used primarily for monitoring and screening prostate cancer, and a test known as TRUQUANT® BR™ RIA, which is used for monitoring breast cancer. The Company is also aware of a number of companies exploring the application of oncogene technology to cancer diagnostics. The Company's diagnostic products will also compete with more invasive or expensive procedures such as 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 the

Company's competitive position. As a result, the Company's products may become obsolete or non-competitive.

A number of companies are attempting to develop automated instruments for Pap smear analysis that would compete with the NMP179 cervical cancer product developed by the Company. These companies are computerizing image analysis techniques to automate much of the work currently done by cytotechnologists. To date, several of these instruments have 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.

The FDA cleared a cervical disease diagnostic product, Hybrid Capture II ("HCII"), for use in detecting HPV, the viral infection believed to lead to cervical cancer in some women. 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.

The Company's products will also compete with more invasive or expensive procedures such as surgery, bone scans, magnetic resonance imaging ("MRI") and other *in vivo* imaging techniques. Matritech believes that its products, if successfully commercialized, improve patient management and lower overall costs, by providing accurate information and, in some cases, by providing alternatives to these invasive or costly procedures.

In addition, there can be no assurance that competing diagnostic products based on other technologies will not be introduced by other companies and adversely affect the competitive position of the Company. See "Management's Discussion and Analysis of Financial Condition and Results of Operations — Factors That May Affect Future Results — Competition" below.

**Patents, Licenses and Trade Secrets**

Matritech's diagnostic technology is protected by claims contained in three United States patents owned by MIT and expiring in 2006, with corresponding foreign patents granted and/or patent applications pending in Canada and selected countries in Europe and Asia. MIT has exclusively licensed to Matritech worldwide rights to its NMP technology contained in these patents in exchange for royalties payable until the expiration of the underlying patent rights.

The protection offered by these patents extends to the detection and measurement of NMPs, or associated nucleic acids, using antibody or gene probe formats, as well as to certain assay methods exploiting NMPs. With regard to related NMP advances, 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. The Company currently has fifteen additional United States patents and seven patent applications on file in the United States on these disclosures. Certain United States patents provide additional protection for Matritech's NMP22 Test Kit for bladder cancer until 2015. The Company intends to file additional patent applications in the future. The Company believes that any patents that may issue from its applications will provide competitive protection for its products after expiration of its license from MIT. The Company also intends to rely on its unpatented proprietary information and trade secrets to maintain its commercial position. The Company has developed certain point-of-care products (similar in appearance and function to over-the-counter type pregnancy kits) that use lateral-flow immunochromatographic test strips. The Company's BladderChek point-of-care product uses lateral-flow immunochromatographic test strips. The Company is investigating whether the manufacture, use, sale, or import of products which include lateral-flow immunochromatographic test strips in certain jurisdictions may require the Company to obtain patent licenses from third parties and, if appropriate, the Company will attempt to obtain such licenses. There is no guarantee, however, that the Company will be able to obtain patent licenses, where appropriate, to permit the Company to make, use, sell, or import such products in the United States or in certain other jurisdictions.

**Government Regulation**

***Diagnostic Products***

The medical devices to be marketed and manufactured by the Company are subject to extensive regulation by the FDA, and, in some instances, by foreign governments. Pursuant to the Federal Food, Drug and Cosmetic Act of 1976, as amended, and the regulations promulgated thereunder (the "FDC Act"), the FDA regulates the clinical testing, manufacturing, labeling, distribution, and promotion of medical devices. 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 clearance or 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 the Company.

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 (for example, 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).

Before a new device can be introduced into the U.S. market, the manufacturer must generally obtain marketing clearance through the filing of either a 510(k) notification or a PMA. A 510(k) clearance 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. 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 four to twelve months from submission to obtain a 510(k) clearance, 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 provide recommendations to the FDA as to whether the device should be approved. 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 clearance 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 clearance 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 clearance of the PMA application or issue a "not approvable letter." The FDA may also determine that additional clinical trials are necessary, in which case a PMA may be substantially delayed while additional clinical trials are conducted and submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved for marketing.

Once a device has successfully completed the PMA process, 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 cleared by the original PMA.

Although clinical investigations of most devices are subject to the investigational device exemption ("IDE") requirements, clinical investigations of *in vitro* diagnostic ("IVDs") tests 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 Test Kit for bladder cancer for sale in the United States as a prognostic indicator for bladder cancer (i.e., as a predictor of bladder cancer recurrence following therapy, such as surgical excision of cancerous tissue). In January 2000 the FDA approved the expanded claim of the Company's NMP22 Test Kit for the additional use of testing previously undiagnosed individuals who have symptoms of or are at risk for bladder cancer.

Two clinical trials investigating the performance of the Company's BladderChek Point-of-Care Test for diagnosing bladder cancer are underway at twenty-four sites around the country. The first involves patients with a previous history of bladder cancer who are being monitored for recurrence. Total enrollment of approximately 650 participants is planned, with submission of data to the FDA to obtain clearance to sell BladderChek in the United States expected in the spring of 2002. The second trial involves previously undiagnosed patients being evaluated for bladder cancer due to symptoms or risk factors. Approximately 1,000 individuals will be included, with data submitted to the FDA in summer 2002. Recruitment for both studies began in September 2001.

Clinical trials to investigate the performance of NMP66 in detecting breast cancer began enrolling patients in May 2001. Ten sites in the United States and three in Germany will recruit over 1,000 women. Approximately 700 of these patients will have biopsies performed due to suspicious findings on mammograms or palpable lumps. NMP66 results will be compared to biopsy outcome. The other 300 women have had at least two consecutive mammograms with no abnormal results, and will be the control group. Results of the study are anticipated in 2002.

Any products manufactured or distributed by the Company pursuant to FDA clearances or 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 the Company 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 clearance or approval has not been obtained. Consequently, in the United States the Company cannot promote the NMP22 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 the Company's ability to conduct testing necessary to obtain market clearance for these products and, consequently, could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company and its products are also subject to a variety of state laws and regulations in those states or localities where its products are or will be marketed. Any applicable state or local regulations may hinder the Company's ability to market its 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. There can be no assurance that the Company will not be required to incur significant costs to comply with such laws and regulations now or in the future or that such laws or regulations will not have a material adverse effect upon the Company's 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. There can be no assurance that the FDA will grant export approval when such approval is necessary, or that the countries to which the devices are to be exported will approve the devices for import. Failure on the part of the Company to obtain export approvals, when required, could significantly delay and impair the Company's ability to continue exports of its devices and could have a material adverse effect on the Company's business, financial condition or results of operations.

The introduction of the Company's developmental-stage test products in foreign markets will also subject the Company to foreign regulatory clearances 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 the Company began selling its NMP22 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 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 Test Kit for sale in the People's Republic of China for the detection and management of bladder cancer.

The approval by the FDA and foreign government authorities is unpredictable and uncertain and no assurance can be given that the necessary approvals or clearances will be granted on a timely basis or at all. Delays in receipt of, or a failure to receive, such approvals or clearances, or the loss of any previously received approvals or clearances, could have a material adverse effect on the business, financial condition and results of operations of the Company.

Changes in existing requirements or adoption of new requirements or policies could adversely affect the ability of the Company to comply with regulatory requirements. Failure to comply with regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations. There can be no assurance that the Company will not be required to incur significant costs to comply with laws and regulations in the future or that laws or regulations will not have a material adverse effect upon the Company's business, financial condition or results of operations.

***CLIA***

Pursuant to the Clinical Laboratory Improvement Amendments ("CLIA"), the FDA will assign 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.

***Other***

In order for the Company to conduct preliminary studies or clinical trials at a hospital or other health care facility, the Company's research collaborators must first obtain approval from the 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, the Company is 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, 2002, the Company had 44 full-time employees, 16 of whom were engaged in research and development. The Company's future success depends in part on its ability to recruit and retain talented and trained scientific, technical, marketing and business personnel. The Company has been successful to date in hiring and retaining such personnel, but there can be no assurance that such success will continue. None of the Company's employees are represented by a labor union, and the Company considers its relations with its employees to be excellent.

**Research and Development**

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

During 1999, 2000 and 2001, Matritech spent approximately $2.5 million, $2.3 million and $3.4 million, respectively, on research and development. Substantially all of these expenditures were related to the development of diagnostic products and conducting clinical trials.

**Item 2. Properties.**

The Company leases corporate headquarters, research and development and manufacturing facilities in Newton, Massachusetts which occupy approximately 22,500 square feet. The Company's 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 term is $405,000. Additionally, the Company leases 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.

**Item 3. Legal Proceedings.**

The Company is 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 2001.

## PART II

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

The Company's Common Stock is traded on The Nasdaq National Market tier of The Nasdaq Stock Market ("Nasdaq National Market") under the symbol: "NMPS." 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 2000** | | |
| First Quarter | $19.375 | $2.875 |
| Second Quarter | 10.500 | 3.563 |
| Third Quarter | 9.688 | 3.000 |
| Fourth Quarter | 7.063 | 2.000 |
| **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 |

As of March 1, 2002, there were approximately 389 shareholders of record. The Company believes that shares of the Company's Common Stock held in bank, money management, institution and brokerage house "nominee" names may account for an estimated 11,400 additional beneficial holders.

The Company has never paid cash dividends on its Common Stock. The Company currently intends to retain any earnings to finance future growth and therefore does not anticipate paying any cash dividends in the foreseeable future.

**Recent Sales of Unregistered Securities**

During the fiscal year ended December 31, 2001, the Company issued the following securities that were not registered under the Securities Act of 1933, as amended (the "Securities Act"):

In December 2001, the Company completed a private placement of 113,969 units, at a purchase price of $9.44 per unit to qualified institutional buyers and accredited investors. 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 the Company if certain conditions are satisfied. The Company received net proceeds of $1,061,000 after deducting transaction expenses. 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, 2001, have been derived from the Company's consolidated financial statements, which have been audited by Arthur Andersen LLP, independent public accountants. 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.

| | 1997 | 1998 | 1999 | 2000 | 2001 |
|---|---|---|---|---|---|
| **Statements of Operations Data:** | | | | | |
| Revenue: | | | | | |
| Product sales and collaboration fees | $ 747,532 | $ 967,759 | $ 622,808 | $ 1,245,611 | $ 2,340,940 |
| Expenses: | | | | | |
| Cost of product sales | 746,659 | 749,436 | 603,349 | 983,466 | 1,705,908 |
| Research, development and clinical | 3,196,731 | 3,260,932 | 2,543,456 | 2,295,097 | 3,362,024 |
| Selling, general and administrative | 4,840,495 | 4,922,114 | 3,803,252 | 5,130,124 | 6,151,330 |
| Total operating expenses | 8,783,885 | 8,932,482 | 6,950,057 | 8,408,687 | 11,219,262 |
| Loss from operations | 8,036,353 | 7,964,723 | 6,327,249 | 7,163,076 | 8,878,322 |
| Interest income | 566,686 | 457,678 | 224,658 | 345,644 | 169,665 |
| Interest expense | 5,420 | 28,479 | 21,625 | 18,822 | 22,170 |
| Net loss | $ (7,475,087) | $ (7,535,524) | $ (6,124,216) | $ (6,836,254) | $ (8,730,827) |
| Basic/diluted net loss per common share(1) | $ (0.43) | $ (0.40) | $ (0.29) | $ (0.28) | $ (0.33) |
| Weighted average number of common shares outstanding(1) | 17,512,242 | 18,608,784 | 21,126,422 | 24,802,015 | 26,319,329 |

| | 1997 | 1998 | 1999 | 2000 | 2001 |
|---|---|---|---|---|---|
| **Balance Sheet Data:** | | | | | |
| Cash and cash equivalents | $ 11,067,414 | $ 4,146,821 | $ 5,612,194 | $ 4,661,005 | $ 4,819,733 |
| Working capital | 10,989,534 | 3,787,709 | 5,341,336 | 4,587,611 | 4,337,372 |
| Total assets | 12,691,773 | 5,511,825 | 6,902,575 | 6,595,468 | 6,612,260 |
| Accumulated deficit | (33,615,492) | (41,151,016) | (47,275,232) | (54,111,486) | (62,842,313) |
| Total stockholders' equity | $ 11,688,674 | $ 4,399,981 | $ 5,943,460 | $ 5,568,008 | $ 5,221,862 |

(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 securityholders, as well as oral statements made by the Company's 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, the Company's future revenues, operating income, EBITDA 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 the Company's other reports filed with the Securities and Exchange Commission (the "Commission").

**Overview**

The Company was incorporated in 1987 to develop, manufacture and market innovative cancer diagnostic products based on its proprietary NMP technology. Matritech has been unprofitable since inception and expects to incur significant operating losses for at least the next several years. For the period from inception to December 31, 2001, the Company incurred a cumulative net loss of approximately $62.8 million.

The results of operations for the year ended December 31, 2001 include the activities of the Company's German 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 the Company's product and other third-party products in Europe.

**Results of Operations**

***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, and an increase in research-use product sales in the United States.

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 products 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 for the year ended December 31, 2001 from $2,295,000 for the year ended December 31, 2000. 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 the Company's BladderChek test, $39,000 for lab supplies expense and $61,000 for temporary help.

Selling, general and administrative expenses increased to $6,151,000 for the year ended December 31, 2001 from $5,130,000 for the year ended December 31, 2000. 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 during the year, 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.

The Company incurred a net loss of $8,731,000 for the year ended December 31, 2001 as compared with a net loss of $6,836,000 for the year ended December 31, 2000. The increase of $1,895,000, or 28%, in the net loss was primarily the result of increased clinical and regulatory expenses, two additional quarters worth of Matritech GmbH operational expense, and increased selling, general and administrative expenses partially offset by increased gross margin.

*Year Ended December 31, 2000 Compared with Year Ended December 31, 1999*

Product sales increased to $1,246,000 from $623,000 for the years ended December 31, 2000 and 1999, respectively. This increase was primarily due to the Company's acquisition of Matritech GmbH on June 28, 2000 along with an increase in sales to Europe and other international locations of products developed and manufactured by Matritech. This increase was partially offset by a decrease in sales to the United States and Japan due to the timing of distributor inventory purchases.

Cost of product sales increased to $983,000 from $603,000 for the years ended December 31, 2000 and 1999, respectively. As a percentage of product sales, cost of sales decreased to 79% from 97% for the years ended December 31, 2000 and 1999, respectively. The decrease in cost of sales as a percentage of sales is due to the inclusion of Matritech GmbH's sales of third-party products in 2000 which carry higher margins than the products 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 decreased to $2,295,000 for the year ended December 31, 2000, from $2,543,000 for the year ended December 31, 1999. The decrease was primarily due to a $150,000 reduction in bladder clinical trial expenses incurred in 1999 in connection with the related FDA submission and $50,000 of expense accrued in 1999 for cervical clinical trials. Personnel-related expenses declined $77,000 due to decreased headcount, and reliance on clinical consultants and clinical travel declined $55,000 and $52,000, respectively, due to the absence of FDA submissions in 2000. These decreases were offset by increases in supplies of $42,000, repairs and maintenance of $44,000, legal expense of $28,000 and consulting of $23,000 as the blood-based development programs began in 2000.

Selling, general and administrative expenses increased to $5,130,000 for the year ended December 31, 2000, from $3,803,000 for the year ended December 31, 1999. The increase was primarily due to the following: $835,000 increase in compensation expense, related to the issuance of a warrant to an investor relations consultant in July 2000, $539,000 related to Matritech GmbH's operations, increased consulting expense of $263,000, increased administrative personnel costs of $162,000 due to additional headcount, and increased annual report/proxy printing costs of $69,000. These increases were offset by a $101,000 reduction in outside legal costs, a $236,000 reduction in sales personnel costs and a $144,000 reduction in sales travel expenses. Sales expense reductions are due to decreased headcount in the sales department. In addition, advertising costs decreased $94,000 due to reduced reliance on an outside ad agency.

Interest and other income was $346,000 for the year ended December 31, 2000 and $225,000 for the year ended December 31, 1999. The increase was due to higher average cash balances available for investment and higher investment yields in 2000 as compared to 1999.

The Company incurred a net loss of $6,836,000 for the year ended December 31, 2000, as compared with a net loss of $6,124,000 for the year ended December 31, 1999. The increased loss was primarily due to the increased selling, general and administrative expenses partially offset by the increased interest income, increased gross margin and reductions in research, development, clinical and regulatory expenses.

**Liquidity and Capital Resources**

Since its inception, the Company has financed its operations primarily through private and public offerings of its securities and through funded development and marketing agreements. At December 31, 2001, the Company had cash and cash equivalents of $4,820,000 and working capital of $4,337,000. The Company believes that its existing cash resources, plans for equity financings, product sales and corporate partnerships will be sufficient to satisfy its capital needs through 2002. In the absence of additional equity financings and corporate partnerships, the Company would reduce expenses accordingly to maintain operations through 2002.

The Company's operating activities used cash of approximately $6,887,000, $5,710,000 and $5,941,000 for the years ended December 31, 2001, 2000 and 1999, respectively, primarily to fund the Company's operating loss.

The Company's investing activities used cash of approximately $97,000, $306,000 and $34,000 in the years ended December 31, 2001, 2000 and 1999, respectively, primarily for the purchase of lab equipment, and in the 2000 period, for amounts paid in connection with the purchase of Matritech GmbH. The Company acquired net fixed assets of $202,000 in the acquisition of Matritech GmbH.

The Company's financing activities provided cash of approximately $7,128,000, $5,073,000 and $7,441,000 in the years ended December 31, 2001, 2000 and 1999, respectively, primarily from the sale of equity securities and the exercise of stock options and warrants, net of payments on notes payable.

The Company had a term note with Phoenix Leasing Incorporated ("Phoenix Leasing") for equipment purchases. The term note was 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 the Company) upon the conclusion of the term of the note. The monthly payments on this note were paid off in October 2001. The Company elected to make a lump sum payment and is currently in negotiations with Phoenix Leasing to sell it one of the pieces of equipment in satisfaction of the final lump sum payment.

In connection with the acquisition of Matritech GmbH, the Company assumed certain debt obligations. At December 31, 2001, these obligations consist of a $90,000 loan from a bank, a $45,000 third-party demand note, and $13,000 worth of car loans. The bank loan is due in June 2004, bears interest at 5.2% and is secured by trade receivables and inventory. The demand note will be repaid by the Company and the Company will be reimbursed by a key Matritech GmbH employee; the Company has recorded a corresponding asset for this employee receivable. The car loans bear interest between 6.99% and 7.50% and are due in monthly installments totaling $1,000.

In June 2000, the Company signed an amendment to the original 1995 lease agreement for the Company's 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, are substantially unchanged.

In July 2000, the Company filed a Form S-3 shelf registration statement with the Commission for the issuance of up to 2.45 million shares of the Company's common stock. In August 2000, the Company entered into a common stock purchase agreement covering the sale of up to $30 million (a maximum of 2.45 million shares) of the Company's 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 the Company of $5,013,000. The Acqua agreement terminated on October 22, 2001.

In December 2001, the Company 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 the Company's 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, the Company 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 the Company if certain conditions are satisfied. The Company received net proceeds of $1,061,000 after deducting transaction expenses.

On March 4, 2002, the Company 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 are exercisable until November 30, 2002 and are callable by the Company if certain conditions are satisfied. The Company received net proceeds of approximately $4,167,000 after deducting transaction expenses.

In July 2000, the Company issued a fully vested, nonforfeitable warrant to an investor relations consultant for the purchase of up to 450,000 shares of the Company's common stock for a price of $2.50 per share

expiring in July 2005. In 2001, 50,000 of these warrants were exercised, providing proceeds to the Company of $125,000.

The Company expects to incur continued research and development expenses and other costs, including costs related to clinical studies to commercialize additional products based upon its NMP technology. The Company will require substantial additional funds to fund operations, complete new product development, conduct clinical trials and manufacture and market its products.

The Company's future capital requirements will depend on many factors, including, but not limited to: continued scientific progress in its research and development programs; the magnitude of its research and development programs; progress with clinical trials for its 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 the Company's products.

The Company is also actively seeking additional long-term funding for its operations from public and private sources including strategic collaborations and partnerships. There can be no assurance, however, that capital will be available on terms acceptable to the Company, if at all. If the Company uses equity to finance its capital needs, such a financing could result in significant dilution to existing stockholders.

The foregoing discussion includes forward-looking statements that are subject to risks and uncertainties and actual results may differ materially from those currently anticipated depending on a variety of factors including those discussed below. See "Factors That May Affect Future Results." The survival of the Company in the long term is dependent on its ability to generate revenue from sales of its products. There can be no assurance that, in the long term, the Company will be able to generate sufficient revenue to achieve and maintain profitability.

**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. The Company does not believe there is a great likelihood 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***

The Company recognizes revenue from product sales upon shipment; revenue from collaboration fees as milestones are achieved; revenue from nonrefundable license agreements and research grants as earned over the life of the agreement. For each of the three years presented in the accompanying statements of operations, substantially all of the Company's revenue is from product sales.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements*. SAB No. 101 requires companies to recognize certain upfront non-refundable fees and milestone payments over the life of the related alliance when such fees are received in conjunction with alliances which have multiple elements or ongoing performance obligations, among other things. The Company believes that its revenue recognition policies comply with SAB No. 101 and, therefore, the adoption of SAB No. 101 did not have a material effect on its future or historically reported operating results.

***Long-Lived Assets***

In accordance with Financial Accounting Standards Board ("FASB") SFAS No. 141, *Business Combinations*, and No. 142, *Goodwill and Other Intangible Assets*, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized but, instead will be subject to annual impairment tests. The Company will apply the new rules on accounting for goodwill and other intangible assets beginning in the first quarter of 2002. During 2002, the Company will perform the first of the required impairment tests of goodwill and indefinite lived intangible assets as of January 1, 2002, and has not yet determined what effect, if any, applying those tests will have on the Company's financial position and results of operations. The Company is subject to financial statement risk to the extent that it's goodwill and indefinite lived intangible assets become impaired. At December 31, 2001, the Company had approximately $133,000 of goodwill and recognized approximately $87,000 of amortization expense related to this balance for the year ended December 31, 2001.

**Factors That May Affect Future Results**

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

*Access to Capital.* The Company will need additional funding to continue to market its NMP22 Test Kit for bladder cancer, to conduct research and development, to conduct clinical trials and to manufacture and market its products as it currently contemplates. The Company is currently seeking to raise additional capital and will consider various financing alternatives, including equity or debt financings and corporate partnering arrangements. However, the Company may not be able to raise needed capital on terms that are acceptable to it, or at all. If the Company does not receive additional financing, it may be required to curtail its expenses or take other steps that could hurt its future performance. Any future equity financings will dilute the ownership interest of existing investors in the Company and may have an adverse impact on the price of the Common Stock.

*History of Operating Losses and Anticipated Future Losses.* The Company has incurred operating losses since it 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 exceeded the Company's revenues, which to date have been generated primarily from initial sales of its NMP22 Test Kit and other diagnostic products, its development agreements, government grants and interest income. The Company expects to incur continuing operating losses in the near term. The Company's ability to be profitable depends in part on its ability to market its existing products, obtain required regulatory approvals and develop new products. The Company may not be able to market its existing products successfully, obtain required regulatory approvals or develop, commercialize, produce and market its future products or achieve or maintain profitability.

*Fluctuation in Operating Results.* The Company's 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 the Company's customers and distributors; regulatory approvals and the introduction of new products by the Company; and the market acceptance of the Company's products. The Company's 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.

*Uncertainties Associated with Future Performance.* The Company's success in the market for diagnostic products will depend, in part, on the Company's ability to: successfully develop, test, produce and market its products; obtain necessary governmental approvals in a timely manner; attract and maintain key employees; and successfully respond to technological changes in its marketplace. The Company has limited internal marketing and sales resources and personnel. In order to successfully market the Company's current and future products in the United States, Germany and other territories in which it does not, or does not intend to, use third-party distributors, the Company will need to develop a larger marketing and sales force with appropriate technical expertise and distribution capability. The Company may be unable to establish the

marketing and sales capabilities that it needs, and the Company may be unsuccessful in gaining wide market acceptance for its products.

*Reliance on Distributors.* The Company has limited internal marketing and sales resources and personnel. The Company derives a significant portion of its sales revenue from distribution agreements with two distributors. Konica has an exclusive right to sell the Company's NMP22 Test Kit in Japan. Fisher has a co-exclusive right with the Company to sell its NMP22 Test Kit to hospitals and commercial laboratories in the United States. In addition, General Biologicals Corporation ("General Biologicals") has the right to sell the Company's NMP22 Test Kit in connection with an annual screening program in Taiwan, and US Summit has the right to distribute the Company's product in the People's Republic of China and other countries in South East Asia. Because the Company does not deal directly with customers when selling through distributors, it depends on the ability of Konica and Fisher and, to a lesser extent, General Biologicals, US Summit and other current or future distributors, to market actively, to forecast demand accurately and to maintain appropriate levels of inventory. The Company has minimal control over its distributors, and these distributors are under no obligation to purchase a set quantity of the Company's products (although in some cases the agreement may be terminable by the Company if certain minimum purchases are not made by the distributor). The failure or delay by a distributor in selling the Company's products, or any material breach of their agreements with the Company could significantly reduce the Company's revenues. The Company may be unable to enter into additional distribution relationships on favorable terms, if at all. These events could reduce anticipated future sales growth.

*Near-Term Dependence Upon A Limited Number of Products.* The Company anticipates that in the near-term the Company's success will be substantially dependent on the success of a limited number of products. The Company would experience a material adverse effect on its business, financial condition and results of operations if those products do not achieve wide market acceptance. The Company's other products have not been approved by the FDA or are in development, and there can be no assurance that the Company will be successful with such regulatory approvals and product development.

*Market Acceptance of NMP22 Test.* The Company expects to generate a significant share of all of the Company's near-term product sales from the sale of the Company's NMP22 tests, which were first cleared 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. The Company's results of operations may suffer if the NMP22 tests do not achieve wide market acceptance because NMP22 is a major source of sales revenue. The remainder of the Company's products still require FDA approval or are in development and do not result in significant revenues.

*Reliance on Sole Supplier.* The Company currently relies on sole suppliers for certain key components and the assembly thereof for its NMP22 tests. If the components from these suppliers or the services of these assemblers should become unavailable for any reason, the Company would seek alternative sources of supply or assembly. In order to maintain the FDA validation of the Company's manufacturing process, the Company would have to show that these alternative sources of supply are equivalent to its current sources. Although the Company attempts to maintain an adequate level of inventory to provide for these and other contingencies, if its 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 the Company's requirements, the Company may be unable to meet its commitments to customers. The Company's failure or delay in meeting its 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.

*Competition.* Although the Company is 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 the Company does.

The Company expects that certain of its clinical tests will compete with existing FDA-approved clinical tests, including tests known as BTA and ImmunoCyt™ bladder cancer test, 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 PSA, which is used primarily for monitoring and screening prostate cancer, and a test known as TRUQUANT® BR™ RIA, which is used for monitoring breast cancer. The Company is also aware of a number of companies exploring the application of oncogene technology to cancer diagnostics. The Company's diagnostic products will also compete with more invasive or expensive procedures such as 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 the Company's competitive position. As a result, the Company's products may become obsolete or non-competitive.

*Future Product Development and Marketing.* Other than the NMP22 tests and other diagnostic products distributed by the Company's European subsidiary, all of the Company's products are under development and are not expected to be commercially available in the United States for some time. The majority of the Company's products under development will require significant additional development, laboratory testing, clinical testing and regulatory approval prior to commercialization. The development of the Company's products involves the use of advanced technical methods that require both a high degree of skill and judgment in their application. The Company may encounter unexpected technical difficulties in the course of the development process that it may be able to overcome only if it expends additional funds and time, if at all. The Company may not successfully complete its product development efforts, and it may not obtain the required regulatory approvals. In addition, any future products, if and when introduced, may not be successfully commercialized, produced and marketed or achieve customer acceptance. The Company believes that the market value of the Company's stock is based in part on an expectation of future revenue-producing products. If the Company is unable to develop and market future products, or if the market believes that the Company is experiencing difficulty developing future products, its stock price may drop. For example, the market reacted negatively when the Company announced that one of its products would not receive expedited FDA review.

*Government Regulation.* The FDA and, in some instances, foreign governments, extensively regulate the medical devices that the Company markets and manufactures. The FDA regulates the clinical testing, manufacture, labeling, distribution and promotion of medical devices in the United States. If the Company fails to comply with the FDA's requirements, including Good Manufacturing Practices, as such term is defined by the FDA, it 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 the Company manufactures or distributes.

Any products that the Company manufactures or distributes in accordance with FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including:

- device manufacturers and distributors are required to comply with recordkeeping 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 such term is defined by the FDA, regulations which impose certain procedural and documentation requirements on the Company 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 the Company only as a prognostic indicator or as a testing device for use by 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 pre-market clearance or approval has not been obtained. Consequently, the Company cannot currently promote the NMP22 Test Kit for any unapproved use. If the Company fails to comply with these requirements, it may face regulatory enforcement action by the FDA that would prevent the Company from manufacturing or selling its products, hurt its ability to conduct testing necessary to obtain market clearance for these products and reduce its potential sales revenues.

The Company is also subject to a variety of state laws and regulations in those states or localities where its products are or will be marketed. Any applicable state or local regulations may hinder the Company's ability to market its 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. The Company 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.

*Proprietary Technology.* The Company relies on a combination of patent, trade secret and trademark laws, nondisclosure and other contractual provisions and technical measures to protect the proprietary rights in its current and planned products. These protections may be inadequate, and the Company's competitors may independently develop technologies that are substantially equivalent or superior to its technology. Patent law relating to the scope of claims in the biotechnology field is still evolving and, therefore, the degree of future protection for the Company's proprietary rights is uncertain. In addition, the laws of certain countries in which the Company's products are, or may be, licensed or sold do not protect its products and intellectual property rights to the same extent as the laws of the United States.

The Company believes that the use of the patents for nuclear matrix protein technology licensed to it and the use of its trademarks and other proprietary rights do not infringe upon the proprietary rights of third parties. However, the Company may not prevail in any challenge of third-party intellectual property rights, and third parties may successfully assert infringement claims against it in the future. In addition, the Company may be unable to acquire licenses to any of these proprietary rights of third parties on reasonable terms.

*Licenses.* The Company has developed certain point-of-care products which use lateral-flow immunochromatographic test strips. The Company is investigating whether the manufacture, use, sale, or import of point-of-care products which include the lateral-flow immunochromatographic test strips in certain jurisdictions may require the Company to obtain patent licenses from third parties and, if appropriate, the Company will attempt to obtain such licenses. There is no guarantee, however, that the Company will be able to obtain patent licenses, where appropriate, to permit the Company to make, use, sell, or import such products in the United States or in certain other jurisdictions.

*Healthcare Reform.* The Company's ability to commercialize successfully its planned products will depend in part on the extent to which reimbursement for the cost of its 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 the Company does successfully sell its products to managed care

providers, it is possible that these sales will involve significant pricing pressure on its products and keep our per-product revenues low. Healthcare reform is an area of continuing national attention and a priority of many governmental officials. Certain reform proposals, if adopted, could impose limitations on the prices the Company will be able to charge in the United States for its products or the amount of reimbursement available for its products from governmental agencies or third-party payors. While the Company cannot predict whether any of these legislative or regulatory proposals will be adopted or the effect that these proposals may have on its business, the announcement or adoption of these proposals could hurt its business by reducing demand for its products and could hurt its stock price because of investor reactions.

*Marketing and Sales Force.* The Company has limited internal marketing and sales resources and personnel. In order to market successfully, the Company's current and future products in the United States and other territories in which the Company does not, or does not intend to, use third-party distributors, the Company will need to develop a larger marketing and sales force with appropriate technical expertise and distribution capability. The Company may be unable to establish the marketing and sales capabilities that the Company needs, and the Company may be unsuccessful in gaining market acceptance for any of the Company's products.

*Manufacturing Volumes.* The Company has been manufacturing and assembling its test kits for limited commercial sales since 1995, but has not yet manufactured the large product volumes necessary for it to achieve profitability. The Company 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. The Company may not be able to achieve reliable, high-volume manufacturing at a commercially reasonable cost. In addition, numerous governmental authorities extensively regulate the Company's manufacturing operations. Failure to satisfy the Company's manufacturing needs could result in decreased sales, loss of market share and potential loss of certain distribution rights.

*Key Personnel.* The Company's success depends, in large part, upon its ability to attract and retain a highly qualified scientific and management team. The Company has no employment contracts with any of its key personnel. The loss of key personnel or the failure to recruit the necessary additional personnel needed for a qualified team might impede the achievement of developmental objectives. The Company faces competition for qualified personnel from other companies, research and academic institutions, government entities and other organizations. The Company may not be successful in hiring or retaining qualified scientific or management personnel on acceptable terms, given the competition among numerous pharmaceutical and biotechnology companies, government entities and research and academic institutions for qualified personnel.

*Hazardous Materials.* The Company's research and development activities involve the controlled use of hazardous materials, including radioactive compounds. Although the Company believes that its safety procedures for handling and disposing of its 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, the Company 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.

*Product-Related Liabilities.* 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 the Company. Although the Company currently has insurance covering its products, it may not be able to maintain this insurance at acceptable costs in the future, if at all. In addition, the Company's 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 the Company's product.

*Acquisition of Foreign Subsidiary.* In June 2000, the Company completed the acquisition of Matritech GmbH. Although the Company has integrated the operations of this subsidiary it still must coordinate geographically separate organizations, manage personnel with disparate business backgrounds and adjust to differing corporate cultures. There can be no assurance that the acquired business or its products will be successful or that the Company will achieve the desired financial and strategic benefits from the transaction.

*Foreign Exchange.* To the extent that foreign currency exchange rates fluctuate in the future, the Company may be exposed to continued financial risk. These can be no assurance that the Company will be successful in limiting its exposure.

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

*Investment Portfolio.* The Company owns financial instruments that are sensitive to market and interest rate risks as part of its investment portfolio. The investment portfolio is used to preserve the Company's capital until it is required to fund operations including the Company's research and development activities. None of these market-risk sensitive instruments are held for trading purposes. The Company's investment policy prohibits investing in derivatives and the Company stringently adheres 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 accounts of Matritech GmbH are translated in accordance with SFAS No. 52, *Foreign Currency Translation*. In translating the accounts of Matritech GmbH into U.S. dollars, assets and liabilities are translated at the rate of exchange in effect at year-end, while stockholders' equity is translated at historical rates. Revenue and expense accounts are translated using the weighted-average exchange rate in effect during the period. Foreign currency translation and transaction gains or losses for Matritech GmbH are included in the accompanying consolidated statements of operations since the functional currency for Matritech GmbH is the Deutsche Mark. The Company had sales of approximately $667,000 denominated in foreign currency from June 28, 2000 to December 31, 2000, the period during which the acquisition was effective. In 2001, the Company had sales of approximately $1,729,000 denominated in foreign currency.

**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.***

There have been no changes in or disagreements with accountants on accounting or financial disclosure matters during the Company's two most recent fiscal years.

## PART III

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

**Directors**

The information concerning directors of the Company required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2001 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 the Company required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2001 under the headings "Occupations of Directors and Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance."

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

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2001 under the heading "Compensation and Other Information Concerning Directors and Officers."

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

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2001, 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 the Company's definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission within 120 days after the close of the Company's fiscal year ended December 31, 2001, under the heading "Certain Relationships and Related Transactions."

## PART IV

**Item 14.** ***Exhibits, Financial Statement Schedules, and Reports on Form 8-K.***

(a) 1. Consolidated Financial Statements.
Report of Independent Public Accountants.
Consolidated Balance Sheets as of December 31, 2000 and 2001.
Consolidated Statements of Operations for the Years Ended December 31, 1999, 2000 and 2001.
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 1999, 2000 and 2001.
Consolidated Statements of Cash Flows for the Years Ended December 31, 1999, 2000 and 2001.
Notes to Consolidated Financial Statements.

2. No schedules are submitted because they are not applicable, not required or because the information is included in the Consolidated Financial Statements or Notes to Consolidated Financial Statements.

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 the Company's Registration Statement No. 33-46158 on Form S-1 and re-filed herewith in electronic form). |
| 3.2** | Amended and Restated By-Laws of the Registrant (originally filed as Exhibits 3.2, 4.1 to the Company's Registration Statement No. 33-46158 on Form S-1 and re-filed herewith in electronic form). |
| 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 the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1995 and re-filed herewith in electronic form). |
| 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 the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1995 and re-filed herewith in electronic form). |
| 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 the Company's 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 the Company's 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 the Company's Form 8-K, filed on November 22, 1999 and incorporated herein by reference). |
| 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 the Company's 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 the Company's 8-K, filed on January 4, 2002 and incorporated herein by reference). |

| Exhibit Number | Description of Exhibit |
|---|---|
| 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 the Company's Registration Statement No. 33-46158 on Form S-1 and re-filed herewith in electronic form). |
| 10.2#** | 1988 Stock Plan (originally filed as Exhibit 10.8 to the Company's Registration Statement No. 33-46158 on Form S-1 and re-filed herewith in electronic form). |
| 10.3# | 1992 Stock Plan as amended June 16, 2000 (filed as Exhibit 4.6 to the Company's 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 the Company's 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 the Company's Registration Statement No. 33-46158 on Form S-1 and re-filed herewith in electronic form). |
| 10.6** | Form of Indemnity Agreement with directors (originally filed as Exhibit 10.14 to the Company's Registration Statement No. 33-46158 on Form S-1 and re-filed herewith in electronic form). |
| 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 the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1997 and re-filed herewith in electronic form). |
| 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 the Company's Form 10-Q for the fiscal quarter ended March 31, 1994 and re-filed herewith in electronic form). |
| 10.9**@†† | Exclusive Distribution Agreement between the Company and Konica Corporation dated as of November 9, 1994 (originally filed as Exhibit 10.26 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1994 and re-filed herewith in electronic form). |
| 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 the Company's 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 the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1995 and re-filed herewith in electronic form). |
| 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 the Company's 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). |

| Exhibit Number | Description of Exhibit |
|---|---|
| 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 the Company's 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 the Company's 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 the Company's 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 the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2001 and incorporated herein by reference). |
| 23** | Consent of Arthur Andersen LLP. |

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@ 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.

(b) Reports on Form 8-K.

i) On December 10, 2001, the Company filed a Current Report on Form 8-K dated as of December 10, 2001 including Items 5 and 7.

Item 5 reported the following other event: The Company issued a press release announcing that it presented results of its Matritech NMP48 prostate cancer blood test.

Item 7 included the press release issued by the Company, dated December 10, 2001.

ii) On December 19, 2001, the Company filed a Current Report on Form 8-K dated as of December 17, 2001 including Items 5 and 7.

Item 5 reported the following other event: In December, 2001, the Company completed a private placement of 1,063,523 shares of Common Stock for an aggregate selling price of $2,411,053.02.

Item 7 included a Form of Purchase Agreement dated by and between the Company and certain investors and the Engagement Letters between the Company and Granite Financial Group, Inc.

(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 15th day of March, 2002.**

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<br>Stephen D. Chubb | Director, Chairman, and Chief Executive Officer (Principal Executive Officer) | March 15, 2002 |
| /s/ DAVID L. CORBET<br>David L. Corbet | Director, President and Chief Operating Officer | March 15, 2002 |
| /s/ JOHN S. DOHERTY, JR.<br>John S. Doherty, Jr. | Vice President, Chief Financial Officer and Treasurer (Principal Accounting and Financial Officer) | March 15, 2002 |
| /s/ JUDITH KURLAND<br>Judith Kurland | Director | March 15, 2002 |
| /s/ DAVID RUBINFIEN<br>David Rubinfien | Director | March 15, 2002 |
| /s/ RICHARD A. SANDBERG<br>Richard A. Sandberg | Director | March 15, 2002 |
| /s/ T. STEPHEN THOMPSON<br>T. Stephen Thompson | Director | March 15, 2002 |
| /s/ C. WILLIAM ZADEL<br>C. William Zadel | Director | March 15, 2002 |

**MATRITECH, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

## 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

## MATRITECH, INC.

## CONSOLIDATED BALANCE SHEETS

| | December 31, 2000 | December 31, 2001 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 4,661,005 | $ 4,819,733 |
| Accounts receivable, net | 250,937 | 291,902 |
| Inventories | 334,527 | 337,087 |
| Interest receivable and prepaid expenses | 193,182 | 176,748 |
| Total current assets | 5,439,651 | 5,625,470 |
| Property and equipment, at cost: | | |
| Laboratory equipment | 1,831,109 | 1,898,125 |
| Office equipment | 253,228 | 273,148 |
| Laboratory furniture | 62,739 | 62,739 |
| Leasehold improvements | 56,981 | 88,865 |
| Automobiles | 34,059 | 33,205 |
| | 2,238,116 | 2,356,082 |
| Less — Accumulated depreciation and amortization | 1,456,774 | 1,636,365 |
| | 781,342 | 719,717 |
| Goodwill, net | 219,432 | 132,615 |
| Other assets, net | 155,043 | 134,458 |
| | $ 6,595,468 | $ 6,612,260 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| CURRENT LIABILITIES: | | |
| Current maturities of notes payable | $ 110,322 | $ 46,366 |
| Accounts payable | 365,811 | 491,993 |
| Accrued expenses | 367,474 | 720,201 |
| Deferred revenue | 8,433 | 29,538 |
| Total current liabilities | 852,040 | 1,288,098 |
| Notes payable, less current maturities | 157,381 | 102,300 |
| Long-term liabilities | 18,039 | — |
| Commitments (Note 4) | | |
| 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 — 40,000,000 shares | | |
| Issued and outstanding — 25,541,282 shares in 2000 and 28,332,073 shares in 2001 | 255,413 | 283,321 |
| Additional paid-in capital | 59,611,684 | 67,882,572 |
| Deferred compensation | (178,582) | (107,146) |
| Cumulative translation adjustment | (9,021) | 5,428 |
| Accumulated deficit | (54,111,486) | (62,842,313) |
| Total stockholders' equity | 5,568,008 | 5,221,862 |
| | $ 6,595,468 | $ 6,612,260 |

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

## MATRITECH, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

| | Years Ended December 31, | | |
|---|---|---|---|
| | 1999 | 2000 | 2001 |
| REVENUE: | | | |
| Product sales and other | $ 622,808 | $ 1,245,611 | $ 2,340,940 |
| EXPENSES: | | | |
| Cost of product sales | 603,349 | 983,466 | 1,705,908 |
| Research, development and clinical expense | 2,543,456 | 2,295,097 | 3,362,024 |
| Selling, general and administrative expense | 3,803,252 | 5,130,124 | 6,151,330 |
| Total operating expenses | 6,950,057 | 8,408,687 | 11,219,262 |
| Loss from operations | 6,327,249 | 7,163,076 | 8,878,322 |
| Interest income | 224,658 | 345,644 | 169,665 |
| Interest expense | 21,625 | 18,822 | 22,170 |
| Net loss | $(6,124,216) | $(6,836,254) | $(8,730,827) |
| Basic and diluted net loss per common share | $ (0.29) | $ (0.28) | $ (0.33) |
| Basic and diluted weighted average number of common shares outstanding | 21,126,422 | 24,802,015 | 26,319,329 |

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 | Cumulative Translation Adjustment | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|
| | Number of shares | Par Value | | | | | |
| Balance, December 31, 1998 | 18,626,602 | 186,266 | $45,364,731 | — | — | $(41,151,016) | $ 4,399,981 |
| Sale of common stock and warrants, net of commissions and issuance costs of $120,578 | 4,896,305 | 48,963 | 7,407,338 | — | — | — | 7,456,301 |
| Exercise of common stock options | 27,427 | 274 | 48,508 | — | — | — | 48,782 |
| Issuance of common stock under employee stock purchase plan | 2,650 | 27 | 3,949 | — | — | — | 3,976 |
| Compensation related to issuance of common stock warrants | — | — | 158,636 | — | — | — | 158,636 |
| Net loss | — | — | — | — | — | (6,124,216) | (6,124,216) |
| Balance, December 31, 1999 | 23,552,984 | 235,530 | 52,983,162 | — | — | (47,275,232) | 5,943,460 |
| 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 |
| Cumulative translation adjustment | — | — | — | — | $(9,021) | — | (9,021) |
| Net loss | — | — | — | — | — | (6,836,254) | (6,836,254) |
| Balance, December 31, 2000 | 25,541,282 | 255,413 | 59,611,684 | (178,582) | (9,021) | (54,111,486) | 5,568,008 |
| 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 2) | 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 |
| Cumulative translation adjustment | — | — | — | — | 14,449 | — | 14,449 |
| Net loss | — | — | — | — | — | (8,730,827) | (8,730,827) |
| Balance, December 31, 2001 | 28,332,073 | $283,321 | $67,882,572 | $(107,146) | $ 5,428 | $(62,842,313) | $ 5,221,862 |

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

## MATRITECH, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Years Ended December 31, | | |
|---|---|---|---|
| | 1999 | 2000 | 2001 |
| Cash Flows from Operating Activities: | | | |
| Net loss | $(6,124,216) | $(6,836,254) | $(8,730,827) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 121,441 | 205,804 | 266,408 |
| Amortization of deferred compensation | — | 35,718 | 71,436 |
| Expense related to issuance of common stock to former ADL shareholders (Note 2) | — | — | 30,800 |
| Expense related to issuance of common stock warrants to consultant | 158,636 | 1,020,684 | 1,020,684 |
| Expense related to issuance of common stock to consultant | — | 90,000 | |
| Changes in assets and liabilities: | | | |
| Accounts receivable | (48,755) | 108,280 | (40,965) |
| Inventories | 35,501 | 77,892 | (2,560) |
| Interest receivable and prepaid expenses | 926 | (56,329) | 16,434 |
| Accounts payable | (55,472) | (185,698) | 126,182 |
| Accrued expenses | (36,677) | (168,320) | 334,688 |
| Deferred revenue | 7,750 | (1,454) | 21,105 |
| Net cash used in operating activities | (5,940,866) | (5,709,677) | (6,886,615) |
| Cash Flows from Investing Activities: | | | |
| Purchases of property and equipment | (36,781) | (135,945) | (117,966) |
| (Increase) decrease in other assets | 2,291 | (68,779) | 20,585 |
| Cash paid for acquisition costs in purchase of ADL, net of cash acquired (Note 2) | — | (100,813) | — |
| Net cash used in investing activities | (34,490) | (305,537) | (97,381) |
| Cash Flows from Financing Activities: | | | |
| Payments on notes payable | (68,330) | (250,375) | (119,037) |
| Proceeds from sale of common stock and warrants | 7,456,301 | 1,475,949 | 6,994,167 |
| Proceeds from exercise of common stock warrants | — | 3,392,959 | 125,000 |
| Proceeds from exercise of common stock options | 48,782 | 450,013 | 93,031 |
| Proceeds from issuance of common stock under Employee Stock Purchase Plan | 3,976 | 4,500 | 35,114 |
| Net cash provided by financing activities | 7,440,729 | 5,073,046 | 7,128,275 |
| Effect of foreign exchange on cash and cash equivalents | — | (9,021) | 14,449 |
| Increase (Decrease) in cash and cash equivalents | 1,465,373 | (951,189) | 158,728 |
| Cash and cash equivalents, beginning of year | 4,146,821 | 5,612,194 | 4,661,005 |
| Cash and cash equivalents, end of year | $ 5,612,194 | $ 4,661,005 | $ 4,819,733 |
| Supplemental Cash Flow Information: | | | |
| Cash paid during the year for interest | $ 21,625 | $ 18,822 | $ 22,170 |
| 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. (the "Company") 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 the Company by the Massachusetts Institute of Technology ("MIT").

The Company is devoting substantially all of its efforts toward product research and development, raising capital and marketing products. The Company is 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, 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 the development of its future products.

On June 28, 2000, the Company 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 the Company's NMP22 Test Kit for bladder cancer (see Note 2).

### *(a) Principles of Consolidation*

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

### *(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*

The Company recognizes revenue from product sales upon shipment; revenue from collaboration fees as milestones are achieved; revenue from nonrefundable license agreements and research grants as earned over the life of the agreement. For each of the three years presented in the accompanying statements of operations, substantially all of the Company's revenue is from product sales. Deferred revenue consists of upfront collaboration fees which are recognized as milestones are achieved.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements*. SAB No. 101 requires companies to recognize certain upfront non-refundable fees and milestone payments over the life of the related alliance when such fees are received in conjunction with alliances which have multiple elements or ongoing performance obligations, among other things. The Company believes that its revenue recognition policies comply with SAB No. 101.

### *(d) Cash and Cash Equivalents*

The Company considers all highly liquid investments with original maturities of 90 days or less to be cash equivalents. The Company follows the provisions of Statement of Financial Accounting Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, in accounting for its marketable

securities. Securities held at December 31, 2000 and 2001 include only cash and cash equivalents, which consist of auction market preferred stocks and money market accounts.

*(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, | |
|---|---|---|
| | 2000 | 2001 |
| Raw materials | $150,981 | $147,234 |
| Work-in-process | 1,796 | 3,804 |
| Finished goods | 181,750 | 186,049 |
| | $334,527 | $337,087 |

*(f) Depreciation and Amortization*

The Company provides for depreciation and amortization 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 | 4-5 years |
| Laboratory furniture | 5 years |
| Leasehold improvements | Life of lease |
| Automobiles | 5 years |

*(g) Long-Lived Assets*

The Company follows the provisions of SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, which establishes accounting standards for the impairment of long-lived assets and certain identifiable intangibles to be held and used and for long-lived assets and certain identifiable intangibles to be disposed of. The Company reviews the carrying values of its long-lived, identifiable intangible assets and goodwill for possible impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Based on its review, management believes that the carrying value of the Company's long-lived assets does not require any adjustment.

*(h) Concentration of Credit Risk and Significant Customers*

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and trade accounts receivable. The Company maintains its cash in financial institutions of high credit standing and places its investments in investment-grade securities. The Company believes that no significant concentration of credit risk exists at December 31, 2001 or 2000, as it has not experienced any losses on its investments or any significant accounts receivable write-offs to date.

The Company 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, 1999 | 30% | 49% | — |
| Year ended December 31, 2000 | 13% | 18% | — |
| Year ended December 31, 2001 | — | 11% | 14% |

The Company had accounts receivable balances greater than 10% of total accounts receivable from the following customers as of December 31, 2000 and 2001:

| | Customer | | | | | |
|---|---|---|---|---|---|---|
| | A | B | C | D | E | F |
| As of December 31, | | | | | | |
| 2000 | 17% | 24% | 14% | — | 12% | — |
| 2001 | 13% | 17% | — | 15% | — | 14% |

*(i) Disclosure of Fair Value of Financial Instruments*

The Company's financial instruments consist mainly of cash and cash equivalents, accounts receivable, accounts payable and notes payable. The carrying amounts of the Company's financial instruments approximate their estimated fair values at December 31, 2000 and 2001. The estimated fair values have been determined through information obtained from market sources and management estimates.

*(j) Net Loss per Common Share*

The Company computes 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 the Company's potential common stock are antidilutive. Potential common stock consists of stock options and warrants as well as 37,153 and 22,914 contingently issuable shares of common stock held in escrow in connection with the ADL acquisition at December 31, 2000 and 2001, respectively. The number of antidilutive common stock equivalents excluded from the computation of diluted loss per share were 2,724,156, 1,556,440 and 1,801,079 for the years ended December 31, 1999, 2000 and 2001, respectively.

*(k) Comprehensive Income (Loss)*

The Company 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. During 2001, the Company incurred a translation gain of $5,429 relating to Matritech GmbH. This gain, along with the fiscal 2001 reported net loss, creates a comprehensive net loss for the year ended December 31, 2001 of $8,725,398. During 2000, the Company incurred a translation loss of $9,021 relating to Matritech GmbH. This loss, along with the fiscal 2000 reported net loss, creates a comprehensive net loss for the year ended December 31, 2000 of $6,845,275. The Company's comprehensive loss was the same as the reported net loss for the year ended December 31, 1999.

*(l) Foreign Currency Translation*

The financial statements of the Company's non-U.S. subsidiary are translated in accordance with SFAS No. 52, *Foreign Currency Translation*. The functional currency of the Company's foreign subsidiary is the U.S. dollar, accordingly, all assets and liabilities of the foreign subsidiary are translated using the exchange

rate at the balance sheet date except for property and equipment and stockholders' equity, which are translated at historical rates. Revenues and expenses are translated at average rates during the period, except for depreciation and amortization, which are translated at historical rates. Transaction and translation gains and losses are included in the accompanying consolidated statements of operations for the years ended December 31, 2000 and 2001 and were not material to the financial statements taken as a whole.

*(m) Recent Accounting Pronouncements*

In June 2001, the FASB issued SFAS No. 141, *Accounting for Business Combinations*. SFAS No. 141 requires all business combinations initiated after June 30, 2001 to be accounted for using the purchase method. The Company does not expect the adoption of this statement to have a material impact on their financial statements.

In June 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 142, *Goodwill and Other Intangible Assets*. This statement modifies the Company's treatment of goodwill and other intangible assets existing as of January 1, 2002, and for acquisitions consummated after June 30, 2001. The statements require that goodwill existing at the date of adoption be reviewed for possible impairment and that impairment tests be periodically repeated, with impaired goodwill written down to fair value. Additionally, existing goodwill and intangible assets must be assessed and classified with the Statement's criteria. Intangible assets with estimated useful lives will continue to be amortized over those periods. Amortization of goodwill and intangible assets with indeterminable lives will cease. Although the Company has not yet determined the full impact of this statement on reported results, amortization of goodwill for the twelve months ended December 31, 2000 and 2001 totaled $49,021 and $86,817, respectively.

In June 2001, the FASB issued SFAS No. 143, *Accounting for Asset Retirement Obligations*. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. This Statement applies to all entities. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. This Statement does not apply to obligations that arise solely from a plan to dispose of a long-lived asset. This Statement shall be effective for financial statements issued for fiscal years beginning after June 15, 2002. The Company does not expect the adoption of this statement to have a material impact on their financial statements.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This statement requires that a long-lived asset to be abandoned, exchanged for a similar productive asset, or distributed to owners in a spin-off be considered held and used until it is disposed of. The changes in this Statement require that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and by broadening the presentation of discontinued operations to include more disposal transactions. The provisions of this Statement are effective for financial statements issued for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years, with early application encouraged. The provisions of this Statement generally are to be applied prospectively. The Company does not expect the adoption of this statement to have a material impact on their financial statements.

**(2) Acquisition of ADL**

On June 28, 2000, the Company acquired all of the outstanding shares of capital stock of ADL, now called Matritech GmbH, a European distributor of diagnostic testing products, including the Company's 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 the Company's 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, the Company issued 37,153 shares of the Company's 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. The Company 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 of the Company assume 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, | |
|---|---|---|
| | 1999 | 2000 |
| Total revenue | $ 2,567,024 | $ 1,935,121 |
| Net loss | $(6,536,615) | $(7,069,385) |
| Net loss per share — basic and diluted | $ (.31) | $ (.29) |

**(3) Income Taxes**

The Company follows the provisions of SFAS No. 109, *Accounting for Income Taxes*. Under the provisions of SFAS No. 109, the Company recognizes 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 carryforwards to the extent they are realizable.

The Company's net deferred tax asset consists of the following:

| | December 31, | |
|---|---|---|
| | 2000 | 2001 |
| Net operating loss carryforwards | $ 15,933,000 | $ 18,526,000 |
| Capitalized research and development expenses | 4,483,000 | 5,057,000 |
| Tax credits | 2,095,000 | 2,311,000 |
| Other temporary differences | (417,000) | (429,000) |
| Deferred tax asset | 22,094,000 | 25,465,000 |
| Valuation allowance | (22,094,000) | (25,465,000) |
| Net deferred tax asset | $ — | $ — |

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

The net operating loss carryforwards and tax credits expire as follows:

| Expiration Date | Federal Net Operating Loss Carryforwards | State Net Operating Loss Carryforwards | Tax Credit Carryforwards |
|---|---|---|---|
| 2002 | — | 3,925,000 | — |
| 2003 | $ 410,000 | 5,144,000 | — |
| 2004 | 1,254,000 | 4,651,000 | $ 33,000 |
| 2005 | 2,335,000 | 5,607,000 | 76,000 |
| 2006-2026 | 45,696,000 | 6,661,000 | 2,202,000 |
| | $49,695,000 | $25,988,000 | $2,311,000 |

The U.S. Internal Revenue Code of 1986, as amended (the Code), contains provisions that may limit the net operating loss and tax credit carryforwards available to be used in any given year upon the occurrence of certain events, including changes in the ownership interests of significant stockholders. In the event of a cumulative change in ownership in excess of 50% over a three-year period, the amount of the net operating loss carryforwards and tax credit carryforwards that the Company can utilize in any one year may be limited. In the event of a change in ownership, as defined, the annual limitation on the use of the existing net operating loss and tax credit carryforwards is equal to an amount determined by multiplying the value of the Company at the time of the ownership change by the U.S. applicable federal rate of interest, as determined by the U.S. Internal Revenue Service. The Company has determined that its net operating losses and tax credit carryforwards have not been limited.

A reconciliation of the federal statutory rate to the Company's effective tax rate is as follows:

| | December 31, | | |
|---|---|---|---|
| | 1999 | 2000 | 2001 |
| 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% |

**(4) Lease Commitments**

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

| | |
|---|---|
| 2002 | $ 532,000 |
| 2003 | 523,000 |
| 2004 | 505,000 |
| 2005 | 487,000 |
| 2006 | 9,000 |
| Total | $2,056,000 |

Rent expense for the years ended December 31, 1999, 2000 and 2001 was approximately $283,000, $341,000 and $509,000 respectively.

**(5) Notes Payable**

The Company 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 the Company) upon the conclusion of the term of the note. The monthly payments on this note were paid off in October 2001. The Company elected to make a lump sum payment and is currently in negotiations with Phoenix Leasing to sell it one of the pieces of equipment in satisfaction of the final lump sum payment.

In connection with the acquisition of ADL, the Company assumed certain debt obligations. At December 31, 2001, these obligations consist of a $90,000 loan from a bank, a $45,000 third-party demand note and $13,000 worth of automobile loans. The bank loan is due in June 2004, bears interest at 5.2% and is secured by trade receivables and inventory. The demand note will be repaid by the Company and the Company will be reimbursed by a key Matritech GmbH employee. The Company has 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 totaling $1,000.

Maturities of debt obligations are as follows:

| | |
|---|---|
| 2002 | $ 46,366 |
| 2003 | 39,676 |
| 2004 | 62,624 |
| Total | $148,666 |

**(6) Stockholders' Equity**

*(a) Sale of Common Stock*

In April 1999, the Company completed a private placement of 3,094,965 shares of its common stock resulting in net proceeds of $3,910,000 after deducting transaction expenses. In November 1999, the Company 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, the Company 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 the Company of $1,981,000.

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

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

On various closing dates throughout December 2001, the Company 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 the Company's 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, the Company 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 for the two-year period ending December 2003 and are callable by the Company if certain conditions are satisfied. The Company received net proceeds of $1,061,000 after deducting transaction expenses.

*(b) Warrants*

In April 1997, the Company issued a warrant to an investor relations consultant for the purchase of up to 150,000 shares of the Company's 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. The Company expensed $150,000 as a component of selling, general and administrative expense 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 the Company of $375,000.

In May 1997, in connection with a private placement, the Company 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 the Company of $536,000.

In July 2000, the Company issued a fully vested, nonforfeitable warrant to an investor relations consultant for the purchase of up to 450,000 shares of the Company's 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. The Company 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 the Company of $500,000 and $125,000, respectively.

*(c) Stock Option and Purchase Plans*

The Company has granted incentive and nonqualified options under its 1988 and 1992 option plans and the 1992 Directors' Plan. 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 1,119,437 common shares available for future grants under existing option plans at December 31, 2001. The following table summarizes stock option activity:

| | Number of Options | Option Price Per Share | Weighted Average Price Per Share |
|---|---|---|---|
| Options outstanding, December 31, 1998 | $1,209,160 | $1.37 - $13.13 | $5.31 |
| Granted | 472,670 | 0.84 - 3.69 | 1.82 |
| Exercised | (27,427) | 1.37 - 2.44 | 1.78 |
| Terminated | (221,148) | 1.34 - 10.63 | 3.30 |
| 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 |
| 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 |
| Options exercisable, December 31, 1999 | 760,701 | $1.44 - $13.13 | $5.92 |

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Price | Number Outstanding | Weighted Average Remaining Contractual Life (in Years) | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
| $ 0.84 - $ 1.16 | 131,000 | 7.65 | $ 0.91 | 81,000 | $ 0.96 |
| 1.34 - 2.00 | 156,838 | 5.79 | 1.56 | 107,154 | 1.54 |
| 2.03 - 2.85 | 243,642 | 7.63 | 2.49 | 147,067 | 2.31 |
| 3.17 - 4.34 | 375,417 | 8.56 | 3.40 | 112,484 | 3.62 |
| 5.00 - 6.69 | 56,325 | 7.03 | 6.26 | 51,975 | 6.25 |
| 7.88 - 10.63 | 445,337 | 4.99 | 7.89 | 445,336 | 7.89 |
| 13.13 | 30,000 | 4.44 | 13.13 | 30,000 | 13.13 |
| Total | 1,438,559 | 6.77 | $ 4.52 | 975,016 | $ 5.35 |

The Company has reserved and may issue up to an aggregate of 225,000 shares of common stock under the Employee Stock Purchase Plan pursuant to which stock is sold at 85% of fair market value, as defined. At December 31, 2000 and 2001, the Company has accumulated payroll deductions of $21,402 and $27,017, respectively, for the issuance of 6,572 and 10,308 shares of common stock, respectively, which are issued in the following year to employees pursuant to the plan. At December 31, 2001, 170,395 shares are available for issuance under the plan.

SFAS No. 123, *Accounting for Stock-Based Compensation*, requires the measurement of the fair value of stock options, including stock purchase plans, or warrants granted to employees to be included in the statement of operations or disclosed in the notes to financial statements. The Company has determined that it will continue to account for stock-based compensation for employees under APB Opinion No. 25 and elect the disclosure-only alternative under SFAS No. 123. The Company has computed the pro forma disclosures required under SFAS No. 123 for options granted in 1999, 2000 and 2001 and stock issued pursuant to the stock purchase plan using the Black-Scholes option-pricing model prescribed by SFAS No. 123. The weighted average assumptions used for 1999, 2000 and 2001 are as follows:

| | 1999 | 2000 | 2001 |
|---|---|---|---|
| Risk-free interest rate | 4.65% - 6.38% | 5.28% - 6.33% | 4.56 - 5.41% |
| Expected dividend yield | — | — | — |
| Expected life | 7 years | 7 years | 7 years |
| Expected volatility | 65% | 65% | 65% |

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option-pricing models require the input of highly subjective assumptions including expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

The total fair value of the options granted during 1999, 2000 and 2001 was computed as approximately $530,000, $396,000 and $671,000, respectively, and the weighted average fair value of grants was $1.12, $3.19, and $2.09 per share for 1999, 2000 and 2001, respectively. The total pro forma compensation expense (which includes amounts related to prior years' grants) for 1999, 2000 and 2001 was computed as approximately $1,140,000, $1,016,000 and $508,000, respectively. The remaining amount, approximately $1,297,000, would be amortized over the remaining vesting period of the underlying options. The resulting pro forma compensation expense may not be representative of the amount to be expected in future years as pro forma compensation expense may vary based upon the number of options granted.

The pro forma net loss and pro forma net loss per common share presented below have been computed assuming no tax benefit. The effect of a tax benefit has not been considered since a substantial portion of the stock options granted are incentive stock options and the Company does not anticipate a future deduction associated with the exercise of these stock options.

The pro forma effect of SFAS No. 123 for the years ended December 31, 1999, 2000 and 2001 is as follows:

| | 1999 | |
|---|---|---|
| | As Reported | Pro Forma |
| Net loss | $(6,124,216) | $(7,264,040) |
| Basic and diluted net loss per share | $ (0.29) | $ (0.34) |

| | 2000 | |
|---|---|---|
| | As Reported | Pro Forma |
| Net loss | $(6,836,254) | $(7,851,876) |
| Basic and diluted net loss per share | $ (0.28) | $ (0.32) |

| | 2001 | |
|---|---|---|
| | As Reported | Pro Forma |
| Net loss | $(8,730,827) | $(9,239,205) |
| Basic and diluted net loss per share | $ (0.33) | $ (0.35) |

*(d) Reserved Shares*

As of December 31, 2001 the following shares of common stock were reserved and available for future issuance:

| | |
|---|---|
| Stock Option Plans | 2,557,996 |
| 1992 Employee Stock Purchase Plan | 170,395 |
| Exercise of warrants outstanding | 339,606 |
| | 3,067,997 |

**(7) License Agreements**

*(a) MIT License Agreement*

MIT has granted the Company a worldwide exclusive license to certain technology, which was extended when the Company obtained Food and Drug Administration approval of its first cancer diagnostic product in 1996, until the expiration of all patent rights in 2006. Pursuant to the license agreement, the Company pays royalties on the sales of products incorporating the licensed technology. The Company paid $6,944, $12,510 and $10,715 in royalties in the years ended December 31, 1999, 2000 and 2001.

*(b) Hybritech License Agreement*

In August 1994, the Company 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. The Company is required to pay a royalty equal to the greater of 8% of net sales of licensed products or $25,000 per year until the expiration of patent rights on a country-by-country basis beginning in 2000 through 2008. The Company paid $42,540, $25,000 and $25,000 in royalties in the years ending December 31, 1999, 2000 and 2001, respectively.

**(8) Accrued Expenses**

Accrued expenses consist of the following:

| | December 31, | |
|---|---|---|
| | 2000 | 2001 |
| Payroll and related costs | $143,162 | $416,410 |
| Professional fees | 116,207 | 170,012 |
| Clinical trials costs | 70,731 | 10,802 |
| Other | 37,374 | 122,977 |
| | $367,474 | $720,201 |

## (9) Segment and Geographic Information

The Company applies 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. The Company's chief decision maker, as defined under SFAS No. 131, is a combination of the Chief Executive Officer, President and the Chief Financial Officer. To date, the Company has viewed its operations and manages its 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 the Company's products were shipped from its facilities located in the United States or, since June 28, 2000, from its facilities in Freiburg, Germany. Product sales by destination are as follows:

| | Revenue ($ in 000's) | | | | | |
|---|---|---|---|---|---|---|
| | 1999 | | 2000 | | 2001 | |
| | $ | % | $ | % | $ | % |
| United States | $330 | 53% | $ 240 | 19% | $ 351 | 15% |
| Japan | 187 | 30 | 156 | 13 | 163 | 7 |
| Europe | 25 | 4 | 707 | 57 | 1,729 | 74 |
| Rest of world | 81 | 13 | 143 | 11 | 98 | 4 |
| Total | $623 | 100% | $1,246 | 100% | $2,341 | 100% |

The Company's total net fixed assets in the United States and Germany were approximately $573,000 and $147,000 at December 31, 2001, and $604,000 and $177,000 at December 31, 2000, respectively. At December 31, 1999, all of the Company's fixed assets were in the United States.

## (10) Supplemental Financial Disclosure

| 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) |

| Unaudited ($ in 000's, except per share amounts) | Q1-00 | Q2-00 | Q3-00 | Q4-00 |
|---|---|---|---|---|
| Revenue | $ 140 | $ 190 | $ 446 | $ 470 |
| Operating loss | (1,379) | (1,363) | (2,331) | (2,090) |
| Net loss | (1,305) | (1,257) | (2,253) | (2,021) |
| Basic/diluted net loss per share | $ (0.05) | $ (0.05) | $ (0.09) | $ (0.08) |

## (11) Subsequent Events

On March 4, 2002, the Company 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 are exercisable until November 30, 2002 and are callable by the Company if certain conditions are satisfied. The Company received net proceeds of approximately $4,167,000 after deducting transaction expenses.