Matritech Inc
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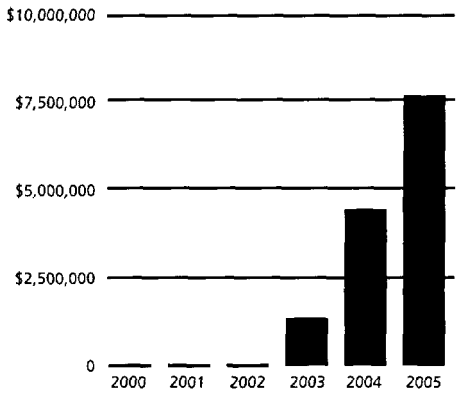
THE MANY FACES OF BLADDER CANCER

2005 ANNUAL REPORT

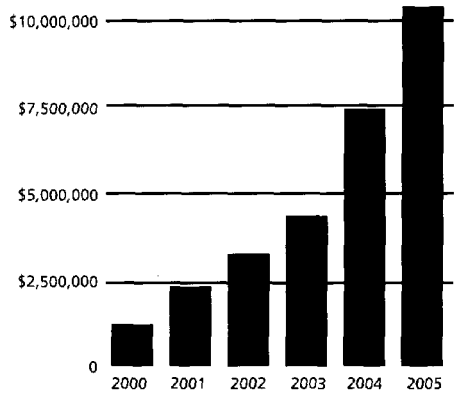
Matritech

Matritech is revolutionizing the diagnosis of bladder cancer and helping to save lives. Adding the NMP22® BladderChek® Test to cystoscopy significantly increases the detection of cancer, up to 99%—even finding life threatening cancers missed by the cystoscope. With more than one million NMP22 BladderChek Tests sold, it is becoming standard of care in the management of bladder cancer.

Total NMP22 BladderChek Sales

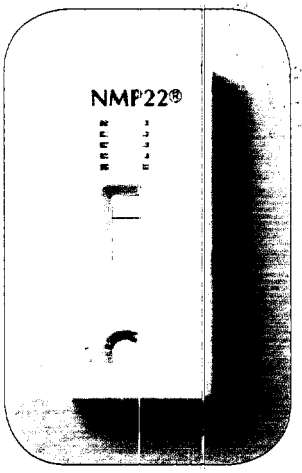


Total Corporate Sales

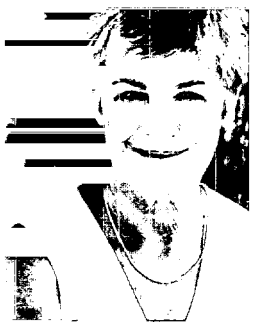


TO OUR SHAREHOLDERS

2005 was another record year for sales of our NMP22® BladderChek® Test—the driver of our progress to profitability. The recognition received from preeminent urologists in their publications, presentations and Continuing Medical Education (CME) programs resonated in the urology community and moved the NMP22 BladderChek Test closer to our objective of it becoming standard of care for diagnosing and monitoring patients with bladder cancer. Twice in less than a year, the Journal of the American Medical Association (JAMA) published reports on its effectiveness in diagnosing and monitoring bladder cancer patients. The most recent publication in January 2006 reported that the NMP22 BladderChek Test combined with the cystoscope detected 99% of recurrent bladder cancers as well as detected life threatening cancers missed by the invasive cystoscopy procedure. These data support similar findings published in JAMA in February 2005 reporting its effectiveness in the initial diagnosis of bladder cancer. We believe the impressive sales growth during 2005 provides evidence that urologists understand the combined sensitivity of the NMP22 BladderChek Test with cystoscopy.



The NMP22® BladderChek® Test is the only in-office test approved by the FDA for the diagnosis of bladder cancer, with results available during the patient visit.

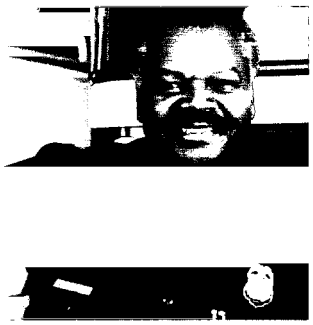


"...the NMP22 assay which is accurate and easy to administer, I believe, will help identify and treat patients earlier when they a have better chance for a good outcome."

Dr. H.B. Grossman, M.D. Anderson Cancer Center

Direct-to-urologist sales in the U.S. of the NMP22 BladderChek Test increased the number of routine users, as well as increased reordering rates from established users. In Germany, we began selling the NMP22 BladderChek Test to gynecologists, adding more than 600 German gynecologists purchasing as of the end of 2005. Similarly in the U.S., we started the planning process to expand our sales reach to the primary care physician market, which would include gynecologists.

In addition, 2005 was a year of progress in the development of other NMP-based diagnostic tests for cervical and breast cancer. Our scientists continued work on the optimization of immunoassays for the NMP66™ breast cancer marker, with the goals of using such an optimized assay to complete development of a serum-based test for breast cancer and to test blood specimens prior to submission to the FDA. In December 2005 at the San Antonio Breast Cancer Symposium, we reported on an improved method of detecting the NMP66 nuclear matrix protein complex in serum from women with breast cancer using an anti-sense affinity capture or AAC procedure. Matritech scientists are testing additional samples using the combination of the AAC-concentration method and the NMP66 immunoassay.



"The NMP22® BladderChek® Test is an important step forward. ...an easy and inexpensive way ...to [diagnose] patients...at higher risk for bladder cancer..."

Mark Soloway M.D., Chairman, Department of Urology, University of Miami School of Medicine

Our partnership with Sysmex Corporation continues in cervical cancer for the development of an automated test for the routine evaluation of cervical specimens using our proprietary NMP179® tumor marker. Sysmex, the driver of this product development program, has announced its plans to launch an automated testing system in 2008. We continue to see this partnership as having upside potential for Matritech, with no financial drain on our resources and single-digit royalties on product sales.

Entering 2006, Matritech is financially stable with cash on the balance sheet. In January 2006, we announced the completion of a $7 million private placement. We intend to use these funds for NMP66 product development and to support selling and marketing programs to strengthen our bladder cancer franchise.

Our mission remains unchanged—improve the detection of cancer. Through our technology and products we are revolutionizing how cancer is detected.

We appreciate your support and will keep working to continue earning it.

Sincerely,

STEPHEN D. CHUBB
Chairman & CEO

DAVID L. CORBET
President & COO

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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2005

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
Common Stock, $.01 Par Value	American Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to filed reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated file" in rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☑

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

Aggregate market value, as of June 30, 2005 of Common Stock held by non-affiliates of the registrant: $30,850,063 based on the last reported sale price on the American Stock Exchange.

Number of shares of Common Stock outstanding on March 15, 2006: 52,776,560

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PART I

Item 1. *Business.*

Overview

Matritech, Inc. is a biotechnology company principally engaged in the development, manufacture, marketing, distribution and licensing of cancer diagnostic technologies, products and services. We are focused primarily on the early detection of various types of cancer because treatment options may be greater and/or more successful and treatment costs may be lower when tumors are detected in their early stages. Our revenues are derived primarily from product sales.

The products we have developed are based on our proprietary nuclear matrix protein ("NMP") technology. The nuclear matrix, a three-dimensional protein framework within the nucleus of cells, plays a fundamental role in determining cell type by physically organizing the contents of the nucleus, including DNA. We focus our research on finding differences in the types and amounts of proteins found in the tissue, blood and urine of patients with and without cancer. We design our products to detect these differences and to provide medically useful information to physicians throughout their screening, diagnosis and treatment activities.

Our first two products, the NMP22[1] Test Kit and NMP22 BladderChek Test, sales of which represent approximately 90% of our total revenue as of the end of 2005, are designed to detect the presence of a specific protein marker in urine correlated with the presence of bladder cancer. On four separate occasions, the Food and Drug Administration (the "FDA") has approved one of these products for detecting the recurrence of or aiding in the initial diagnosis of bladder cancer. Our sales of the NMP22 BladderChek Test are concentrated in the United States and Germany, where our own sales forces sell the NMP22 BladderChek Test directly to prescribing physicians. The NMP22 Test Kit is sold to clinical laboratories by distributors and by our sales force in Germany.

We have discovered other proteins associated with cervical, breast, prostate, and colon cancer. Sysmex Corporation has licensed our NMP179 technology for use in an automated cervical cancer detection system it is developing. Our goal is to utilize these other protein markers to develop, through our own research staff and through strategic alliances, clinical applications to detect other forms of cancer. Our internal research and development resources are currently focused on our NMP66 program to develop a blood-based test for breast cancer. Our German subsidiary, Matritech GmbH, also sells allergy and other diagnostic products manufactured by others.

Cancer Diagnostic Market

The principal role of a diagnostic product is to provide information that physicians or patients find useful in managing a patient's health. Whether testing urine, blood, tissue or the entire body, the results of a diagnostic product or procedure include information that may assist physicians in making a diagnosis or in guiding therapeutic choices. The products of our own research and development are intended to indicate the elevated risks of cancer at early stages when treatment options may be greater and/or more successful and treatment costs may be lower.

The size of cancer diagnostic markets can be measured at two different levels: the patient or insurer payments for test results generated by diagnostic products (the "Service Market") and the payments made by users for the diagnostic products themselves (the "Product Market"). Generally laboratories and physicians performing tests in their offices receive patient or insurer payments in the Service Market and buy the products needed to perform these tests from device manufacturers such as Matritech. In the United States, we estimate that the current size of the Service Market for urine and blood testing for bladder, prostate, and colon cancer exceeds $1.5 billion per year, the Service Market for breast cancer mammograms exceeds $2 billion per year

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

and the Service Market for cervical cancer testing exceeds $1.5 billion per year. We also believe that the Service Market for these tests in the rest of the world is roughly equal to that of the United States. For a Service Market, the cancer testing products used to perform the service can be as little as 10% to more than 50% of the patient payment or insurer reimbursement for such service. As a result, we estimate that the worldwide potential Product Market for blood, urine and cervical cellular testing for bladder, cervical, breast, prostate and colon cancer testing could exceed $1 billion.

Cancer Diagnostic Product Development

Medical Indications — the Medically Useful Information

The medical diagnostics market covers more medical activities than just the diagnosis of disease. The cancer diagnostics market, for example, is composed of several overlapping categories, each corresponding to a different stage in the identification and management of cancer. The major categories include screening, diagnosing, staging, selecting therapies, monitoring and evaluating prognosis. The three for which our currently developed technologies and products are best suited are screening, diagnosis and monitoring.

Screening: Cancer screening tests and procedures are used to identify asymptomatic disease in individuals who may (or may not) have risk factors for the disease, but who have no specific evidence of the disease. Screening tests such as mammograms for breast cancer, Prostate Specific Antigen ("PSA") tests for prostate cancer and Pap smears for cervical cancer are widely used but do not yield a final diagnosis. Instead they prompt a physician to perform additional tests and procedures in order to make a diagnosis.

Diagnosis: While a definitive diagnosis of cancer is usually made after microscopic examination of the suspected cancerous cells by a specially trained physician, numerous tests may be used to indicate the presence and/or location of disease even though the specific cells cannot be immediately identified.

Monitoring: Following diagnosis and treatment, 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 possible recurrence of cancer. In addition, monitoring 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 or urine-based cancer detection assays have generally been approved by the FDA for monitoring patients with known history of disease. Only two such protein marker tests have been approved for use in detecting cancer in previously undiagnosed individuals — the PSA test for prostate cancer and our NMP22 test for bladder cancer.

The considerations that influence the design of our products are the clinical data needs of physicians and the formats most useful for delivering information to physicians in practice. The nuclear matrix protein based products developed and under development by us or our strategic partners utilize three different formats:

- Point-Of-Care Tests — our NMP22 BladderChek Test works like a home pregnancy test and is principally sold directly to physicians;
- Lab Test Kits — our NMP22 Test Kit consists of reagents sold to a medical laboratories, that perform testing procedures using patient specimens pursuant to a physician's order; and
- Cellular Analysis Systems — complex medical instruments that examine cells both visually and biologically.

We believe that our technology could also be incorporated in a Proprietary Laboratory Procedure which would provide diagnostic information much like a Lab Test Kit. Each of these is described more fully in Technology — Product and Service Formats.

Summary of Matritech's Product Development Programs

The following table summarizes some of the important aspects of each of our product development programs. The information in the table is qualified by the more expansive and detailed sections following the table.

Program	Technology Format	Clinical Application	Stage of Development	FDA Review Status	Principal FDA Approved Competitive Products(1)	Major Commercialization Arrangements(2)
NMP22 Bladder	Lab Test Kit	Monitoring	Commercialized	Approved (1996)	BTA Trak UroVysion	(1) Matritech direct marketing — Germany (2) Wampole Laboratories — U.S. — Distributor
NMP22 Bladder	Lab Test Kit	Diagnosis	Commercialized	Approved (2000)	UroVysion	(1) Matritech direct marketing — Germany (2) Wampole Laboratories — U.S. — Distributor (3) Konica Minolta — Japan — Distributor
NMP22 Bladder	BladderChek Point-Of-Care Test	Monitoring	Commercialized	Cleared (2002)	BTA Stat	(1) Matritech direct marketing — U.S. and Germany (2) Other Distributors — Other Territories
NMP22 Bladder	BladderChek Point-Of-Care Test	Diagnosis	Commercialized	Approved (2003)	None	(1) Matritech direct marketing — U.S. and Germany (2) Medical and Biological Laboratories — Japan (3) Other Distributors — Other Territories
NMP179 Cervical	Automated Cellular Analysis System	Screening	Sysmex, our licensee, is conducting further pre-clinical trials	Not submitted	Imaging Directed Cytology™ (Cytyc) Focal Point™ Slide Verifier (TriPath Imaging)	(1) Sysmex — World — Manufacturer and Marketer for Non- Slide-Based System
NMP66 Breast	To be determined	Not Determined	Research and Development	Not submitted	Mammography, TRUQUANT®BR RIA CA27.29, CA15.3	(1) Mitsubishi Kagaku Iastron. — Japan
NMP48 Prostate	To be determined	Not Determined	Deferred	Not submitted	PSA	None
NMP35 Colon	None	Not Determined	Inactive	Not submitted	CEA, CA19.9	None

(1) Each of the products listed as competitive to our NMP products may compete for use in each indication for our NMP products, not simply those specifically listed in a category. Those listed for each category represent the competitive products most directly comparable in technology or approach for the given indication.

(2) Other distributors not listed under major commercialization arrangements have paid less than $50,000 in upfront fees, do not have cumulative sales in excess of $500,000 and do not have rights other than those of a conventional distributor.

Commercial Products

NMP22 Bladder Cancer Program

Our first cancer program to reach commercialization is a product line of diagnostic devices designed to detect bladder cancer. This program is based on discoveries made by our scientists that detect the presence of certain proteins (which we refer to as NMP22) in the urine of bladder cancer patients which are generally present at much lower levels or completely absent from the urine of individuals free of the disease.

Bladder cancer has the 3rd highest prevalence and the 4th highest incidence in U.S. males — levels that we believe are not recognized by individuals at risk. New cases of bladder cancer are almost as common in men as colon cancer, and occur in:

- Males — 4 times greater occurrence than females
- Older people — over 90% of initial diagnoses occur in individuals over the age of 40;
- Smokers — are twice as likely as non-smokers to contract the disease; and
- Certain occupations — firefighters, truck drivers, petrochemical and rubber workers, hairdressers, painters, textile workers are among those at higher risk due to the inhalation of toxic fumes and substances.

Our NMP22 program has created two complementary products designed to detect bladder cancer — the Point-Of-Care NMP22 BladderChek Test ("NMP22 BladderChek Test") and our NMP22 Test Kit ("NMP22 Test Kit") — each of which has been approved by the FDA to provide medically useful information for both diagnosing and monitoring bladder cancer.

We have concentrated our selling efforts in the United States and Germany because we believe those countries provide major revenue opportunities for us in four different, but related categories of patient needs.

Patient Category	Monitoring Patients with Cancer	Diagnosing Patients with Symptoms	Evaluating Patients with Symptoms	Screening at-Risk Asymptomatic Individuals(1)
Physician Focus	Urologist	Urologist	PCP + ObGyn	PCP + ObGyn
Estimated Number of Patients	700,000(2)	2,000,000(3)	5,000,000(3)	20,000,000(4)
Estimated Available Market Opportunity(5)	$33,000,000(6)	$33,000,000	$ 83,000,000	$ 330,000,000

(1) Additional regulatory approval not likely to be required in Germany, but may be required in the U.S. for us to promote this application

(2) Based on prevalence of about 499,000 patients in the U.S. (based on 2002 NCI-SEER data) and about 250,000 in Germany (derived by us from incidence data reported by Robert Koch Institute in 2004)

(3) Based on our estimates

(4) Based on our estimates including estimates of the population of male smokers over the age of 40

(5) Based on projected average pricing of NMP22 BladderChek Test in United States and Germany

(6) Our estimate based on American Urological Association monitoring guidelines

Urologist Market

To accelerate product adoption in the United States and Germany, we have established our own sales forces which have been principally focused on selling our products directly to urologists. This direct selling activity to urologists began in Germany at the end of 2001 and in the United States in November, 2003. Our principal product is our NMP22 BladderChek Test which is sold to urologists and can be performed in the doctor's office during patient visits. It generates income for the urologist from the patient or the patients' insurer. Our NMP22 Test Kit, which is sold by our sales force in Germany and by distributors in the United States and elsewhere, is principally distributed to clinical laboratories. These laboratories perform the

test pursuant to a physician's order and they are typically the sole recipient of any reimbursement provided by the patient or the patient's insurer.

Independent clinical trials are an important tool to demonstrate the performance of a new diagnostic test to physicians. In one clinical study reported in the Journal of the American Medical Association (JAMA), urologists evaluating patients with no previous history of bladder cancer performed an invasive cystoscopy exam together with our noninvasive NMP22 BladderChek Test and detected over 90% of all cases of bladder cancer, including virtually all invasive, life-threatening cases. In a second clinical trial also reported in JAMA, urologists monitoring patients for recurrence of disease reported that the combination of cystoscopy with the NMP22 BladderChek Test detected significantly more cancers (99%) than cystoscopy alone. In over 40 presentations and peer-reviewed papers, urologists have reported NMP22 products to be accurate, convenient and inexpensive tests that, when used with other detection and monitoring methods, improve patient management. Some of these papers reported that our NMP22 products can reduce costs and identify patients with cancer which was missed during the cystoscopic examination.

Primary Care Market

As NMP22 products become more widely accepted by urologists, we believe that their growing use will influence use of the NMP22 BladderChek Test by gynecologists and primary care physicians. Our early experience in the German marketplace has demonstrated that German gynecologists have an interest in a test providing better cancer detection, particularly for those individuals with traditional bladder cancer symptoms (such as microscopic blood in the urine (also known as asymptomatic microscopic hematuria or "AMH") and risk factors (such as a history of smoking, dangerous occupations or other factors). It is estimated that over 20 million people in Germany and the United States have AMH each year. The American Urological Association recommends that an appropriate renal or urologic evaluation be performed in all patients with AMH who are at risk for urologic disease or primary renal disease. We believe that such an evaluation may include a urine-based test using one of our NMP22 products and if so, that this application could represent a major marketing opportunity for us. We began a formal sales and marketing program to gynecologists in Germany during the summer of 2005. Based on our initial experience selling to gynecologists in that market, we plan to begin a program to market the NMP22 BladderChek Test to gynecologists in the U.S. in 2006. Eventually we expect to expand our sales efforts to primary care physicians but have no plans to undertake that program during 2006.

Other Private and Public Sector Markets

Firefighters, truck drivers, petrochemical workers and others are at an increased risk for bladder cancer due to the toxic materials with which they come into contact in the course of their work. In 1999, the Michigan Environmental Science Board reported that the incidence of bladder cancer in firefighters is more than twice as high as in non-firefighters. A number of states already recognize that firefighter disability and mortality are caused by occupational exposure to carcinogens and have passed laws providing funds to address these problems. In 2004, legislation was introduced in both the House of Representatives and Senate of the Massachusetts legislature which, if passed, would provide voluntary routine testing of firefighters for bladder cancer in Massachusetts. Other legislative proposals for firefighter testing are pending in Rhode Island and New York. At the national level, a proposed Federal Firefighter's Fairness Act, which includes provisions aimed at firefighter health and testing services, was introduced, but it has not yet been voted upon in the United States Congress.

It is widely recognized that other workers such as truck drivers, petrochemical and rubber workers, hairdressers, painters, and textile workers are among those at elevated risk of bladder cancer due to contact with toxic substances during the course of their employment. We believe that industrial or government testing of people employed in these at-risk occupations may become another source of potential growth for NMP22 products.

Point-of-Care NMP22 BladderChek Test. 90% of our NMP22 product sales in the fourth quarter of 2005 came from our NMP22 BladderChek Test. In this point-of-care format, the reagents that identify the NMP22

marker are configured in a device similar to a urine-based home pregnancy test and detect the NMP22 marker in patient urine specimens. Because the device delivers a test result in about 30 minutes, physicians or the staff in their offices can perform the NMP22 BladderChek Test during a patient's visit. In addition, in contrast to laboratory testing, the physician earns income by using our product to provide medical information (a test result) which is paid for by the patient or his insurer.

Approach to Market: In the United States and Germany we sell our NMP22 BladderChek Test directly to urologists. We began selling directly to urologists in Germany in 2001 and began selling directly to urologists in the United States in November 2003. Through the end of 2004, Cytogen Corporation ("Cytogen") (NASDAQ: CYTO) also distributed this product to certain physicians in the United States.

In Germany the cost of our NMP22 BladderChek Test is not reimbursed by the national or regional health plans but is instead paid for directly by the patient (or, in some instances, by private supplemental insurance that some German patients carry). In the United States, the NMP22 BladderChek Test is reimbursed by all 50 state Medicare insurers and, we believe, by a majority of private insurers.

We have NMP22 BladderChek Test distribution agreements in other parts of the world. Several distributors market the NMP22 BladderChek Test in Southeast Asia and in the People's Republic of China. In the summer of 2005, our distributor in Japan, Medical and Biological Laboratories Group ("MBL"), received regulatory approval from the Japanese Ministry of Health and Welfare ("Koseisho") for sale of the product in that country and MBL began marketing the product in Japan shortly thereafter. Our NMP22 BladderChek Test is distributed to European countries other than Germany through Matritech GmbH, our German Subsidiary, and various other distributors throughout Europe. We also have a distributor covering portions of the Middle East.

NMP22 Test Kit for Bladder Cancer. Our first product, the NMP22 Test Kit for bladder cancer, uses our proprietary reagents to detect the NMP22 marker in a semi-automated 96-well microtiter plate format used by licensed clinical laboratories to test urine specimens. Excluding the time to transport the specimen to the lab and the time to deliver the test report to the physician, the test provides a completed result in about four hours. With the NMP22 Test Kit, the laboratories typically receive a fee directly from the patient or his insurer.

Approach to Market: We have direct marketing and sales activities in Germany for our NMP22 Test Kit. Currently, Wampole Laboratories, Inc. ("Wampole") sells the NMP22 Test Kit in the United States and Matritech GmbH sells the NMP22 Test Kit directly to hospital, clinic and physician office laboratories in Germany and to distributors in other parts of Europe.

In Germany, the cost of our NMP22 Test is not reimbursed by national or regional health plans, but is instead paid for directly by the patient (or, in some instances, by private supplemental insurance that some German patients carry). In the United States, the NMP22 Lab Test is reimbursed by all 50 state Medicare insurers and, we believe, by a majority of the private insurers.

We have several NMP22 Test Kit product distribution arrangements in other parts of the world. In 1994, we entered into an exclusive agreement with Konica Corporation (now Konica Minolta Medical and Graphic, Inc. "Konica") to distribute our NMP22 Test Kit in Japan. In 1998, Koseisho approved the NMP22 Test Kit for sale in Japan for use in diagnosing previously undiagnosed patients for bladder cancer. The NMP22 Test Kit is currently being marketed in Southeast Asia and China by other distributors. 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.

Fully-Automated Format of NMP22 Test Kit: In 2001, we entered into an eight-year, non-exclusive product supply and marketing agreement with Diagnostic Products Corporation ("DPC") (NYSE:DP) enabling DPC to develop and market an automated format of our NMP22 Test Kit. Pursuant to our notice of termination, this agreement was terminated effective December 31, 2005.

Other Commercial Diagnostic Products.

Our German subsidiary, Matritech GmbH, has distributed third party allergy and other diagnostic testing products on behalf of several manufacturers for many years. Until September 30, 2005, the most significant of these distribution agreements was with Hitachi Chemical Diagnostics ("Hitachi"), from 1997 to 2005. In 2005 we provided notice of non-renewal of the Hitachi agreement and after the effective date of termination of the Hitachi agreement, Matritech GmbH began selling allergy products manufactured by another company. We expect sales of these allergy products by Matritech GmbH to continue for at least the remainder of 2006.

Research and Development Programs

Cervical Cancer Program (NMP179)

Our scientists have identified a nuclear matrix protein associated with cervical cancer and cervical precancerous conditions ("NMP179"). Traditional cervical cancer testing (often referred to as "Pap smear" testing) uses specialized medical technologists ("cytotechnologists" or "cytotechs") to analyze cervical cells visually using a microscope and to refer to pathologists those specimens needing further examination to diagnose disease. Our NMP179 technology was developed to reduce the time and increase the accuracy of identifying those cervical cells which need further visual inspection by a pathologist. We conducted three preclinical studies comparing the accuracy of Pap smear testing using this protein to testing without it.

Approach to Market: In 2002, we granted an exclusive worldwide license for the use of our NMP179 technology for automated, non-slide-based laboratory instruments to Sysmex Corporation ("Sysmex"). As a part of this transaction, Sysmex purchased shares of our common stock at a premium, agreed to pay us milestone payments based on reaching certain research and product development goals, committed to make minimum quarterly payments to support our research, contracted to purchase all NMP179 reagents from us and pay us a royalty on all reagent sales related to their cervical cancer screening system.

Sysmex is developing new systems which will automate the process of screening cervical cell specimens (currently done by cytotechs using a microscope) by combining our NMP179 technology with Sysmex's expertise in flow cytometry, image analysis and laboratory automation. Sysmex believes that this automation will reduce cytotech errors and reduce the overall cost of screening cervical specimens. In the spring of 2004, Sysmex commenced pre-clinical trials in Europe of their new cellular analysis system incorporating our NMP179 technology. Following completion of clinical trials, we expect Sysmex will file an FDA submission for a Class III device subject to a premarket approval ("PMA") regulatory process. Sysmex has indicated that its goal is to introduce this product to the market in the U.S. and Europe during the first half of 2008.

Breast Cancer Program (NMP66)

In 1999, our scientists, using a research configured, low-throughput mass spectrometer instrument ("research mass spectrometry"), discovered some characteristics of a distinct set of proteins ("NMP66") in the blood of breast cancer patients that were generally not present in the blood of women without known breast malignancy. We believe that measurement of certain NMP66 proteins and/or nucleic acids associated with the NMP66 protein complex may enable physicians to obtain breast cancer diagnostic information that is more accurate than the blood testing services that are currently available and could complement and supplement mammography. Our current development goal is to complete sample preparation and testing methods including high-throughput mass spectrometers, reverse transcriptase polymerase chain reaction ("RT-PCR") and conventional immunoassay techniques that will be more reproducible, controlled and cost effective than the research methods used to make the initial discovery.

Approach to Market: We have entered into an agreement with Mitsubishi Kagaku Iastron, Inc. ("MKI") whereby they or their designees will serve as our Japanese clinical laboratory partner for further validation of our NMP66 technology and development of a Proprietary Laboratory Procedure using some of the technology described in the preceding paragraph. Pursuant to this agreement we may negotiate with MKI for distribution rights for the Japanese market for products and services incorporating the NMP66 technology. We may enter

into an agreement with U.S. clinical laboratory if and when our Proprietary Laboratory Procedure has been optimized.

We have collected over 800 blood specimens according to an Institutional Review Board ("IRB")-approved protocol for use in generating reproducible and controlled clinical data. Like all blood-based research specimens we hold, these specimens have been stored in freezers at -80 degrees Celsius since they were collected and are available for immediate evaluation as soon as appropriate tests are developed. We believe these specimens will be suitable for use as part of our submission to the FDA for regulatory approval.

Prostate Cancer Program (NMP48)

In 1999, we entered into a collaboration agreement with Alan Partin, M.D., Ph.D., Professor of Urology at Johns Hopkins University School of Medicine, to develop an improved, blood-based prostate cancer test. During 1999, our scientists, using a research mass spectrometer, discovered some characteristics of a distinct set of proteins ("NMP48") in the blood of prostate cancer patients that were generally not present in the blood of individuals without known prostate malignancy.

We have collected over 600 blood specimens according to an IRB-approved protocol for use in generating reproducible and controlled clinical data prior to launching a Proprietary Laboratory Procedure. We believe that these specimens will be suitable for use as part of our submission to the FDA for regulatory approval.

Beginning in 2004, we chose to focus virtually all our research and development resources on our NMP66 program and deferred further development of our NMP48 technology. We do not yet have any distribution arrangements for potential Lab Test Kits or Point-Of-Care Tests using our NMP48 technology. If a test for prostate cancer is developed, we intend to utilize our own urology sales force in the United States and Germany to sell such products and would consider using some of our NMP22 distributors in other parts of the world to sell the finished product.

Colon Cancer Program (NMP35)

During 1999, our scientists, using research mass spectrometry, discovered some characteristics of a distinct set of proteins ("NMP35") in the blood of patients with colon cancer, that were generally not present in the blood of individuals without cancer or in the blood of patients with certain benign conditions of the lower digestive tract. This program is currently inactive due to our focus on the NMP 66 breast cancer program. We intend to use our research and development resources to develop blood-based colon cancer tests based on the NMP35 marker after developing Proprietary Laboratory Procedures or products for NMP48 proteins (prostate cancer) and NMP66 proteins (breast cancer).

Blood specimens for use in generating reproducible and controlled clinical data prior to launching a Proprietary Laboratory Procedure have been collected pursuant to an IRB-approved protocol. We believe that these specimens will be suitable for use as part of our submission to the FDA for regulatory approval.

Technology — Nuclear Matrix Protein Markers

The nuclear matrix, a three-dimensional protein framework within the nucleus of cells, helps organize active genes in the nucleus. In this way, the nuclear matrix plays a fundamental role in determining cell type and cell function. Although the specific mechanisms of action are not yet fully understood, our scientists and independent scientists have demonstrated that there are differences in the types and amounts of nuclear matrix proteins found in cancerous and normal tissues and also among different types of normal cells. These differences create opportunities to develop tests which may be correlated with cancer for a certain organ or type of tissue, thus providing greater information to physicians and patients. Independent academic investigators have reported, in papers published in scientific journals, the cell type specificity of nuclear matrix proteins specific to bone, kidney, prostate, breast and colon cancer tissues. We have also demonstrated that cell death, including cell death related to early tumor development, results in the release of nuclear matrix proteins into bodily fluids. As a result, elevated levels of certain nuclear matrix proteins have been found in the bodily

fluids of cancer patients. We are not aware of any other cancer protein, or class of proteins, which exhibit this level of clinical specificity and sensitivity.

We licensed our original nuclear matrix protein technology exclusively from the Massachusetts Institute of Technology ("MIT") and these licensed patents begin expiring in 2006. We do not believe the expiration of those licensed patents will have any significant impact on our current product line or programs under development. In the last 9 years, we have made additional discoveries related to nuclear matrix proteins and other useful proteins and have obtained 18 additional U.S. patents which expire on various dates ranging from 2011 to 2020. U.S. patents relating to our NMP22 product line have scheduled expiration dates through 2015.

Mass spectrometry has been an important tool for discovering potentially useful proteins. Mass spectrometry (both research mass spectrometry and high-throughput mass spectrometry) activates proteins (both nuclear matrix proteins and others) from a specially prepared serum or urine sample and detects the molecular weight of those proteins present by measuring the time it takes for them to reach a detector in the instrument. This technology enables us to characterize useful proteins by their molecular weight and then begin the process of identifying and isolating them and developing antibodies to the most useful of those identified.

Developing products from promising proteins (nuclear matrix proteins as well as others) discovered using our original two-dimensional gel procedure and, more recently, mass spectrometry has invariably involved serious reproducibility problems. In our early history, independent research scientists using the methods disclosed in our patents and two-dimensional gels reported different cancer-related nuclear matrix proteins than our own scientists. In recent years, we, as well as other scientists using the procedures and equipment provided by mass spectrometry manufacturers, have generated different test results than earlier stage research. We are continuing efforts to prepare samples according to a reproducible and controlled protocol because we believe this is a critical technical step required to eliminate substances which may interfere with the detection of targeted proteins and the utility of mass spectrometry data reports. We believe that our experience in reducing variability and making reproducible, controlled tests and test protocols is an important strength. However, as has been the case in the development of all our products, we expect to encounter technical challenges during product development. We will continue to attempt to overcome these challenges in order to achieve the reproducibility needed to provide medically useful products.

Medically useful products derive their value from the medical or clinical utility of the information generated, not from their technology base or their performance in discovery research. Therefore, while we must base our research programs on the data we have generated during discovery research, our physician customers will base their long-term purchase decisions on the clinical information they obtain and whether such information helps them make medical decisions.

One of the most important roles of the FDA is to require manufacturers like us to conduct reproducible and controlled clinical trials to demonstrate that our products generate information which is, among other things, limited in variability from one lab to another and likely to be of value to physicians. While minimally invasive laboratory tests like ours can reduce the need for more invasive or expensive procedures, the information they provide, just like that from the more expensive and invasive tests, is not perfect.

Ideally, the results from any medical test 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 FDA applications as well as other studies and trials may not be directly comparable, as results may be affected by laboratory-to-laboratory variation, differences in specimen handling, the number of subjects studied, variability in the stages of disease present in the subject population and the demographic composition of the subject population, among other factors. Nonetheless, the data described above (not the data reported during our discovery phase) are the only basis upon which physicians can initially appraise the clinical value of a test.

However, it should also be understood that there is no "gold standard" with regard to such information, and the perceived value of this clinical information (even if generated by an FDA-approved study protocol) is

likely to differ from physician to physician and must ultimately be judged useful by the physician himself or herself (not by the FDA) to have long term use in his or her practice.

Technology — Product and Service Formats

Each "product" or "service" format for our technology provides testing technology at a modest cost and that can be used on blood, urine or other specimens obtained with minimal invasion into the body. These tests are generally less expensive and involve less patient discomfort than the more invasive procedures for detecting and managing cancer, such as biopsy, surgery, bone scans and other *in vivo* imaging procedures. As discussed below, each test format uses our technology in a number of different ways to generate useful information.

Product Formats

Point-Of-Care Tests, such as our NMP22 BladderChek Test for bladder cancer, are generally sold for use in a physician's office by personnel who are not required to be licensed to perform laboratory tests. Point-Of-Care Tests are similar to the qualitative urine-based pregnancy test devices and the blood-based glucose test strips sold in pharmacies, but our NMP22 BladderChek Test is sold for use only by physicians or their staff. Such Point-Of-Care tests currently generate the highest revenue per test for us, are sold directly to physicians and enable the physician to earn money each time he performs the test.

Lab Test Kits, such as our NMP22 Test Kit, are generally sold for use in appropriately licensed clinical laboratories or doctors' office laboratories to perform lab testing services. These laboratories perform a service, only upon a treating physician's request, using our products to test patient specimens. After testing, the laboratory provides test results from the Lab Test Kit to the treating physician in a written report. In the U.S., until 2003 when we began to market and sell our NMP22 BladderChek Test, the principal product format for delivering our bladder cancer technology was the NMP22 Test Kit. Our revenue per test for NMP22 Test Kits is less than for our NMP22 BladderChek Tests, but the laboratory using our product reaches treating physicians who are required to or prefer to send their specimens to an outside lab facility, thus creating an additional market for us.

Cellular Analysis Systems, such as the cervical cancer system under development by Sysmex, employ our technologies to identify markers such as the NMP179 protein in cells. We expect the Sysmex system will utilize imaging analysis techniques to detect abnormal cells by examining thousands of cells in a short period of time ("flow cytometry") and will include NMP179 technology to detect abnormal cell proteins indicating the presence of cancerous or precancerous conditions. If aberrations from normal are found, the cells will be further examined visually by a pathologist to make the actual diagnosis of disease. Systems like these rely on reagents as a critical component to enhance instrument performance. If Sysmex is successful in commercializing its system, we will receive a royalty on the NMP179 reagents they sell to users of their systems.

Service Format

Proprietary Laboratory Procedures, which is a format we may use upon the introduction of our breast cancer and prostate cancer technologies, are laboratory analytical procedures are custom designed to the instrumentation and techniques of a specific clinical laboratory to measure clinically useful proteins. Proprietary Laboratory Procedures are likely to be confined to a limited number of licensed clinical laboratories which would be expected to invest in the development and marketing of a lab testing service specific to their equipment, processes and personnel. If we develop this procedure in compliance with appropriate regulations, we may not require FDA approval of the Proprietary Laboratory Procedures prior to launch. We do not expect these Proprietary Laboratory Procedures to be profitable for us, but instead we may use these Proprietary Laboratory Procedures to help us gain early market exposure and to enable physicians and laboratories to gain preliminary clinical experience with our technologies prior to our introducing Lab Test Kits or Point-Of-Care Tests.

Marketing and Sales

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

We believe that in major markets such as the U.S. and Germany, a dedicated sales force is more effective than distributors in addressing the issues involved in making a new diagnostic test part of a physician's standard of care. Our prior experiences with distributors in these markets and others have confirmed the value of our own dedicated sales force. Our European subsidiary, Matritech GmbH, has a direct sales force that is principally devoted to selling our NMP22 products in Germany to urologists and laboratories. In addition, Matritech GmbH's direct sales force began marketing the NMP22 BladderChek Test to gynecologists in 2005. Since mid 2005, our U.S. sales force has been focused on developing greater demand for our NMP22 BladderChek Test among urologists.

Before establishing our own U.S. sales force we signed an exclusive agreement with Cytogen in October 2002 for it to sell our NMP22 BladderChek Test to urologists and oncologists. The Cytogen agreement was amended in November 2003 to permit Cytogen to continue to sell NMP22 BladderChek Tests directly to oncologists, and we reclaimed the rights to sell the product directly to urologists. The agreement with Cytogen expired in December 2004. Since January 2005, our direct sales force has been solely responsible for selling our NMP22 BladderChek Tests to urologists in the U.S.

Our distribution partner, Wampole, distributes our NMP22 Test Kit to hospitals and commercial laboratories within the United States. Matritech GmbH's direct sales force is responsible for sales of our NMP22 Test Kit in Germany and its management oversees the distribution of all NMP22 products to distributors in European countries other than Germany.

In 1994, we entered into an agreement with Konica to distribute the NMP22 Lab Test Kit in Japan. Other than in the U.S. and Germany, we sell the NMP22 Test Kit through various distributors. Several distributors currently market the NMP22 BladderChek Test in Southeast Asia and in the People's Republic of China. In March 2002, we signed a seven-year agreement with MBL of Nagoya, Japan for the exclusive (subject to certain minimum purchase requirements) distribution of our NMP22 BladderChek Test in Japan. In the summer of 2005, MBL received regulatory approval from Koseisho for sale of our NMP22 BladderChek Test product in that country and it has been marketing the product in Japan since that time.

We have retained rights to sell all of our products in the United States except for any flow-cytometry-based products using NMP179 competitive to those being developed by Sysmex.

No customer accounted for more than 10% of our total revenues in fiscal 2003, 2004 or 2005.

Foreign Operations

In 2000, we acquired all of the outstanding shares of capital stock of Gesellschaft fur Allergie, Diagnostika und Laborkonzepte ("ADL"), now called Matritech GmbH, a European distributor of diagnostic testing products, including our NMP22 Test Kit. Matritech GmbH is located in Freiburg, Germany.

During 2003, 2004 and 2005, 15%, 33% and 38%, respectively, of our total product sales were from customers in the United States and 85%, 67% and 62% respectively, were from customers in foreign countries. Product sales generated outside the United States during 2003, 2004, and 2005, were primarily in Europe. See Note 10 of Notes to Consolidated Financial Statements — "Segment and Geographic Information".

At December 31, 2005, approximately 20% of our total assets were located at our German subsidiary, and for fiscal year 2005, approximately 54% of our revenue and 28% of our expenses, including cost of product sales were related to our European operations.

Third-Party Reimbursement

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

In the case of private insurance, the reimbursement of any medical test, whether it is FDA approved or for investigational or research use only, is at the sole discretion of a 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 the cost of a new medical procedure or test is made by an insurance carrier's medical director or review committee. This group will base its reimbursement decision on published clinical data and information provided by treating physicians. Even if a procedure has been approved for reimbursement, the insurance carrier may elect at any time in the future to discontinue reimbursement for the procedure.

Health care reform is an area of continuing national and international attention and a priority of many government officials. Health care policies and regulations may impose limitations on the prices we are able to charge now and in the future in the United States and elsewhere for our products or the amount of reimbursement available for tests based on our products from government agencies or third-party payors.

Currently we believe that U.S. laboratories performing NMP22 tests using our NMP22 Test Kit and physicians performing such tests using our NMP22 BladderChek Test are being reimbursed by most insurance carriers, including the carriers managing Medicare reimbursement programs. However, as with all new medical products, reimbursement is not universal, and we are working, on a case-by-case basis, with individual physicians and laboratories to obtain reimbursement where requested. In Germany we believe that most patients receiving a test result from either the NMP22 Test Kit or our NMP22 BladderChek Test are not reimbursed by insurance carriers or federal healthcare reimbursement programs and are paying for the test themselves (or in some instances by private supplemental insurance that German patients carry).

Manufacturing and Facilities

We currently assemble our NMP22 Test Kits in a portion of our 22,500 square-foot facility in Newton, Massachusetts and rely on subcontractors for certain components and processes for these Test Kits. Our NMP22 BladderChek Test is produced by a contract manufacturer experienced in the assembly of Point-Of-Care Tests. Our lease for our Newton facility requires annual base rental payments of $414,360 and expires on December 31, 2010. We have an option to extend the lease for an additional five years at a base rent to be agreed upon with the lessor consistent with market rates in 2010.

We have retained all manufacturing rights for our products and products under development, except for (1) any flow-based products developed by Sysmex based on our NMP179 technology, (2) rights that could be granted to Konica, our NMP22 Test Kit distribution partner in Japan, if we fail to perform under our agreement with Konica and (3) rights that could be exercised by SDS Capital Group SPC, Ltd., as collateral agent, which holds a security interest in and contingent license related to our NMP22 product line as a result of our January 2006 financing transaction.

We currently rely on sole suppliers for certain key components for our NMP22 Test Kit and our NMP22 BladderChek Test. In the event that these suppliers are unable to supply these components or assemblies for any reason, we would seek alternative sources of supply or assembly, which could require reapproval by the FDA for such alternate suppliers. Although we attempt to maintain adequate levels of inventory to provide for these and other contingencies, should our manufacturing processes be disrupted as a result of a shortage of

key components, a revalidation of new components or the failure of an assembler to meet our requirements, we may not be able to meet our commitments to customers. We are also subject to the FDA's Good Manufacturing Practice ("GMP") requirements.

Competition

We are not aware of any other company selling FDA approved diagnostic or therapeutic products based on nuclear matrix protein technology. We have notified one company that its announced intention to develop certain products is likely to infringe certain claims contained in patents owned by or licensed exclusively to us. However, competition in the development and marketing of cancer diagnostics and therapeutics, using a variety of other technologies, is intense. Competing diagnostic products based on other technologies may be introduced by other companies and could adversely affect our competitive position. As a result, our products may become obsolete or non-competitive.

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

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

In the market for urine-based diagnostic tests, our NMP22 Test Kits and our NMP22 BladderChek Tests are also competing with existing cellular-based tests such as the microscopic examination of suspicious cells (cytology) and a test known as UroVysion, which is a fluorescent in-situ hybridization test (FISH). In addition to the fact that these tests are generally done by laboratories, not physicians, we believe that each of these has important drawbacks in the markets for screening and monitoring information — cytology because it is less sensitive and twice the cost of NMP22 tests, FISH because it can be ten times more expensive although its accuracy is comparable to NMP22 tests.

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

A number of companies are attempting to develop automated instruments for Pap smear screening that would compete with the instruments and systems which Sysmex intends to develop using NMP179 technology. These companies are developing computerized image analysis techniques to automate much of the work currently done by cytotechnologists. To date, two 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, and more companies are expected to submit applications for similar systems within two to three years. In addition, one company is developing a vaccine for human papilloma virus ("HPV"), which, if approved and widely adopted in the developed world, may obviate the need for the type of system Sysmex is developing.

The FDA approved a diagnostic product, Hybrid Capture II ("HCII"), for use in detecting HPV, the viral infection believed to be the cause of most cervical cancer. 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.

Patents, Licenses and Trade Secrets

Our diagnostic technology is protected today primarily by patents owned by us and secondarily by claims contained in patents owned by MIT and licensed exclusively to us. We have filed United States patent applications and, in certain circumstances, foreign counterparts in selected other countries on developments relating to our nuclear matrix protein technology and to other cancer marker related technologies. We currently have 18 United States patents and four pending patent applications on file in the United States relating to these additional developments. Certain of our United States patents provide additional protection for our NMP22 Test Kit and for our NMP22 BladderChek Test until 2015. It is our practice to file additional patent applications when we believe our scientists have made commercially significant discoveries whether they relate to nuclear matrix proteins or not. We believe that patents that have issued and may issue from our applications can provide competitive protection for our products after expiration of our license from MIT. We also will continue to rely on our unpatented proprietary information and trade secrets to maintain our commercial position.

The MIT license relates to three United States patents owned by MIT which expire in 2006 and corresponding foreign patents granted in Japan, Canada and selected countries in Europe. MIT has exclusively licensed to us worldwide rights to the nuclear matrix protein technology contained in these patents in exchange for royalties payable until expiration of the underlying patent rights. The protection offered by these patents extends to the detection and measurement of nuclear matrix proteins, or their associated nucleic acids, using antibody or gene probe formats, as well as to certain assay methods exploiting nuclear matrix proteins. We have obtained 18 additional U.S. patents relating to nuclear matrix proteins, our current product line or programs under development with scheduled expiration dates from 2011 to 2020. We do not believe that expiration of MIT licensed patents will have any significant impact on our current product line or programs under development.

Our NMP22 BladderChek Test uses lateral-flow absorbent test strips having antibodies located at different positions along the test strips. The manufacture, use, sale, or import of point-of-care products which include this test strip technology in certain jurisdictions will require us to obtain patent licenses. We are currently selling our NMP22 BladderChek Test and are attempting to obtain appropriate licenses or waivers. In August, 2004, we entered into a license agreement, effective as of April 1, 2004, with one holder of patent rights, Abbott Laboratories, and we are continuing to explore other licensing arrangements covering our NMP22 BladderChek Tests. There is no guarantee that we will be able to obtain the appropriate patent licenses to permit us to make, use, sell, or import such products in the United States or in other countries.

Government Regulation

Diagnostic Products

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

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

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

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

Commercial distribution of a device in the U.S. for which a 510(k) notification is required can begin only after the FDA issues an order finding the device to be "substantially equivalent" to a predicate device. It generally takes from three to twelve months from submission to obtain a 510(k) 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 up to a year 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, may be convened to review and evaluate the application and recommend to the FDA whether to approve or disapprove the device. The FDA is not bound by the recommendations of the advisory committee but generally follows them. Toward the end of the PMA review process, the FDA generally will conduct an inspection of the manufacturer's facilities to ensure that the facilities are in compliance with applicable GMP requirements.

If the FDA's evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions which must be met in order to secure final approval for sale of the device. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter, authorizing commercial marketing of the device for certain indications. If the FDA's evaluations of the PMA application or manufacturing facilities are not favorable, the FDA will delay or deny approval of the PMA application or issue a "not approvable letter." The FDA may also determine that additional clinical trials are necessary, in which case approval may be substantially delayed while additional clinical trials are conducted and submitted.

The PMA process can be expensive, uncertain and lengthy. A number of devices for which FDA approval has been sought by other companies have never been approved for marketing.

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

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

In 1996, the FDA approved our NMP22 Test Kit for bladder cancer for sale in the United States as a predictor of occult or rapidly recurring bladder cancer. In 2000, the FDA approved the expanded claim of our NMP22 Lab Test Kit for the additional use of diagnosing previously undiagnosed individuals who have symptoms of or are at risk for bladder cancer. In 2002, the FDA approved our NMP22 BladderChek Test for sale in the United States as an aid in monitoring the recurrence of bladder cancer. In 2003, the FDA approved the expanded claim of our NMP22 BladderChek Test for the additional use of diagnosing previously undiagnosed individuals who have symptoms of or are at risk for bladder cancer.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences with the use of the device. We, like other device manufacturers, are required to register our establishments and list our 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 with respect to manufacturing and quality assurance activities.

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

Foreign Sales

The FDA must approve in advance the export of unapproved products subject to the PMA requirements 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 which must be met and information must be provided to the FDA, including, with some exceptions, documentation demonstrating that the product is approved for import into a country to which it is to be exported and safety data from animal or human studies. In some cases the FDA may not grant export approval, and some countries to which the devices are to be exported may not approve the devices for import. Failure on our part to obtain export and import approvals, when required, could significantly delay and impair our ability to sell our devices outside the U.S., which could have a material adverse effect on our business.

The introduction of our developmental-stage and FDA-approved cancer diagnostic products in foreign markets will also subject us to foreign regulatory registrations and/or approvals which may impose additional substantial costs and burdens. International sales of medical devices are subject to the regulatory requirements of each country. The regulatory review process varies from country to country. Many countries also impose product standards, packaging requirements, labeling requirements and import restrictions on devices. For example, member countries of the European Union require that products bear the CE mark, which necessitates the creation and maintenance of dossiers documenting quality systems and standards for manufacturing, labeling and testing. Further, for some types of diagnostic tests the European Union also requires audits of the manufacturing site by a Notified Body. In addition, each country has its own tariff regulations, duties and tax requirements. In 1998, Koseisho approved our NMP22 Test Kit for sale in Japan for use in screening previously undiagnosed patients and, in 2005 Koseisho approved our NMP22 BladderChek Test for sale in Japan for use in diagnosis of previously undiagnosed patients. In 1999, the State Drug Administration in the People's Republic of China approved our NMP22 Test Kit for sale in the People's Republic of China for the detection and management of bladder cancer. Approval by the FDA and foreign government authorities is unpredictable and uncertain. Delays in receipt of, or a failure to receive, required approvals, or the loss of any previously received approvals, would likely have a material adverse effect on our business.

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

CLIA

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

Other

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

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

laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those states or localities. Manufacturers are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. Compliance with applicable laws and regulations now or in the future could result in significant additional expense or result in material adverse effects upon our ability to do business.

Employees

As of March 1, 2006, we had 77 full-time employees, 15 of whom were engaged in research and development. Our future success depends in part on our ability to recruit and retain talented and trained scientific, technical, marketing and business personnel and competition for these kinds of personnel is intense. None of our employees is represented by a labor union, and we consider our relations with our employees to be good.

Research and Development

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

During 2003, 2004 and 2005, Matritech spent approximately $2.6 million, $2.7 million and $2.9 million, respectively, on research, development and clinical affairs. Substantially all of these expenditures were related to the development of diagnostic products and conducting clinical trials.

Recent Developments

On January 13, 2006, we entered into a purchase agreement (the "Purchase Agreement") and related documents, pursuant to which we sold 15% Secured Convertible Promissory Notes maturing January 13, 2009 (the "Secured Convertible Notes"), which were initially convertible into 10,766,092 shares of our common stock, par value $.01 per share, and accompanying warrants to purchase up to 6,459,655 shares of our common stock, for an aggregate consideration of $6,997,960 (before cash commission and expenses of approximately $748,000). The Secured Convertible Notes are convertible into shares of our common stock at an initial conversion price of $0.65 per share of common stock. The warrants, which become exercisable on July 14, 2006 and expire on January 13, 2011, have an exercise price of $0.67 per share. Both the conversion price and the exercise price are subject to adjustment in the event of subsequent dilutive issuances.

The Secured Convertible Notes allow for payment of both principal and interest in shares of our common stock, so long as stock payment conditions are satisfied. The effective conversion price for payments to be made in stock is the lower of the then conversion price, currently $0.65, or 85% of the 10 day volume weighted average price of common stock (the "10-day VWAP") on the American Stock Exchange ("AMEX") at the time any payment is due. No payments are due on the Secured Convertible Notes prior to January 2007. Interest is payable quarterly, in arrears, after the initial first year's interest payment is made in January 2007, and principal payments of $291,582 per month (assuming no prepayment or conversion by any Note holder) are due monthly beginning in January 2007. We cannot issue any shares in conversion of Secured Convertible Notes, whether for a conversion initiated by the holders of the Secured Convertible Notes or a repayment of a portion of the Secured Convertible Notes by us, at a price below $0.61 per share until after stockholder approval is received for payments below that price. The Secured Convertible Notes provide anti-dilution protection for the holders, but such protection is limited to a floor of the $0.61 closing sale price of the stock on the day before the closing until after stockholder approval is obtained for any payments in stock at a lower price.

We must meet all of the following stock payment conditions in order to make interest and principal payments on the Secured Convertible Notes in shares of common stock instead of cash: (i) one or more registration statements is effective and available for the resale of the shares required to be registered by the terms of a Registration Rights Agreement entered into in connection with the January 2006 financing; (ii) the shares of our common stock are designated for quotation or listed on the Nasdaq Capital Market, Nasdaq Global Market or AMEX and have not been suspended from trading on any of such exchanges or markets and no written notice of delisting by any of such exchanges or markets have been received and not resolved; (iii) issuance of the shares will not result in a Secured Convertible Note holder and its affiliates owning more than 9.99% of the outstanding shares of our common stock, unless waived by the holder; (iv) the number of shares to be issued to all holders on a specific payment date shall not exceed 10% of the trading volume (as reported by Bloomberg) of our common stock for the period of 20 consecutive trading days ending on the trading day immediately prior to such payment date; (v) our common stock is not selling at a price below $0.50 per share; (vi) the current price per share of the common stock delivered in payment is equal to or greater than $0.61, or we receive stockholder approval to allow issuances below that price; (vii) prior to receipt of that stockholder approval, the 10-day VWAP of our common stock is equal to or greater than the then-effective conversion price, which is $0.65 as of March 1, 2006; and (viii) we have not issued any notice relating to the redemption of any warrant(s) during the 30 day period immediately prior to the payment date. If we are unable to make payments due in stock because we have not received stockholder approval of payments below $0.61 per share, the interest rate on the Secured Convertible Notes will be increased to 17% for the affected payments.

While the Secured Convertible Notes are outstanding, we have restrictions on incurring additional indebtedness (other than receivables financing not to exceed 80% of receivables and equipment purchase or lease financing not to exceed $200,000), as well as restrictions on payment of cash dividends and redemption of securities. Our obligations under the Secured Convertible Notes are secured by first priority liens, effective April 1, 2006, against certain assets related to our NMP22 product line. The security interest covers cell lines, equipment, inventory and general intangibles related to the NMP22 product line, as well as proceeds from the sale of the product line. We also entered into a contingent license agreement with the Collateral Agent, SDS Capital Group SPC, Ltd., granting license rights in the field of bladder cancer detection to some of our patents related to the NMP22 products, sublicense rights to patents licensed to us and used in connection with the NMP22 product line, and license rights to trademarks used exclusively in connection with the NMP22 product line. The contingent license allows the Collateral Agent to rely on and use the licensed patent rights if we default in our payment obligations under the Secured Promissory Notes relating to bankruptcy or similar insolvency proceedings or arrangements. The license rights will terminate upon payment in full of all amounts payable under the Convertible Secured Promissory Notes or earlier upon the expiration date of the underlying licensed patents.

We have granted the holders of Secured Convertible Notes or shares of our common stock issued upon conversion of the Secured Convertible Notes valued at or in excess of $250,000 the right to participate in future financing transactions. These rights are subject to the prior right of holders of at least $495,000 of our Series A Convertible Preferred Stock ("Series A Preferred Stock") to participate in future financings closed on or before December 20, 2006. The holders of the Secured Convertible Notes who qualify for participation rights in our future financing transactions also have the right to exchange up to 50% of the then-held principal value of their Secured Convertible Notes for participation in the transaction, subject to an overall restriction for all holders that limits them to an aggregate of 50% of each future financing transaction.

The Secured Convertible Notes require us to pay interest and liquidated damages and may become immediately due and payable in cash at a premium of 120% of the outstanding principal amount plus accrued interest and damages in the event we default under their terms. Potential defaults would include, among other things:

- our failure to make payments as they become due;
- our failure to remain listed on any of the Nasdaq Capital Market, New York Stock Exchange, AMEX or the Nasdaq Global Market;

- our failure to have an effective registration statement available for resale of the shares upon conversion of the Secured Convertible Notes;
- failure to timely remove restrictive legends from any stock certificates delivered upon conversion;
- our written notice or public announcement of the intention not to issue shares upon conversion;
- our making an assignment for the benefit of creditors, or applying for or consenting to the appointment of a receiver or trustee for a substantial portion of our property or business or that of any subsidiary;
- bankruptcy, insolvency or similar proceedings being filed by or against us or any subsidiary;
- a sale or disposition of substantially all our assets;
- our failure to pay our 2003 Convertible Debentures when due;
- our default on our existing or future liabilities in excess of $250,000; and
- a breach of any material term of any other transaction document we entered into with the purchasers of the Secured Convertible Notes.

In conjunction with the sale of the Secured Convertible Notes, we issued accompanying warrants (the "Purchaser Warrants") exercisable beginning on July 14, 2006 and expiring on January 13, 2011 to purchase up to 6,459,655 shares of our common stock at an exercise price of $0.67 per share. The Purchaser Warrants also provide anti-dilution protection for the holders, but this protection is limited to a floor of $0.61 until after stockholder approval is obtained for issuances below that price. We also issued warrants to two placement agents in connection with the January 2006 financing to purchase up to 1,036,609 shares of our common stock at an exercise price of $0.65 per share (the "Agent Warrants"). These Agent Warrants are exercisable beginning on July 14, 2006 and expiring on January 13, 2011 and have the same anti-dilution provisions as the Purchaser Warrants.

Under the terms of the transaction documents, we were obligated to file a registration statement covering the shares into which the Secured Convertible Notes may be converted and the shares for which the warrants may be exercised which we filed on February 10, 2006. The registration statement was declared effective on February 21, 2006, and we are obligated to keep it available for resale of these shares. We are also obligated to keep our stock listed for trading on AMEX, NYSE or Nasdaq. If we fail to timely register the shares we have committed to register, we may be subject to penalties, including payment of 1.5% of the consideration paid for the Secured Convertible Notes for each thirty day period of delay in registration. Further, we agreed to seek stockholder approval of an increase in authorized shares of our common stock and of the issuance of our common stock in satisfaction of our obligations under the Secured Convertible Notes or the Warrants at a conversion price or exercise price below the $0.61 closing price of our common stock on the last trading day before the closing of the January 2006 financing. We intend to present these matters to our stockholders at our Annual Meeting of Stockholders to be held prior to June 15, 2006.

The sale of the Secured Convertible Notes and the Purchaser Warrants has been deemed to be a dilutive issuance under the terms of our Convertible Debentures and accompanying March 2003 warrants, our Series A Preferred Stock and accompanying March 2005 warrants, and some warrants previously issued to a placement agent. As a result, as of January 13, 2006 the Convertible Debentures became convertible at a price of $0.73 per share, and we reserved an additional 269,822 shares for payment of these Convertible Debentures. The exercise price of our March 2003 warrants was also adjusted to $0.65 per share. As of January 13, 2006, our Series A Preferred Stock became convertible at a price of $0.70 per share, resulting in an increase of the number of shares issuable upon conversion to 1,463,788, and the exercise price of the accompanying March 2005 warrants was adjusted to $1.34 per share. The exercise price of warrants granted in October 2003 and March 2004 to a placement agent to purchase an aggregate of 105,821 shares of our common stock were adjusted from $1.67 and $2.00 per share to $0.65 per share.

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.

Available Information

We are subject to the informational requirements of the Securities Exchange Act, and in accordance with those requirements file reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy the reports, proxy statements and other information that we file with the Commission under the informational requirements of the Securities Exchange Act at the Commission's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call 1-800-SEC-0330 for information about the Commission's Public Reference Room. The Commission also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Commission. The address of the Commission's website is www.sec.gov. Our website is www.matritech.com. We make available through our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Commission. Information contained on our website is not a part of this Annual Report on Form 10-K. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements unless required.

Item 1A. ***Risk Factors.***

The following risk factors should be considered carefully along with the other information contained or incorporated by reference in this Prospectus. The risk and uncertainties described or incorporated by reference herein are not the only ones we face. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also affect our business.

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

We have a history of operating losses, are continuing to lose money and may never be profitable.

We have incurred losses since we began operations in 1987. These losses have resulted principally from costs incurred in research and development and from selling, general and administrative costs associated with our market development and selling efforts. Our accumulated deficit from inception through December 31, 2005 is $98.0 million. Our product sales and net losses for each of the past three fiscal years have been:

	2003	2004	2005
Product Sales	$4,018,000	$ 7,275,000	$10,290,000
Net Losses	$7,878,000	$11,123,000	$ 7,865,000

We expect to continue to incur additional operating losses in the future as we continue to develop new products and seek to commercialize the results of our research and development efforts. Our ability to achieve long-term profitability is dependent upon our success in those development and commercializing efforts. We do not believe we will be profitable until sometime in 2007 at the earliest.

We will need to obtain additional capital in the future and if we are unable to obtain such capital on acceptable terms, or at the appropriate time, we may not be able to continue our operations.

We do not currently generate revenues sufficient to operate our business at breakeven and do not believe we will do so until sometime in 2007 at the earliest. In our fiscal year ended December 31, 2005, we had an operating loss of $7.7 million, a net loss of $7.9 million, and as of December 31, 2005, we only had $1.8 million of cash and cash equivalents. As a result, we must rely on our ability to raise capital from outside

sources in order to continue operations. In March 2003, we sold Convertible Debentures and accompanying warrants. In October and November 2003, we sold common stock and accompanying warrants. In March 2004, we sold common stock and accompanying warrants. In March 2005, we sold Series A Convertible Preferred Stock and accompanying warrants for common stock. In January 2006, we sold Secured Convertible Notes and accompanying warrants resulting in net proceeds of approximately $6.25 million. We will, as we deem necessary or prudent, continue to seek to raise additional capital through various financing alternatives, including equity or debt financings, issuances of securities convertible into equity and corporate partnering arrangements. However, we may not be able to raise needed capital on terms that are acceptable to us, or at all.

The terms of our 2003 sale of Convertible Debentures, our 2005 sale of Series A Convertible Preferred Stock and our 2006 sale of Secured Convertible Notes greatly restrict our ability to raise capital. Under the terms of our Convertible Debenture financing, we are prohibited from entering into obligations that are senior to the debentures. Under the terms of our Series A Convertible Preferred Stock, we are prohibited from issuing senior equity securities or having indebtedness in excess of $7.5 million except in limited forms. Under the terms of our Secured Convertible Notes, we are prohibited from issuing any debt securities or incurring any indebtedness except in limited forms with ceilings on the level of such borrowings. These provisions may severely limit our ability to attract new investors and raise additional financing on acceptable terms. In addition, in order to attract new investors and obtain additional capital, we may be forced to provide rights and preferences to new investors, which are not available to current stockholders and which may be adverse to existing investors.

If we do not receive an adequate amount of additional financing in the future or such financing does not occur on a timely basis, we may be unable to fund future cash operating deficits or to meet our cash payment obligations required by the Secured Convertible Notes. We may also be required to curtail our expenses or to take other steps that could hurt our future performance, including but not limited to, the premature sale of some or all of our assets or product lines on undesirable terms, merger with or acquisition by another company on unsatisfactory terms or the cessation of operations.

We may not be able to meet our payment obligations on our outstanding debt if we are required to make these payments in cash.

As a result of our 2006 sale of Secured Convertible Notes, we substantially increased our indebtedness from approximately $800,000 at the end of 2005 to approximately $7.6 million as of January 31, 2006.

The Secured Convertible Notes permit us to make interest and principal payments in shares of common stock instead of cash, but only if we are in compliance with all of the following: (i) one or more registration statements is effective and available for the resale of the shares required to be registered by the terms of a Registration Rights Agreement entered into in connection with the January 2006 financing; (ii) the shares of common stock are designated for quotation or listed on the Nasdaq Capital Market, Nasdaq Global Market or the American Stock Exchange ("AMEX") and have not been suspended from trading on any of such exchanges or markets and no written notice of delisting by any of such exchanges or markets have been received and not resolved; (iii) issuance of the shares will not result in a Secured Convertible Note holder and its affiliates owning more than 9.99% of the outstanding shares of our common stock, unless waived by the holder; (iv) the number of shares to be issued to all holders on a specific payment date shall not exceed 10% of the trading volume (as reported by Bloomberg) of our common stock for the period of 20 consecutive trading days ending on the trading day immediately prior to such payment date; (v) our common stock is not selling at a price below $0.50 per share; (vi) the current price per share of the common stock delivered in payment is equal to or greater than $0.61, or we receive stockholder approval to allow issuances below that price; (vii) prior to receipt of that stockholder approval, 85% of the 10-day volume weighed average price, or VWAP, of our common stock is equal to or greater than the then-effective conversion price, which was $0.65 as of March 15, 2006; and (viii) we have not issued any notice relating to the redemption of any warrant(s) during the 30 day period immediately prior to the payment date. If we are not able to make interest and principal payments on the Secured Convertible Notes in shares of stock, these payments must be made in cash. Unless we are able to

raise additional capital from another source, we may not have sufficient funds to make these payments. If we make such payments in stock, however, it will result in significant dilution.

In addition, the Secured Convertible Notes require us to pay interest and liquidated damages and may become immediately due and payable in cash at a premium of 120% of the outstanding principal amount plus accrued interest and damages in the event we default under their terms. Potential defaults would include, among other things:

- our failure to make payments as they become due;
- our failure to remain listed on any of the Nasdaq Capital Market, New York Stock Exchange, AMEX or the Nasdaq Global Market;
- our failure to have an effective registration statement available for resale of the shares;
- failure to timely remove restrictive legends from any stock certificates delivered upon conversion;
- our written notice or public announcement of the intention not to issue shares upon conversion;
- our making an assignment for the benefit of creditors, or applying for or consenting to the appointment of a receiver or trustee for a substantial portion of our property or business or that of any subsidiary;
- bankruptcy, insolvency or similar proceedings being filed by or against us or any subsidiary;
- a sale or disposition of substantially all our assets;
- our failure to pay our 2003 Convertible Debentures when due;
- our default on our existing or future liabilities in excess of $250,000; and
- a breach of any material term of any other transaction document we entered into with the purchasers of the Secured Convertible Notes.

If we default under the terms of the Secured Convertible Notes, it is likely that we will not be able to meet our payment obligations. In addition, the level of our indebtedness could, among other things:

- make it difficult for us to make payments on this debt and other obligations;
- make it difficult for us to obtain future financing;
- require redirection of significant amounts of cash flow from operations to service our indebtedness;
- require us to take measures such as the reduction in scale of our operations that might hurt our future performance in order to satisfy our debt obligations; and
- make us more vulnerable to bankruptcy.

We may not be able to repay our outstanding debt in stock or raise additional capital through the sale of equity or convertible securities unless we receive stockholder approval of an increase in our authorized common stock.

In June 2004, our stockholders approved an increase in our authorized common stock from 60,000,000 shares to 90,000,000 shares. Since that time, we have completed two additional private placements which have required us to reserve for issuance to the investors more than 32,000,000 shares of common stock. Since March 2003, we have reserved shares to satisfy our obligations under the Convertible Debentures and have had to increase the number of shares reserved for that purpose on four occasions when dilutive issuances have caused a reduction in the conversion price of the Convertible Debentures. We also have other shares reserved to satisfy our obligations under various outstanding warrants issued to investors and placement agents in our March 2003 Convertible Debenture financing, our October and November 2003 private placements, our March 2004 private placement and our March 2005 private placement, as well as shares reserved for issuance upon conversion of our Series A Convertible Preferred Stock. Further shares are reserved for our outstanding stock options and stock option pools. As a result of these reservations of shares of common stock, we now

have fewer than 700,000 shares of common stock authorized which are free to be issued or reserved. Among other consequences of this situation, we currently have fewer than 700,000 shares available to pay our obligations under the Secured Convertible Notes beyond the repayment of principal at a conversion price of $0.65 per share. We also have fewer than 700,000 shares available to sell in future financings. If we cannot repay our Secured Convertible Notes in stock, we must repay them in cash, but without further stockholder action we have fewer than 700,000 shares available to sell to obtain additional cash for these repayments.

We have granted a security interest in our NMP22 product line to purchasers of our Secured Convertible Notes which restricts our operation of this product line and could result in the loss of all assets related to this product line if we default on our obligations.

In connection with the sale of our Secured Convertible Notes, we granted to SDS Capital Group SPC, Ltd., as Collateral Agent for the purchasers, a security interest in collateral including some cell lines, equipment, inventory and general intangibles related to the NMP22 product line, as well as proceeds from any sale of the product line. The collateral excludes receivables for product sales. We also entered into a Contingent License Agreement with the Collateral Agent granting license rights in the field of bladder cancer detection to some of our patents related to the NMP22 products, sublicense rights to patents licensed to us and used in connection with the NMP22 product line, and license rights to trademarks used exclusively in connection with the NMP22 product line. The security interest covers assets related to both our NMP22 Test Kit and our NMP22 BladderChek Test, the two products that represent approximately 90% of our product sales in the fourth quarter of 2005. The security agreement and license agreement impose restrictions on our sale or abandonment of the collateral and the patent rights. Further, these agreements afford the Collateral Agent the right to assume control of and sell the collateral and to use the license rights exclusively within the field of bladder cancer detection in the event of our default in our obligations under the Secured Convertible Notes. If we default on these obligations, and the collateral is sold, we will lose our primary source of revenue, which would have a material adverse effect on our business and would severely jeopardize our ability to continue operations.

We may fail to meet the standards for continued listing of our shares of common stock on the American Stock Exchange or for listing of such shares on another national exchange.

National stock trading exchanges, including AMEX where our common stock is currently listed, maintain standards and requirements for listing and for continued listing of securities. While we have not received any notice from AMEX of any failure to comply with its listing standards, our market capitalization has diminished along with our share trading price during 2005 and AMEX may in the future examine our financial and equity position and request that we address any perceived areas of concern. If requested to do so, we expect we would be able to develop plans satisfactory to maintain our listing on AMEX or another national exchange. Failure to develop satisfactory plans or to adhere to the requirements of such plans could result in suspension of or delisting of shares from trading on AMEX. Suspension of trading or delisting of our shares, if not remedied, would violate terms of our various financing documents, could result in the declaration of an event of default in our outstanding Convertible Debentures and in our Secured Convertible Notes and could trigger liquidated damage payments to holders of other securities. In addition, any suspension of trading or delisting of our shares could make it more difficult for us to raise needed additional capital on terms acceptable to us or at all. Further, suspension of trading or delisting of our shares could seriously impair the ability of our stockholders to sell shares of our stock.

Direct sales to physicians may result in higher accounts receivable and longer collection cycles which may negatively affect our financial condition.

Since November 2003 we have been responsible for sales of NMP22 BladderChek Tests to urologists in the U.S., including invoicing and collecting the revenue from sales. We have increased our sales and marketing expenditures and added order processing, shipping and collection resources to perform functions which had in the past been performed by our U.S. distributor.

Sales of products directly to physicians may result in larger accounts receivable and longer collection cycles than sales to distributors and may increase the risk that accounts receivable will not be collected. Carrying larger accounts receivable balances and assuming greater collection risk may also increase our financing requirements for future reporting periods. We expect our Days Sales Outstanding to increase beyond 40 days, the level calculated from our December 31, 2005 financial statements.

If we are unable to manufacture or otherwise obtain the product volumes we need, we may be unable to achieve profitability.

We currently manufacture our NMP22 Test Kits and package our NMP22 BladderChek Tests in our Newton facility but we rely on subcontractors for certain components and processes for each of these products. Neither we nor our subcontractors have experience in manufacturing and assembling our NMP22 Test Kits and our BladderChek Tests in large volumes. The volume of BladderChek Tests we have sold has increased substantially from the fourth quarter of 2004, when we sold $1.6 million of such tests, to the fourth quarter of 2005, when we sold $2.3 million of such tests. We expect the sales volume of this product will continue to grow. We and/or our subcontractors for the BladderChek Test may encounter difficulties in scaling up production of products, 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 quantities of product to satisfy customer needs and could result in customer dissatisfaction and decreased sales. In addition, if quality problems arise or if we need to undertake any significant manufacturing change in order to achieve desired product volumes, we may be subject to review and/or other action by governmental authorities which extensively regulate our manufacturing operations.

If we lose the services of our suppliers or assemblers, we may be unable to meet commitments to our customers and our results of operations would suffer.

We do not currently have alternative suppliers for certain key components and processes which are provided by some subcontractors for our NMP22 Test Kits and our NMP22 BladderChek Tests. If the components from these suppliers or the services of these assemblers become unavailable for any reason, including their failure to comply with FDA regulations, or should any of our suppliers or assemblers be unable to provide the quantity of products or services we require, we would need to seek alternative or additional sources of supply or assembly. In order to maintain the FDA acceptance of our manufacturing process, we would have to demonstrate to the FDA that other sources of supply are equivalent to our current sources, which is likely to involve a submission and approval process. Although we attempt to maintain an adequate level of inventory to provide for these and other contingencies, if our manufacturing processes are disrupted because key components are unavailable, because new components must be revalidated or because an assembler fails to meet our requirements, we may be forced to modify our products to enable another subcontractor to meet our sales requirements or we may be required to cease production of such products altogether until we are able to establish an adequate replacement supplier. Disruptive changes of this nature may make us unable to meet our sales commitments to customers. Our failure or delay in meeting our sales commitments would likely cause sales to decrease, could result in significant expense to obtain alternative sources of supply or assembly with the necessary facilities and know-how, and would negatively affect our results of operations.

We may need to stop selling our NMP22 BladderChek Tests if we cannot obtain necessary licenses or waivers to use lateral flow technology, and we may need to stop selling other products if third parties assert infringement claims against us.

Our BladderChek Test uses lateral flow technology consisting of an absorbent material that soaks up urine from a small reservoir at one end of the container housing the test strip and exposes the urine to chemicals and antibodies arranged on the surface of or imbedded in the test strip. After a reaction with our proprietary antibodies, a test result appears in a window located on the container housing the test strip. The manufacture, use, sale, or import of point-of-care products which include lateral flow technology requires us to obtain patent licenses in some jurisdictions. In August 2004, we entered into a license agreement, effective as of April 1, 2004, with one holder of certain patent rights, Abbott Laboratories, and we are continuing to investigate other licensing arrangements covering our BladderChek Tests. If we are unable to obtain patent licenses to permit us to make, use, sell, or import our BladderChek Test products in the United States or in certain other jurisdictions, we will have to stop selling our BladderChek Tests in these jurisdictions until the expiration of the relevant patents or until we are able to develop an alternative non-infringing design solution that uses a different technology, which we may not be able to do on a timely basis. In addition, we may also be subject to litigation that seeks a percentage of the revenues we have received from the sale of our BladderChek Tests. We accrue estimated royalties on sales of the BladderChek Test based on estimates of our obligations under existing licensing agreements and, when probable and estimable, based upon our appraisal of intellectual property claims to which we may be subject. If we are required to obtain additional licenses, the additional royalties due for those licenses may substantially reduce our gross profits and make it difficult or impossible for us to achieve profitability without new products or sources of revenue.

We have not identified or been advised by third parties of any rights owned by others which would require us to secure licenses or waivers in order to manufacture, use, sell or import our NMP22 Test Kit product. We believe that our NMP22 Test Kit does not infringe upon the proprietary rights of third parties. However, it may be difficult or impossible to identify, prior to receipt of notice from a third party, the patent position or other intellectual property rights of the third party, either in the United States or in foreign jurisdictions. If our NMP22 Test Kits are found to infringe other parties' proprietary rights and we are unable to come to terms with such parties, we may be forced to modify the NMP22 Test Kits to make them non-infringing or to cease production of such products altogether.

We will not be able to significantly increase revenue or achieve profitability unless we increase the number of urologists using our BladderChek Test, increase the per-urologist usage of the test and/or successfully penetrate markets other than urologists.

Currently the primary market for our NMP22 BladderChek Test consists of urologists who utilize the BladderChek Test as an adjunct to their cystoscopic examination of patients for detecting initial cases of bladder cancer and monitoring diagnosed cases for recurrence. We have focused our sales and marketing on developing urologist users for either or both of these applications. In order to achieve increased revenue and profitability, we must increase sales to urologists, increase the usage per urologist and/or expand our market for this product to other physicians, such as gynecologists and primary care doctors. While we have had success in developing new urologist customers, we are still in the early stages of convincing a large number of them to use the test more widely than their current practice. In addition, we have had limited experience in implementing our strategy of expanding users to include gynecologists and other physicians in Germany. In the United States, we have not yet implemented a program to sell BladderChek Tests to physicians other than urologists and we may not be successful in penetrating these physician markets. We may not be able to significantly expand the categories of physicians who use the BladderChek Test. Failure to achieve one or more of these objectives may significantly limit our long term revenue potential and may require substantially more investment to achieve profitability.

Our inability to develop and commercialize additional products may adversely affect our ability to achieve profitability.

We believe that our ability to achieve and maintain profitability in the future will be affected by our progress in producing additional revenue-generating products and technologies. We will receive royalties and other payments from Sysmex Corporation if and when it is successful in commercializing a cervical cancer testing system incorporating our NMP179 technology. Other than our NMP22 products, the allergy and other diagnostic products distributed by our European subsidiary and any product or test that may be offered by Sysmex Corporation incorporating our NMP179 technology, none of our technologies is close enough to commercialization to be expected to generate revenue in the foreseeable future, if at all. If we are unable to successfully develop and commercialize other products or technologies, the future prospects for our business, sales and profits will be materially limited. In addition, if we are unable to develop and commercialize additional products to diversify our revenue streams, greater reliance will be placed on the success of our few existing products.

We compete with other methods of diagnosing cancer that are in existence or may be successfully developed by others and our products may not prevail.

Although we are not aware of any other company selling FDA-approved diagnostic or therapeutic products which incorporate nuclear matrix protein technology, 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 cancer diagnostic products. Many of these organizations have greater financial, manufacturing, marketing and human resources than we do.

We expect that our current and future products will compete with existing FDA-approved tests, such as tests known as BTA and UroVysion bladder cancer tests, the latter of which has been approved for both monitoring and diagnosing bladder cancer and the former of which has been approved for monitoring bladder cancer and may become approved for diagnosis of bladder cancer; a test known as CEA, which is used primarily for monitoring colorectal and breast cancers; a test known as CA19.9, which is used primarily for monitoring colorectal and gastric cancers; a test known as PSA, which is used primarily for monitoring and screening prostate cancer; tests known as TRUQUANT® BR RIA, CA15.3 and CA27.29, which are used for monitoring breast cancer; and cervical specimen collection and analysis systems known as Imaging-Directed Cytology™ (Cytyc) and FocalPoint™ slide profiler (TriPath Imaging). We are also aware of a number of companies that have announced that they are engaged in developing cancer diagnostic products based upon oncogene technology such as OncoType Dx. Our diagnostic products will also compete with more invasive or expensive procedures such as minimally invasive surgery, bone scans, magnetic resonance imaging and other in vivo imaging techniques. In addition, other companies may introduce competing diagnostic products based on alternative technologies that may adversely affect our competitive position. As a result, our products may become less competitive, obsolete or non-competitive.

Low reimbursement rates could limit the per-unit revenues for our products and make it uneconomical to sell or distribute them, and limitations on the medical circumstances for which reimbursement is provided could reduce the potential market for our products.

Our ability to sell our products depends in part on sufficient levels of payment from insurers and/or patients to enable us and our customers (both physicians and laboratories) to make an adequate profit. Third-party reimbursement policies, patient attitudes and abilities to pay for some or all of their healthcare, national healthcare cost control measures and physician or hospital preferences may each influence per-unit revenues for our products, usually in different ways in different countries.

In most countries, third party reimbursement is the most important factor in achieving adequate per-unit pricing. Typically a necessary but not sufficient condition for obtaining third party reimbursement is an approval from that nation's healthcare product regulatory authorities (such as the FDA in the United States). Approval by the FDA does not ensure approval by similar authorities in other countries. In addition, approvals

by these authorities typically do not compel reimbursement by medical insurers, do not establish a reimbursement price nor set forth the specific medical circumstances required to be satisfied in order to qualify for reimbursement. These are typically the province of the health care plans, whether private or public. Further, initial approval by a health care plan does not ensure continued reimbursement or stable prices. At a later date some insurers may decide not to continue reimbursement at all, not to continue reimbursement for certain medical applications and/or to decrease the reimbursement amount.

Insurers make reimbursement coverage decisions and set reimbursement rates based on a variety of factors. Low reimbursement, no reimbursement or reimbursement which requires a patient to pay a significant portion of the cost could have a material adverse impact on our potential revenues if patients are not willing to pay for part or all of the charge for our products themselves.

In the United States, where patients generally expect insurers to negotiate reimbursement rates, to establish medical circumstances for reimbursement and to pay for 80% or more of the charges, broad scale reimbursement (including both national healthcare plans such as Medicare and most private insurers) has removed financial barriers for a substantial majority of all potential patients. This has created an opportunity for our physician customers to sell diagnostic services based on our products to most of their patients as an aid in diagnosing or monitoring bladder cancer at prices established by the various insurers. Currently, our products are reimbursed by Medicare and many private insurers. If such insurers were to lower reimbursement rates, it may change the number of patients who are tested with our products. We believe lower reimbursement rates would be likely to substantially reduce our revenues from such products in part because physicians may have decreased interest in using our products. Lower reimbursement rates, however, could enable a far greater number of patients to be tested with the products which would offset the per-unit revenue decline for the physicians.

To date in Germany, where the national reimbursement bodies have not approved our product to be reimbursed, our sales to physicians are the result of patients paying for our products themselves ("self-pay patients"). This lack of reimbursement may have limited the number of potential patients for our product. On the other hand, our product sales may have benefited because there have not been restrictions on the amounts that physicians are able to charge and physicians have not been restricted to order the test only in those medical circumstances contained in a reimbursement policy. However, if the national reimbursement bodies were to designate our products as reimbursable and did so at a low rate or for very limited clinical indications, this could substantially reduce the number of self-pay patients undergoing testing with our products as well as the amounts that self-pay patients would be willing to pay and that we would ultimately receive from physicians on a per-unit basis. Lower prices or limitations on test ordering due to medical conditions might decrease the prices we could charge, lower the volume of tests which may be ordered and, in general, decrease the interest of physicians in using our products. Reimbursement designation, however, could enable a far greater number of patients to be tested with our products which would partially offset such per-unit revenue decline for us and for the physicians who order our products.

Reimbursement decisions can also be affected by national policies designed to keep healthcare costs under control. These policies can limit prices paid for tests or limit the circumstances in which such tests will be reimbursed. For example, Medicare has frozen reimbursement for clinical laboratory tests at 2003 levels and future changes could impose limitations on the prices our physician and laboratory customers can charge for the services based on our products. In addition, in the United States, many private insurers determine the reimbursement for diagnostic testing on an individual basis without regard to the prices and medical circumstances set forth by Medicare. While we cannot predict whether any legislative or regulatory proposals will be adopted or the effect that such proposals could have on our business, the announcement or adoption of such proposals could reduce the profitability of our business.

We expect that reimbursement approval will be obtained in some other countries where our products are sold, but do not believe reimbursement rates in all countries will be as favorable as in the United States. Broad scale reimbursement approval for the BladderChek Test has not yet occurred in the principal countries of Asia (except in Japan) or in the principal countries of Europe (including Germany).

Even with apparently attractive reimbursement levels, the attitudes of physicians, hospitals, laboratories, clinics and other customers may limit our per-product revenue because their profit expectations may influence their use of our products and their attitudes toward the price we charge them. To the extent that we are unable to price our products to achieve physician or laboratory profit expectations, sales of our products may suffer.

We and our distributors are subject to extensive government regulation which adds to the cost and complexity of our business, may result in unexpected delays and difficulties, may impose severe penalties for violations and may prevent the ultimate sale or distribution of our products in certain countries.

The FDA and many foreign governments stringently regulate the medical devices that we manufacture and that we and our distributors market to physicians or other customers. The FDA regulates the clinical testing, manufacture, labeling, distribution and promotion of medical devices in the United States and agencies in the European Union, Japan and other countries where we sell our products each have their own regulations. If our products do not receive appropriate approvals from medical device regulatory authorities in any country, we can not sell our products in that country, either on our own or through any distributor.

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

- keeping records and reporting adverse experiences with the use of the devices we make and distribute;
- registering our establishments and listing our devices with the FDA. Manufacturing establishments are subject to periodic inspections by the FDA and certain state agencies; and
- requiring our products to be manufactured in accordance with complex regulations known as Quality System Regulations which include procedural and documentation requirements for our manufacturing and quality assurance activities.

If we fail to comply with any FDA requirement, we may face a number of costly and/or time consuming enforcement actions, including:

- fines;
- injunctions;
- civil penalties;
- recall or seizure of products;
- total or partial suspension of production;
- delay or refusal of the agency to grant premarket clearance or premarket approval for other devices in our development pipeline;
- withdrawal of marketing approvals; and
- criminal prosecution.

The FDA and foreign governmental agencies have the authority to request the repair, replacement or refund of the cost of any device that we manufacture or distribute if it is faulty. Failure to comply with medical device and quality regulations in countries outside the United States where we sell our products can result in fines, penalties, seizure or return of products and the inability to sell the product in those countries either on our own or through our distributors.

Labeling and promotional activities are subject to scrutiny in the United States by the FDA and, in certain instances, by the Federal Trade Commission, and by regulatory bodies in most countries outside the United States where we sell products. For example, our NMP22 Test Kit has received FDA approval and may be promoted by us only as an aid in the management of patients with bladder cancer or as a diagnostic aid for use for previously undiagnosed individuals who have symptoms of or are at risk for bladder cancer. The FDA actively enforces regulations prohibiting the promotion of devices for unapproved uses and the promotion of

devices for which premarket approval or clearance has not been obtained. Consequently, for example, we cannot promote the NMP22 Test Kit or the BladderChek Test for any unapproved use.

In addition to federal regulations regarding manufacture and promotion of medical devices, we are also subject to a number of state laws and regulations which may hinder our ability to market our products in those states or localities. Manufacturers in general are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with these laws and regulations in the future, which could increase future losses or reduce future profitability.

We may be unable to establish and maintain relationships with key distributors in jurisdictions where we do not have a direct sales force.

We rely primarily on distributors to market NMP22 BladderChek Tests in territories other than the United States and Germany. To date, our distribution arrangements in those other territories have not produced sales levels or sales growth consistent with the progress achieved by our own direct-to-the-doctor sales forces operating in the United States and Germany. We have limited experience in selecting and managing distributors and we do not know whether our existing distributors or others we may engage in the future will achieve substantial sales levels of our products in the near term or at all. Failure to establish successful product distribution could severely limit the growth potential for our products, and our revenue and results of operation could be negatively affected.

We have no demonstrated success in developing cellular analysis systems and any future success in this area will be highly dependent upon Sysmex.

We believe the future success of our business will also depend, in part, upon Sysmex Corporation developing a satisfactory cellular analysis system incorporating our NMP179 technology to measure clinically useful cervical disease proteins. Even if Sysmex completes its product development efforts to its satisfaction, it is expected to face significant obstacles (including but not limited to those set forth in "Risk Factors — Successful technical development of our products does not guarantee successful commercialization") in developing a system which will be approved by the FDA (or similar regulatory authorities in other countries) and selling such systems to cervical cancer testing laboratories at a satisfactory price. Our success in cervical disease cellular analysis systems is almost entirely dependent on the success of Sysmex in utilizing our technology and on its ability to educate physicians, patients, insurers and its distributors about the medical utility of the new products. Even if Sysmex successfully educates the market, competing products may prevent Sysmex from gaining wide market acceptance of its products.

We have no demonstrated success in developing Proprietary Laboratory Procedures as a profitable service business and any future success will be dependent upon satisfaction and approval of our clinical lab partners.

We believe the future success of our business may depend in part upon developing a service business based on Proprietary Laboratory Procedures which would be custom designed to the instrumentation and techniques of each clinical laboratory to measure clinically useful proteins. We believe our current product research work can, when development is completed, be adapted to such a Proprietary Laboratory Procedure but we have no demonstrated success in this area. In addition, because we expect that use of any Proprietary Laboratory Procedure will likely be confined to a limited number of licensed clinical laboratories who would be expected to invest in the development and marketing of a lab testing service specific to their equipment, processes and personnel, the success of these procedures will be dependent upon acceptance by each laboratory. Although we may complete our own product development efforts to our satisfaction, we may not be able to obtain the agreement and approval from a clinical lab partner that the technology is compatible with their laboratory environment or that it has the medical performance and information value that they originally expected. Because Proprietary Laboratory Procedures utilize methods which are, by their nature, more

operator-dependent than those involved in products such as NMP22 Test Kits and BladderChek Tests, the risks regarding successful commercial acceptance are increased.

We may incur substantially greater costs and delays than we currently expect in the development process.

From time to time, we have experienced delays in our research and development efforts and may encounter further obstacles in the course of the development of additional technologies, products and services. We may not be able to overcome these obstacles or may have to expend significant additional funds and time. For example, in 1997 we elected to terminate development of a blood-based test for PC1, a candidate marker for prostate cancer, due to unexpected difficulties. Despite encouraging initial results from an earlier low throughput research testing method, we were unable to develop such a kit for use in testing prostate cancer patients even when we employed 1997 state-of-the-art detection methods. We have subsequently announced that a different set of proteins (NMP48), discovered using a different discovery method, are the primary candidates in our prostate cancer program. More recently, we and others have observed that the testing results of a low throughput research mass spectrometry instrument are not readily reproducible or transferable to high throughput mass spectrometry instruments. This has required us to try a number of changes in our procedures to improve controls, reproducibility and costs in order to measure these proteins. Changes in our technology and procedures may result in products or services that cannot reproduce our original discovery results or that either do not perform at all or do not perform as well as the results reported using our discovery research procedure. Technical obstacles and challenges we face in our research and development process may result in delays in product commercialization, may substantially increase the costs of development and may negatively affect our results of operations.

The research results we obtain in the laboratory frequently cannot be replicated in clinical trials.

Investors should not expect products that we commercialize to perform as well as preliminary discovery research results in the small numbers of samples reported by us. In large-scale clinical trials, such as those required by the FDA, we expect to encounter greater variability and risks including but not limited to:

- obtaining acceptable specimens from patients and healthy individuals;
- testing a much larger population of individuals than we tested in early discovery which will be likely to include more biologic variability;
- preparation methods for the specimens using lower cost, high throughput procedures which might result in performance different from those used in early discovery; and
- inability to develop an economic and reproducible test methods for the substance to be measured.

We believe that testing our final products in a clinical setting will result in product performance which may not be as accurate as the results reported during the discovery phase. Therefore, the best comparative data to be used in evaluating our product development programs are the results of physician trials of commercial products such as those reported since 1996 for our NMP22 products.

Successful technical development of our products does not guarantee successful commercialization.

We may successfully complete technical development for one or all of our product development programs, but still fail to develop a commercially successful product for a number of reasons, including the following:

- failure to obtain the required regulatory approvals for their use;
- prohibitive production costs;
- clinical trial results might differ from discovery phase data; and
- variation of perceived clinical value of products from physician to physician.

Our success in the market for the diagnostic products we develop will also depend greatly on our ability to educate physicians, patients, insurers and our distributors on the medical benefits of our new products. Even if we successfully educate the market, competing products may prevent us from gaining wide market acceptance of our products.

If our intellectual property is not adequately protected, we could lose our ability to compete in the marketplace.

Protection of our intellectual property is necessary for the success of our products and our business. Patent protection can be limited and not all intellectual property is or can be patent protected. We rely on a combination of patent, trade secret and trademark laws, nondisclosure and other contractual provisions and technical measures to protect our proprietary rights in our current and planned products. We have little protection when we must rely on trade secrets and nondisclosure agreements. Our competitors may independently develop technologies and products that are substantially equivalent or superior to our technology and products. If our competitors develop superior or competing technology and are able to produce products similar to or better than ours, our revenues could decrease.

While we have obtained patents where advisable, patent law relating to the scope of certain claims in the biotechnology field is still evolving. In some instances we have taken an aggressive position in seeking patent protection for our inventions and in those cases the degree of future protection for our proprietary rights is uncertain. In addition, the laws of certain countries in which our products are, or may be, licensed or sold do not protect our products and intellectual property rights to the same extent as the laws of the United States.

If we are unable to recruit and retain key management, scientific and sales personnel, our business would be negatively affected.

For our business to be successful, we need to attract and retain highly qualified scientific, sales and management personnel. We presently employ fewer than 80 employees. The loss of key members of our scientific staff or a number of our sales staff, within a short period of time and the failure to recruit the necessary additional or replacement personnel when needed with specific qualifications and on acceptable terms might impede our research and development efforts and/or our direct-to-the-urologist marketing strategy. Our success is also greatly dependent on the efforts and abilities of our management team. The simultaneous loss of multiple members of senior management may delay achievement of our business objectives due to the time that would be needed for their replacements to be recruited and become familiar with our business. We face intense competition for qualified personnel from other companies, research and academic institutions, government entities and other organizations.

The operations of our European subsidiary involve currency exchange rate variability and other risks that could negatively affect our results of operations.

Matritech GmbH, our European subsidiary, accounted for approximately 55% of our product sales in 2005. Accounts of our European subsidiary are maintained in euros and are translated into U.S. dollars. To the extent that foreign currency exchange rates fluctuate in the future, we may be exposed to significant financial variability, both favorable and unfavorable. During 2005, exchange rate fluctuations were unfavorable. Rate changes in the future may also lead to unfavorable results.

In addition, although we have integrated the operations of this subsidiary since its acquisition in June 2000, we still must coordinate geographically separate organizations, manage personnel with disparate business backgrounds and conduct business in a different regulatory and corporate culture. It remains to be seen whether the use of this subsidiary to spearhead the marketing effort of our products in Europe outside of Germany will be successful in the long term.

If we are sued for product-related liabilities, the cost could be prohibitive to us.

The testing, marketing and sale of human healthcare products entail an inherent exposure to product liability claims, and third parties may successfully assert these product liability claims against us. Although we

currently have insurance covering claims against our products, we may not be able to maintain this insurance at acceptable cost in the future, if at all. In addition, our insurance may not be sufficient to cover large claims. Significant product liability claims could result in large and unexpected expenses as well as a costly distraction of management resources and potential negative publicity and reduced demand for our products.

If the products we distribute which are made by other companies become unavailable or do not meet quality standards, we may lose revenues and may face liability claims.

If the products we distribute, but do not manufacture, become unavailable for any reason or fail to meet our quality standards, we would need to seek alternative sources of supply. If we are unable to find alternative sources of an equivalent product we may be required to cease distribution of this type of product, which could cause revenues to decrease or be lost permanently. Furthermore, if products which we distribute, but do not manufacture, should be found defective, we could be sued for product liability or other claims.

During 2003, we received reports from customers that a product we were distributing in Germany for another manufacturer failed to perform correctly and provided results about false patients' conditions. We believe the product performance problems were addressed by the manufacturer of the products, the manufacturer accepted responsibility for defective products and we did not experience any claims by customers. We may face product liability and other claims if the manufacturer fails to satisfactorily address all issues raised by our customers and the patients affected. We terminated the distribution agreement with this manufacturer effective September 30, 2005.

Our activities involve the use of hazardous materials, and we may be held liable for any accidental injury from these hazardous materials.

Our research and development and assembly activities involve the use of hazardous materials, including carcinogenic compounds. Although we believe that our safety procedures for handling and disposing of our hazardous materials comply with the standards prescribed by federal, state and local laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident or exposure, we could be held liable for resulting damages, and significant and unexpected costs, including costs related to damage 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.

Market volatility and fluctuations in our stock price and trading volume may cause sudden decreases in the value of an investment in our common stock.

The market price of our common stock has historically been, and we expect it to continue to be, volatile. This price has ranged between $0.52 and $1.46 in the fifty-two week period ended December 31, 2005. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology sector, which have often been unrelated to the operating performance of particular companies. Factors such as announcements of technological innovations or new products by our competitors or disappointing results by third parties, as well as market conditions in our industry, may significantly influence the market price of our common stock. For example, in the past our stock price has been affected by announcements of clinical trial results and technical breakthroughs at other biotechnology companies. Our stock price has also been affected by our own public announcements regarding such things as quarterly sales and earnings, regulatory agency actions and corporate partnerships. Consequently, events both within and beyond our control may cause shares of our stock to lose their value rapidly.

In addition, sales of a substantial number of shares of our common stock by stockholders could adversely affect the market price of our shares. In the fourth quarter of 2005, our shares had an average daily trading volume of only approximately 147,000 shares. In connection with our January 2006 sale of Secured Convertible Notes and accompanying warrants, we filed a resale registration statement covering more than 18,000,000 shares of common stock for the benefit of the selling security holders. In connection with our March 2005 private placement of Series A Convertible Preferred Stock and accompanying warrants, we filed a resale registration statement covering up to 18,922,907 shares of common stock for the benefit of those

investors. In connection with our March 2004 private placement of common stock and accompanying warrants, we filed a resale registration statement covering up to 7,121,031 shares for the benefit of those investors. In 2003, we filed resale registration statements covering up to 5,371,332 shares for the benefit of those investors in connection with the sale of Convertible Debentures and accompanying warrants and an additional approximately 5,419,000 shares for the benefit of those investors in a private placement of common stock and accompanying warrants. We have also filed numerous resale registration statements in connection with previous sales of our equity securities. The actual or anticipated resale by such investors under these registration statements may depress the market price of our common stock. Bulk sales of shares of our common stock in a short period of time could also cause the market price for our shares to decline.

Future financings will result in additional dilution of the ownership interest of our existing investors and may have an adverse impact on the price of our common stock.

We may need to raise additional capital in the future to continue our operations. The primary source of the additional capital we raised from 2003 through early 2006 has been equity and convertible debt, and we expect that equity-related instruments may continue to be a source of additional capital. Any future equity financings will dilute the ownership interest of our existing investors and may have an adverse impact on the price of our common stock.

In addition, the terms of the Convertible Debentures, our Series A Convertible Preferred Stock and our Secured Convertible Notes provide for anti-dilution adjustments in their conversion prices and in the exercise prices of the accompanying warrants. Since their issuance on March 31, 2003, our Convertible Debentures and accompanying warrants have been repriced four times due to later sales deemed to be dilutive issuances under their terms. As a result, the remaining Convertible Debentures are now convertible at a price per share of $0.73 and the March 2003 Warrants are exercisable at an exercise price of $0.65 per share.

The Series A Convertible Preferred Stock and the accompanying warrants issued in connection with our March 2005 private placement also include anti-dilution protection provisions which were triggered by our January 2006 sale of Secured Convertible Notes. As a result, the conversion price of the Series A Convertible Preferred Stock was reduced from $0.88 per share to $0.70 per share and the exercise price of the March 2005 warrants was reduced from $1.47 per share to $1.34 per share. Both the Series A Convertible Preferred Stock and the March 2005 warrants have reached their contractual floor prices and further dilutive issuances will not result in any further reduction in conversion or exercise price for these securities.

Our Secured Convertible Notes and accompanying warrants also contain anti-dilution protection provisions. Currently, the Secured Convertible Notes are convertible at a common stock price of $0.65 per share and the accompanying warrants are exercisable at an exercise price of $0.67 per share. If we do a future financing at a price of less than $0.65 per common share, the conversion price of our Secured Convertible Notes will be reduced to the new financing price per common share and the exercise price of the January 2006 warrants will be reduced to the new financing price per common share, so long as the new financing price per common share is not lower than $0.61 per common share, the floor on the conversion price applicable to the Secured Convertible Notes and on the exercise price of the January 2006 warrants prior to receipt of stockholder approval. If stockholder approval is received, there will be no floor on the new conversion price of the Secured Convertible Notes and new exercise price of the January 2006 warrants that could result from a future financing transaction.

Item 2. ***Properties.***

Our corporate headquarters in Newton, Massachusetts which houses our research and development and manufacturing facilities comprise approximately 22,500 square feet. Our lease expires on December 31, 2010 and we have the right to renew for an additional five-year period at the then market rate. The annual base rent for each year is $414,360. These facilities are adequate to meet our expected growth for at least the next two years, but would require substantial modification or expansion if we were to start manufacturing our NMP22 BladderChek Test at the facility. Additionally, we lease approximately 6,200 square feet of sales office space in Freiburg, Germany. The German lease is for a term of five years and expires on January 31, 2011, and we

have the right to renew for an additional five-year period. The annual base rent for each year of the term is approximately $90,000. These facilities are adequate to meet our expected growth in Germany for at least the next year.

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

In the normal course of conducting our business we are, from time to time, involved in legal proceedings and other claims arising out of our operations. We do not currently anticipate that any pending litigation or dispute will have a materially adverse affect on our business or our financial condition.

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 2005.

PART II

Item 5. ***Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities .***

Since January 6, 2004, our common stock has been listed on the American Stock Exchange under the symbol "MZT". From January 27, 2003 through January 5, 2004, our common stock was traded on the Nasdaq Capital Market under the symbol: "NMPS." The following table sets forth the range of quarterly high and low sales price information and bid price information for the common stock as reported by the American Stock Exchange and the Nasdaq Capital Market, respectively.

	High	Low
Fiscal 2004		
First Quarter	$2.10	$1.32
Second Quarter	1.58	1.10
Third Quarter	1.32	1.00
Fourth Quarter	1.25	0.87
Fiscal 2005		
First Quarter	$1.46	$0.90
Second Quarter	1.07	0.61
Third Quarter	0.73	0.55
Fourth Quarter	0.95	0.52

As of March 1, 2006, there were approximately 350 shareholders of record. We believe that shares of our common stock held in bank, money management, institution and brokerage house "nominee" names may account for an estimated 9,500 additional beneficial holders.

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

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2005 with respect to our shares of common stock that may be issued under our existing equity compensation plans and arrangements.

Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders(1)	3,115,584	$2.82	1,618,231(3)
Equity compensation plans not approved by security holders(2)	1,735,987	$1.74	—
Total	4,851,571	$2.43	1,618,231

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

(2) Consists of the following:

a. warrants to purchase 546,553 shares of common stock at prices ranging from $1.67 to $2.70 per share. These warrants were issued in 2003 to placement agents in connection with a stock offering and are exercisable until October 2008.

b. warrants to purchase 98,039 shares of common stock at a price of $0.88 per share. These warrants were issued in 2003 to a placement agent in connection with a debt offering and are exercisable until March 2008.

c. warrants to purchase 434,475 shares of common stock at a price of $2.00 per share. These warrants were issued in 2004 to placement agents in connection with a common stock offering and are exercisable until March 2009.

d. warrants to purchase 656,920 shares of common stock at a price of $1.47 per share. These warrants were issued in 2005 to a placement agent in connection with a stock offering and are exercisable until March 2010.

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

Recent Sales of Unregistered Securities

During 2005, we issued the following securities that were not registered under the Securities Act of 1933, as amended (the "Securities Act"):

On March 4, 2005, we completed a private placement of 670,272 shares of Series A Convertible Preferred Stock ("Series A Preferred Stock"), with accompanying investor warrants to purchase 4,991,434 shares of our common stock, for an aggregate consideration of $5,898,394 (before cash commissions and expenses of approximately $610,000). In addition, we issued warrants to a placement agent for a total of 656,920 shares of common stock. All of the warrants had an initial exercise price of $1.47 per share, became exercisable on September 5, 2005 and expire on March 4, 2010. Each share of Series A Preferred Stock was initially convertible into ten shares of our common stock, which equated to a price of $0.88 per share of common stock. This conversion price and the exercise price of the warrants were both adjusted in January 2006 as a result of a dilutive issuance. The adjusted warrant exercise price is $1.34 per share and the adjusted conversion price equates to a $0.70 price per share of common stock. The holders of Series A Preferred Stock are entitled to a liquidation preference and have the benefit of covenants of the Company not to liquidate, merge, sell

control or substantially all assets, issue debt or senior equity securities, or amend the charter in any way adverse to the holders. We are also obligated not to issue other securities that would be senior to the Series A Preferred Stock and not to enter into or consummate a transaction which would result in the holders of all the voting power of our outstanding capital stock having less than a majority of voting power of a surviving entity after a merger, consolidation, share exchange or sale. The terms of the Series A Preferred Stock initially restricted us from incurring indebtedness in excess of $2,000,000 except in limited forms, but that restriction was changed in January 2006 so we are now restricted from incurring indebtedness in excess of $7,500,000, excluding indebtedness outstanding on March 4, 2005, and limited receivables and equipment lease financing. In connection with the issuance of shares of Series A Preferred Stock, we committed to file registration statements covering the shares of our common stock into which the Series A Preferred Stock is convertible and the shares for which the March 2005 warrants may be exercised, to list these shares with the American Stock Exchange and to keep sufficient shares reserved to cover our issuance obligations. Our registration statement covering these shares was declared effective on May 9, 2005 and AMEX approved the listing of these shares in March 2005. If we fail to keep the registration statement covering the shares into which the Series A Preferred Stock can be converted effective, we may be subject to penalties, including payment of 1.5% of the consideration paid for the Series A Preferred Stock for each thirty day period of the registration statement is not effective.

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.

Issuer Purchases of Equity Securities

We did not repurchase any shares of our common stock during the fourth quarter of 2005.

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

The selected financial data presented below for each year in the five-year period ended December 31, 2005 have been derived from our audited consolidated financial statements. These data should be read in conjunction with our financial statements, related notes, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information included elsewhere in this Annual Report on Form 10-K.

	2001	2002	2003	2004	2005
Statements of Operations Data:					
Revenue:					
Product sales and collaboration fees	$ 2,340,940	$ 3,280,131	$ 4,375,211	$ 7,483,095	$10,415,470
Expenses:					
Cost of product sales	1,705,908	2,149,115	2,008,954	2,579,581	3,085,465
Research, development and clinical	3,362,024	3,805,435	2,647,716	2,726,030	2,862,744
Selling, general and administrative	6,151,330	5,657,908	6,574,088	10,545,268	12,196,962
Total operating expenses	11,219,262	11,612,458	11,230,758	15,850,879	18,145,171
Gain on sale of fixed assets	—	—	—	—	60,091
Loss from operations	(8,878,322)	(8,332,327)	(6,855,547)	(8,367,784)	(7,669,610)
Interest income	169,665	75,164	76,629	97,741	120,051
Interest expense	(22,170)	(21,111)	(1,099,372)	(2,853,112)	(2,215,102)
Mark to market adjustment from warrants	—	—	—	—	1,899,698
Net loss	$ (8,730,827)	$ (8,278,274)	$ (7,878,290)	$(11,123,155)	$ (7,864,963)
Beneficial conversion feature related to series A convertible preferred stock	—	—	—	—	(1,627,232)
Net loss attributable to common shareholders	$ (8,730,827)	$ (8,278,274)	$ (7,878,290)	$(11,123,155)	$ (9,492,195)
Basic/diluted net loss per common share	$ (0.33)	$ (0.27)	$ (0.24)	$ (0.27)	$ (0.21)
Weighted average number of common shares outstanding	26,319,329	30,490,071	32,956,888	40,686,755	45,002,662

	2001	2002	2003	2004	2005
Balance Sheet Data:					
Cash and cash equivalents(1)	$ 4,819,733	$ 4,172,013	$ 7,518,124	$ 4,906,178	$ 1,789,792
Working capital	4,337,372	3,663,781	5,434,456	3,179,745	1,643,438
Total assets	6,612,260	6,818,173	10,418,320	8,245,996	5,627,984
Long-term debt(2)	102,300	316,433	1,338,062	377,770	9,979
Series A convertible preferred stock	—	—	—	—	729,495
Accumulated deficit	(62,842,313)	(71,120,587)	(78,998,877)	(90,122,032)	(97,986,995)
Total stockholders' equity	$ 5,221,862	$ 3,838,985	$ 4,798,230	$ 3,394,912	$ 1,353,744

(1) On January 13, 2006 we completed a financing with gross proceeds of approximately $7,000,000.

(2) At December 31, 2005, 2004 and 2003 the face value of our current and long-term debt was $792,781, $3,103,991 and $5,326,848 and the carrying value was $658,521, $1,782,191 and $3,193,776, respectively.

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

The following discussion and analysis should be read together with our consolidated Financial Statements and related notes and other financial information appearing elsewhere in this Annual Report on Form 10-K. This Annual Report, other reports and communications to security holders, as well as oral statements made by our officers or agents contain trend analyses and other forward-looking statements which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Any statements in this Annual Report on Form 10-K that are not statements of historical fact are forward-looking statements. These forward-looking statements are based on a number of assumptions and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, or developments in our business or industry, to differ materially from those indicated or anticipated in any forward-looking statement. Factors that may cause such differences or otherwise affect our business, results of operations and financial condition include, but are not limited to, those discussed in Item 1A and elsewhere in this Annual Report and in our other reports filed with the Securities and Exchange Commission ("SEC"). Forward-looking statements are not guarantees of future results, but rather are based on management's current plans, estimates, opinions and projections. We assume no obligation to update forward-looking statements if assumptions or these plans, estimates, opinions or projections should change.

Overview

Our most important source of revenue and revenue growth in the near term is our NMP22 BladderChek Test, a Point-Of-Care test product developed by our scientists based upon our proprietary NMP technology. We have our own sales forces, based in the U.S. and Germany, which sell our NMP22 BladderChek Test directly to physicians. The primary market for this product through 2005 has been urologists, but we are in the early stages of a planned expansion of our user base to include gynecologists and other physicians. We also utilize distributors to sell our NMP22 BladderChek Test in countries other than the U.S. and Germany.

We also sell our NMP22 Test Kit, which is part of our bladder cancer detection product line, directly and through distributors in the U.S.. In Europe, our German subsidiary, Matritech GmbH, directly sells both our NMP22 Test Kit and allergy and other diagnostic products manufactured by others. Both our NMP22 Test Kit and the allergy and other diagnostic products sold by Matritech GmbH became less important sources of revenue for us during 2005. While we generally expect revenue growth in our NMP22 product line and in our NMP22 BladderChek Test in particular, we expect that quarter-over-quarter sales may not always increase and the rate of increase will likely not remain constant. We recognize that our financial future is closely related to increasing sales of our NMP22 BladderChek Tests, and we have and intend to continually address the challenges of manufacturing an adequate supply of quality product to meet future customers.

The increased market penetration of our NMP22 BladderChek Test has resulted in increased sales, increased revenue per NMP22 BladderChek Test, improved in our gross profit margin and increased selling, general and administrative ("SG&A"). Our SG&A expenses have increased substantially during the past two years as we have greatly expanded our dedicated direct-to-the-doctor sales staff, particularly in the U.S. The increased selling expenditures increased our losses in the short term, but our goal is to generate sufficient additional gross profit from increased sales to cover our increased selling expenses. As an indication of that progress, our SG&A expenses as a percentage of our gross profit have declined from 327% in 2003 to 169% in 2005 despite an increase of over $5.6 million in SG&A expense between 2003 and 2005. We have also committed substantial expenditures to our research and development efforts, primarily directed toward development of a new blood-based breast cancer diagnostic test.

We are continuing our collaboration with Sysmex, based in Kobe, Japan, a leading manufacturer of automated laboratory instruments in the field of cervical cell ("Pap smear") testing. We are also continuing the development of our core diagnostic technology in breast cancer. We measure our progress in these programs by achievements such as entering into new strategic partnerships or alliances, obtaining positive clinical trial results, and ultimately securing regulatory approvals such as the four FDA approvals for our NMP22 products. By successfully leveraging strategic partnerships, we hope to meet our goal of limiting the increase in our own annual research and development expenditures to less than 20% per year over the next few years. Research and development expenditures were 5% higher in 2005 than comparable expenses in 2004.

We have been unprofitable since inception and expect to incur significant additional operating losses during at least the next two years. We do not expect to achieve profitability until we greatly expand the number of physicians using our NMP22 BladderChek Test product, increase their rate of usage of that test or develop other sources of revenues from our collaboration and research and development projects. For the period from inception to December 31, 2005, we incurred a cumulative net loss of approximately $98 million. To provide funds to support our new direct sales force and our ongoing research and development efforts, we raised additional capital in 2004, 2005 and in January 2006. A failure to adequately finance the company would have a material adverse impact on our ability to achieve our objectives. Success in raising capital to fund the cost of our product distribution and development programs is an important element of our short and long-term strategies.

Results of Operations

Year Ended December 31, 2004 Compared with Year Ended December 31, 2005

Revenues

	2004	2005	$ Change	% Change
Product Sales (net of allowances):				
NMP22 BladderChek Test Sales	$4,466,000	$ 7,686,000	$3,220,000	72%
NMP22 Test Kit Sales	903,000	857,000	(46,000)	(5)%
Other Product Sales	1,906,000	1,747,000	(159,000)	(8)%
Total Product Sales	7,275,000	10,290,000	3,015,000	41%
Alliance and Collaboration Revenue	208,000	125,000	(83,000)	(40)%
Total Revenue	$7,483,000	$10,415,000	$2,932,000	39%

The increase in revenue from our NMP22 product line is due to a $3,177,000 sales increase, primarily in the U.S. and Germany, offset by a $3,000 unfavorable exchange rate impact. Our NMP22 BladderChek Test sales accounted for approximately 90% of sales in the NMP22 product line in 2005, compared to 83% in 2004, and 74% of our total revenue in 2005, compared to 60% in 2004. Our NMP22 BladderChek Test sales growth is the result of expanding our direct-to-the-doctor sales staff in the U.S., continuing our direct-to-the-doctor selling activity in Germany and obtaining additional reimbursement coverage by health plan insurance payors throughout the United States. We include in the category of NMP22 Test Kit sales the sale by Diagnostic Products Corporation ("DPC") in Germany of a fully automated laboratory test incorporating our NMP22 technology that DPC manufactured for use on its automated laboratory analyzers. We terminated our Product Supply and Marketing Agreement with Diagnostic Products Corporation effective December 31, 2005.

The decrease in revenue from our non-NMP22 products (other product sales) is mainly due to a decrease in sales of third party allergy and other diagnostic products, principally in Germany. Our distribution agreement with Hitachi Chemical Diagnostics, Inc. was terminated effective September 30, 2005 and in the fall of 2005, Matritech GmbH began selling allergy products manufactured by another company. We expect sales of these allergy products by Matritech GmbH to continue for at least the near term, but we expect our Other Product Sales will be lower than in the past. If we do not continue to sell another allergy product line, our Other Product Sales in future quarters could be as much as 50% less than in previously reported quarters.

Alliance and collaboration revenue decreased by $83,000 principally because the amortization of prepaid marketing fees for a distribution agreement ended in 2004.

When we have sufficient history to estimate product returns for a distributor, we recognize revenue when we ship our NMP22 BladderChek Tests to that distributor. In 2005, we sold approximately $173,000 of our NMP22 BladderChek Tests for which we had sufficient history to estimate returns. In 2005, we sold our NMP22 BladderChek Test to certain distributors for which we did not have sufficient history to estimate returns. Accordingly, those shipments were recorded as deferred revenue and will be recognized as revenue when the distributor reports to us that it has either shipped or disposed of the devices (indicating that the possibility of return is remote), or when we are able to reasonably estimate and reserve for returns. At December 31, 2004 and 2005, $285,000 and $212,000 remained in deferred product revenue. See "Critical Accounting Policies" for a description of our allowance of doubtful accounts.

Deferred collaboration fees represent upfront non-refundable payments that are recognized as we complete our performance obligations. See "Critical Accounting Policies" for a description of our allowance of doubtful accounts.

Deferred revenue consists of the following:

	2004	2005	$ Change	% Change
Collaboration fees	$ 738,000	$716,000	$(22,000)	(3)%
Deferred product revenue	285,000	212,000	(73,000)	(26)%
	$1,023,000	$928,000	$(95,000)	(9)%

The decrease in the deferred product revenue balance from 2004 to 2005 is a result of an increase in the number of NMP22 BladderChek Tests our distributors shipped, as well as an increase in the number of distributors for which we have sufficient history to estimate product returns. We recognize revenue when we ship our NMP22 BladderChek Tests to these distributors.

Cost of Product Sales

	2004	2005	$ Change	% Change
Product Sales	$7,275,000	$10,290,000	$3,015,000	41%
Cost of Product Sales	2,580,000	3,085,000	505,000	20%
Gross Profit	$4,695,000	$ 7,205,000	$2,510,000	53%
Gross Profit Margin	65%	70%		
Cost of Product Sales as a % of Product Sales	35%	30%		

The decrease in cost of product sales on a percentage basis and the increase in our gross profit margin is largely the result of increased sales of higher margin NMP22 products worldwide as a percentage of total sales. Cost of product sales includes payroll-related expenses, product materials, rent and related expenses, supplies, depreciation of fixed assets used in production as well as royalties paid to third parties. Gross profit is calculated by deducting the cost of product sales from product sales.

Research & Development and Clinical & Regulatory Expenses

	2004	2005	$ Change	% Change
Research & Development, Clinical & Regulatory Expenses	$2,726,000	$2,863,000	$137,000	5%

Research and development, and clinical and regulatory expenses increased primarily due to a $231,000 increase in payroll-related costs offset by an $86,000 decrease in lab supply costs.

Selling, General and Administrative Expenses

	2004	2005	$ Change	% Change
Gross Profit	$ 4,695,000	$ 7,205,000	$2,510,000	53%
Selling, General and Administrative Expenses	10,545,000	12,197,000	1,652,000	16%
SG&A as % of Gross Profit	225%	169%		

Selling, general and administrative expenses grew primarily due to a $710,000 increase in payroll-related costs resulting from increased headcount for our direct-to-the-doctor sales force and an $833,000 increase in sales-related marketing expenses.

We believe that a decrease in our SG&A expenses as a percentage of our gross profit from 225% in 2004 to 169% in 2005 is a useful measure of our performance. During 2006, we expect gross profits to increase more rapidly than sales as our higher margin NMP22 BladderChek Test continues to represent a larger percentage of our sales and the lower margin non-NMP22 products decrease as a percentage of sales. We also expect the growth in gross profits to exceed the growth in SG&A expenses, and SG&A expenses to continue to decline as a percentage of our gross profit.

Operating Loss

	2004	2005	$ Change	% Change
Operating Loss	$8,368,000	$7,670,000	$(698,000)	(8)%

The operating loss decreased primarily due to higher gross profit offset by increased selling, general and administrative expenses discussed above.

Interest Income

	2004	2005	$ Change	% Change
Interest Income	$98,000	$120,000	$22,000	22%

Interest income increased slightly over 2004 due to higher interest rates.

Interest Expense

	2004	2005	$ Change	% Change
Interest Related to Convertible Debt:				
Interest Paid in Cash	—	—	—	—
Interest Paid (or to be Paid) in Stock	309,000	137,000	(172,000)	(56)%
Non-Cash Charges to Interest Expense	2,536,000	2,077,000	(459,000)	(18)%
Total	$2,845,000	$2,214,000	$(631,000)	(22)%
Interest Related to Other Debt:				
Interest Paid in Cash	$ 8,000	$ 1,000	$ (7,000)	(88)%
Total Interest	$2,853,000	$2,215,000	$(638,000)	(22)%

We completed a $5 million private placement of Convertible Debentures in March of 2003 and, subsequent to issuance, have recorded an additional $4.6 million of non-cash charges related to the Convertible Debentures which will continue to be charged to our income statement through March 2006. As of December 31, 2005, approximately $4.9 million of the $5.0 million non-cash charges and deferred financing costs have been amortized and charged as interest expense and the remaining $.1 million will be amortized using the effective interest rate method during the first quarter of 2006.

The Convertible Debentures allow the interest and principal to be paid in common stock at a discount to valuation, but only if (i) we are not in default under the terms of the Convertible Debentures, (ii) there is an

effective registration statement covering such shares of common stock, (iii) our common stock is listed on one of American Stock Exchange, New York Stock Exchange, Nasdaq Global Market or Nasdaq Capital Market, (iv) we have provided proper notice of our election to make payments in stock and have made payment of all other amounts then due under the Convertible Debentures, (v) the issuance of such shares would not cause the holders to own more than 9.999% of the outstanding shares of our common stock, (vi) no public announcement of a change of control or other reclassification transaction has been made and (vii) we have sufficient authorized but unissued and unreserved shares to satisfy all share issuance obligations under the March 2003 financing. All of the 2005 quarterly interest payments (totaling $152,000) were made in stock, and all of the 2005 monthly principal repayments of $192,000 each (totaling $2,308,000 at December 31, 2005) were made in stock and, unless a default occurs, we expect the make the remaining interest and principal payments in stock.

Non-Cash Charges to Interest Expense in 2005 consisted of:

- $112,000 of amortized deferred financing costs, which contributed to reducing the original $475,000 balance of deferred financing costs to $7,000 at December 31, 2005;
- $335,000 of non-cash charges to record the discount to valuation incurred when making the principal and interest repayments on the Convertible Debentures in stock rather than cash;
- $1,630,000 of amortized debt discount, which contributed to reducing the $4,558,000 of debt discount on our $5,000,000 note to $134,000 at December 31, 2005. This debt discount comprises the following: the fair value allocated to the warrants issued in conjunction with the convertible debt, the charge to account for the beneficial conversion feature recorded at the date the debt was entered into, and additional charges to account for the beneficial conversion feature recorded in the fourth quarter of 2003, the first quarter of 2004 and the first quarter of 2005 as a result of the triggering of the anti-dilution provisions.

The following table summarizes the accounting for the Convertible Debentures and related discounts during 2003, 2004 and 2005 and the resulting balance at December 31, 2005.

	Value of Debentures
Original Value of Debt	$ 5,000,000
Discounts Recorded in 2003	(2,777,000)
2003 Amortization of Discounts	644,000
Carrying Value of Debt at 12/31/2003	$ 2,867,000
Discounts Recorded in 2004	(1,339,000)
2004 Amortization of Discounts	2,150,000
Payment in Stock	(1,923,000)
Carrying Value of Debt at 12/31/2004	$ 1,755,000
Discounts Recorded in 2005	(442,000)
2005 Amortization of Discounts	1,630,000
Payment in Stock	(2,308,000)
Carrying Value of Debt at 12/31/05	$ 635,000

None of the transactions listed in the foregoing table is expected to affect our cash balances unless we are unable to use our common stock to make principal and interest payments. The use of our common stock for these transactions will result in additional dilution.

Mark-to-market adjustment from warrants

	2004	2005	$ Change	% Change
Mark-to-market Adjustment From Warrants	—	$1,900,000	$1,900,000	100%

Mark-to-market adjustment from warrants represents the net decrease in fair value of the 2005 Warrants we issued in connection with our Series A Preferred Stock issuance in March 2005. Transaction costs of $390,000 were allocated to the warrants and expensed upon closing of the transaction, offsetting subsequent mark-to-market warrant adjustments.

Net Loss

	2004	2005	$ Change	% Change
Net Loss	$11,123,000	$7,865,000	$(3,258,000)	(29)%
Net Loss Attributable to Common Shareholders	$11,123,000	$9,492,000	$(1,631,000)	(15)%

The net loss decreased primarily due to increased selling, general and administrative expenses offset by the increase in revenues and mark-to-market adjustment from warrants. The net loss attributable to common shareholders decreased primarily due to the increase in revenues and mark-to-market adjustment from warrants offset by increased selling, general and administrative expenses and the Series A Preferred Stock deemed dividend arising from the beneficial conversion feature charge associated with this preferred stock. The amount of the beneficial conversion feature was immediately accreted as a deemed dividend for the Series A Preferred Stock on the date of issuance since the preferred stock is immediately convertible. The deemed dividends have been reflected as an adjustment to net loss attributable to common shareholders on our Consolidated Statements of Operations.

Year Ended December 31, 2003 Compared with Year Ended December 31, 2004

Revenues

	2003	2004	$ Change	% Change
Product Sales (net of allowances):				
NMP22 BladderChek Test Sales	$1,362,000	$4,466,000	$3,104,000	228%
NMP22 Test Kit Sales	814,000	903,000	89,000	11%
Other Product Sales	1,842,000	1,906,000	64,000	3%
Total Product Sales	4,018,000	7,275,000	3,257,000	81%
Alliance and Collaboration Revenue	357,000	208,000	(149,000)	(42)%
Total Revenue	$4,375,000	$7,483,000	$3,108,000	71%

The increase in our NMP22 product line revenue was due to a $2,956,000 sales increase, primarily in the U.S. and Europe, and a $237,000 favorable exchange rate impact. Our NMP22 BladderChek Test sales accounted for approximately 83% of sales in our NMP22 product line in 2004, compared to 63% in 2003. Our NMP22 BladderChek Test sales growth was the result of increased selling efforts applied to the test, principally through initiating a direct-to-the-doctor selling effort in the United States in the fourth quarter of 2003, continuing our direct-to-the-doctor selling activity in Germany and obtaining additional reimbursement coverage by Medicare and other health plan insurance payors throughout the United States. We include in the category of NMP22 Test Kit sales the sale by Diagnostic Products Corporation ("DPC") of a fully automated laboratory test incorporating our NMP22 technology that DPC manufactures for use on its automated laboratory analyzers. The increase in our NMP22 Test Kit sales was due to continued sales growth in the U.S. offset by a decline in distributor sales in markets other than Germany and the U.S.

Our revenue from sales of non-NMP22 products increased by $64,000 due to a $176,000 favorable exchange rate impact offset by a sales decrease of $112,000. The sales decrease compared to last year is due

to lower customer orders, which we attribute to a drop in the number of office visits caused by a new patient fee structure in Germany.

Alliance and collaboration revenue in 2004 decreased by $149,000 as the 2004 period included alliance revenue related to special projects undertaken on behalf of Sysmex and reimbursed by them. Those projects were essentially completed during 2003.

During 2003 and 2004, we shipped approximately $291,000 and $199,000 of our NMP22 BladderChek Test to distributors for which we did not have sufficient history to estimate returns. We recognized these shipments as revenue when the distributor reported to us that it has either shipped or disposed of the devices (indicating that any potential risk of return has lapsed). In the fourth quarter of 2004, we recorded approximately $60,000 of revenue from a former distributor, Cytogen, because our distribution contract with them expired, indicating that any potential risk of return had lapsed. The rest of our NMP22 BladderChek Test shipments are made directly to physicians and/or their clinics and hospitals. We recognize revenue for these transactions upon shipment when, among other conditions, the risk of loss has passed to the customer.

Deferred collaboration fees represent upfront non-refundable payments that are recognized as we complete our performance obligations. During 2003 and 2004, we collected approximately $159,000 and $118,000 of collaboration fees which were deferred until we complete our obligations.

Deferred revenue consisted of the following:

	2003	2004	$ Change	% Change
Collaboration fees	$ 828,000	$ 738,000	$ (90,000)	(11)%
Deferred product revenue	340,000	285,000	(55,000)	(16)%
	$1,168,000	$1,023,000	$(145,000)	(12)%

Cost of Product Sales

	2003	2004	$ Change	% Change
Product Sales	$4,018,000	$7,275,000	$3,257,000	81%
Cost of Product Sales	2,009,000	2,580,000	571,000	28%
Gross Profit	$2,009,000	$4,695,000	$2,686,000	134%
Gross Profit Margin	50%	65%		
Cost of Product Sales as a % of Product Sales	50%	35%		

The decrease in cost of product sales on a percentage of revenue basis and the increase in our gross profit margin was largely the result of (i) higher price per unit in the United States we receive when selling NMP22 products directly rather than through a distributor, (ii) increased sales of higher margin NMP22 products worldwide as a percentage of total sales and (iii) favorable exchange rates.

Research & Development and Clinical & Regulatory Expenses

	2003	2004	$ Change	% Change
Research & Development, Clinical & Regulatory Expenses	$2,648,000	$2,726,000	$78,000	3%

Research & development and clinical & regulatory expenses increased slightly in 2004 over 2003. The nature of our research and development, clinical and regulatory activities and the related expenses in 2004 did not change significantly over 2003.

Selling, General and Administrative Expenses

	2003	2004	$ Change	% Change
Gross Profit	$2,009,000	$ 4,695,000	$2,686,000	134%
Selling, General and Administrative Expenses	6,574,000	10,545,000	3,971,000	60%
SG&A as % of Gross Profit	327%	225%		

Selling, general and administrative expenses increased primarily due to a $2,194,000 increase in payroll costs resulting from increased headcount, mainly to support our direct sales efforts described above, and a $935,000 increase in sales-related marketing expenses. In addition, we incurred an unfavorable foreign currency exchange rate impact of $250,000 on non-U.S. selling, general and administrative expenses, a $216,000 increase in recruiting costs and an $184,000 increase in costs incurred in our efforts to comply with the Sarbanes-Oxley Act of 2002 and related rule-making. These increases were partially offset by a decrease in outside legal expense of $134,000.

Operating Loss

	2003	2004	$ Change	% Change
Operating Loss	$6,856,000	$8,368,000	$1,512,000	22%

Our operating loss increased primarily due to the increased selling, general and administrative expenses discussed above.

Interest Income

	2003	2004	$ Change	% Change
Interest Income	$77,000	$98,000	$21,000	27%

Interest income increased slightly in 2004 over 2003 due to a higher average cash balance offset by lower interest rates.

Interest Expense

	2003	2004	$ Change	% Change
Interest Related to Convertible Debt:				
Interest Paid in Cash	$ 63,000	$ —	$ (63,000)	(100)%
Interest Paid (or to be Paid) in Stock	224,000	309,000	85,000	38%
Non-Cash Charges to Interest Expense	789,000	2,536,000	1,747,000	221%
Total	$1,076,000	$2,845,000	$1,769,000	164%
Interest Related to Other Debt:				
Interest Paid in Cash	$ 23,000	$ 8,000	$ (15,000)	(65)%
Total Interest	$1,099,000	$2,853,000	$1,754,000	160%

Interest expense increased substantially in 2004 because we completed a $5 million private placement of Convertible Debentures in March 2003 and, subsequent to issuance, have recorded an additional $4.1 million of non-cash charges related to the Convertible Debentures that are being charged to our income statement through March 2006. As of December 31, 2004, approximately $3.2 million of the $4.6 million non-cash charges and deferred financing costs have been amortized and charged as interest expense and the remaining $1.4 million will be amortized using the effective interest rate method over the remaining quarters through March 2006.

The Convertible Debentures allow the interest and principal to be paid in common stock at a discount to valuation, but only if (i) we are not in default under the terms of the Convertible Debentures, (ii) there is an effective registration statement covering such shares of common stock, (iii) our common stock is listed on one

of American Stock Exchange, New York Stock Exchange, Nasdaq Global Market or Nasdaq Capital Market, (iv) we have provided proper notice of our election to make payments in stock and have made payment of all other amounts then due under the Convertible Debentures, (v) the issuance of such shares would not cause the holders to own more than 9.999% of the outstanding shares of our common stock, (vi) no public announcement of a change of control or other reclassification transaction has been made and (vii) we have sufficient authorized but unissued and unreserved shares to satisfy all share issuance obligations under the March 2003 financing. The 2004 quarterly interest payments totaling $309,000 were made in stock and the monthly principal repayments of $192,000 each commencing in March 2004 (totaling $1,920,000 at December 31, 2004) were made in stock. Unless a default occurs, we expect to make the remaining payments scheduled for both interest and principal in stock.

Non-Cash Charges to Interest Expense in 2004 consisted of:

- $211,000 of amortized deferred financing costs, which contributed to reducing the original $475,000 balance of deferred financing costs to $119,000 at December 31, 2004;
- $175,000 of non-cash charges to record the discount to valuation incurred when making the principal and interest repayments in stock rather than cash;
- $2,150,000 of amortized debt discount, which contributed to reducing the aggregate debt discount of $4,116,000 on our $5,000,000 note to $1,322,000 at December 31, 2004. This debt discount is composed of the following: the fair value allocated to the warrants issued in conjunction with the convertible debt, the charge to account for the beneficial conversion feature recorded at the date the debt was entered into, and additional charges to account for the beneficial conversion feature recorded in the fourth quarter of 2003 and the first quarter of 2004 as a result of the triggering of the anti-dilution provisions.

The following table demonstrates the accounting for the Convertible Debentures and related discounts during 2003 and 2004 and the resulting balance at December 31, 2004.

	Value of Debentures
Original Value of Debt	$ 5,000,000
Discounts Recorded in 2003	(2,777,000)
2003 Amortization of Discounts	644,000
Carrying Value of Debt at 12/31/2003	$ 2,867,000
Discounts Recorded in 2004	(1,339,000)
2004 Amortization of Discounts	2,150,000
Payment in Stock	(1,923,000)
Carrying Value of Debt at 12/31/04	$ 1,755,000

None of the types of activities listed in the above table is expected to affect our cash balances unless we are unable to use our common stock to make principal and interest payments. Using our common stock for the above activities will result in additional dilution.

Liquidity and Capital Resources

Our operating activities used cash in 2004 and 2005 primarily to fund our net losses excluding non-cash charges. The non-cash charges comprise depreciation and amortization expenses, amortization of debt discounts and deferred charges related to our convertible debt offset primarily by mark-to-market adjustments related to the warrants issued in our Series A Convertible Preferred Stock ("Series A Preferred Stock") financing in 2005.

	2004	2005
Net Loss	$(11,123,000)	$(7,865,000)
Non-cash Charges	3,112,000	518,000
Changes in Assets and Liabilities	(9,000)	(857,000)
Net Operating Uses	(8,020,000)	(8,204,000)
Net Investment Uses	(230,000)	(167,000)
Net Financing Sources	5,645,000	5,294,000
Foreign exchange effect	(7,000)	(39,000)
Change in cash and cash equivalents	$ (2,612,000)	$(3,116,000)

In 2005, Changes in Assets and Liabilities increased mainly due to an increase in accounts receivable as well as prepaid expenses and other assets and decreases in accrued expenses and deferred revenue. We expect Changes in Assets and Liabilities to be a use of cash in the foreseeable future because we expect accounts receivable and inventory to grow as product sales increase at a faster rate than other working capital accounts.

We expect that the Days Sales Outstanding ("DSO") is likely to be higher in the future than the 40 days reported at December 31, 2005. We expect U.S. direct-to-physician revenues as a percentage of total revenues to increase and, since our DSO on U.S. direct-to-physician sales was 81 days, we expect our average DSO to increase as U.S. sales become a larger percent of our total. Our DSO calculation at December 31, 2004 was 43 days.

Based on our current forecast of cash utilization, our working capital at December 31, 2005 of $1,643,000 plus funds received from our January 2006 private placement are expected to fund operations into the first quarter of 2007, provided we pay interest and principal on our Convertible Debentures and Secured Convertible Notes in stock. We will, as we deem necessary or prudent, continue to seek to raise additional capital through various financing alternatives, including equity or debt financings, issuances of securities convertible into equity and corporate partnering arrangements. However, we may not be able to raise needed capital on terms that are acceptable to us, or at all.

We have substantially increased our indebtedness to approximately $7.6 million as of January 31, 2006. The Secured Convertible Notes that account for almost all of that indebtedness allow for payment of both principal and interest in shares of our common stock, so long as we satisfy certain conditions. The effective conversion price for payments to be made in stock is the lower of the then conversion price, currently $0.65, or 85% of the 10-day VWAP. No payments are due on the Secured Convertible Notes prior to January 13, 2007 when interest on the period between January 13, 2006 and January 13, 2007 will become due and payable. Thereafter, interest is payable quarterly, in arrears, and principal payments of $291,582 per month (assuming no prepayment or conversion by any Note holder) are due monthly beginning in January 2007. We are not permitted to issue any shares upon the conversion of Secured Convertible Notes, whether for a conversion initiated by the holders thereof or a repayment of a portion of the Secured Convertible Notes by us, at a price below $0.61 per share until after we receive stockholder approval allowing payments below that price.

We must meet all of the following conditions in order to make interest and principal payments on the Secured Convertible Notes in shares of our common stock instead of cash: (i) one or more registration statements is effective and available for the resale of the shares required to be registered by the terms of a Registration Rights Agreement entered into in connection with the January 2006 financing; (ii) the shares of

common stock are designated for quotation or listed on the Nasdaq Capital Market, Nasdaq Global Market or the American Stock Exchange ("AMEX") and have not been suspended from trading on any of such exchanges or markets and no written notice of delisting by any of such exchanges or markets have been received and not resolved; (iii) issuance of the shares will not result in a Secured Convertible Note holder and its affiliates owning more than 9.99% of the outstanding shares of our common stock, unless waived by the holder; (iv) the number of shares to be issued to all holders on a specific payment date shall not exceed 10% of the trading volume (as reported by Bloomberg) of our common stock for the period of 20 consecutive trading days ending on the trading day immediately prior to the applicable payment date; (v) our common stock is not selling at a price below $0.50 per share; (vi) the current price per share of the common stock delivered in payment is equal to or greater than $0.61, or we receive stockholder approval to allow issuances below that price; (vii) prior to receipt of that stockholder approval, the 10-day VWAP of our common stock is equal to or greater than the then-effective conversion price, which is $0.65 as of March 15, 2006; and (viii) we have not issued any notice relating to the redemption of any warrant(s) during the 30 day period immediately prior to the applicable payment date. If we are not able to make payments of interest and principal payments on the Secured Convertible Notes in shares of stock, these payments must be made in cash. Unless we are able to raise additional capital from another source, we may not have sufficient funds to make these payments.

We will not be able to raise significant additional capital unless we receive stockholder approval of an increase in our authorized common stock. Currently, we have fewer than 700,000 shares of our common stock available to sell in future financings. The balance of our authorized common stock, 90,000,000 shares, is outstanding or reserved for other existing obligations. If we cannot repay our Secured Convertible Notes in shares of our common stock because we fail to meet the stock payment conditions or because we have no shares of common stock available for issuance, we must repay them in cash. However, without further stockholder action to approve an increase in our authorized shares, we are unlikely to be able to raise sufficient additional cash to cover the required repayments of the Secured Convertible Notes.

Our existing securities restrict our future financing options. For example, our Convertible Debentures contain a prohibition against our having any debt having a ranking senior to the Convertible Debentures and our Series A Preferred Stock imposes a limitation on indebtedness not outstanding on March 4, 2005 in excess of $7,500,000, except in limited forms. While our Secured Convertible Notes are outstanding, we also have restrictions on incurring additional indebtedness (other than receivables financing not to exceed 80% of our receivables and equipment purchase or lease financing not to exceed $200,000), as well as restrictions on payment of cash dividends and redemption of securities. Moreover, we have granted to a collateral agent on behalf of the holders of the Secured Convertible Notes a security interest in collateral including some cell lines, equipment, inventory and general intangibles related to our NMP22 product line, as well as proceeds from any sale of the product line. We also granted license rights to the collateral agent in the field of bladder cancer detection to some of our patents related to the NMP22 products, sublicense rights to patents licensed to us and used in connection with the NMP22 product line, and license rights to trademarks used exclusively in connection with the NMP22 product line. The NMP22 product line, portions of which serve as collateral for the Secured Convertible Notes, includes all of our currently commercialized products. The agreements reflecting the collateral and license arrangements contain restrictions on our sale or abandonment of the collateral and the patent rights. Further, these agreements afford the collateral agent the right to assume control of and sell the collateral and to use the license rights exclusively within the field of bladder cancer detection in the event of our default in our obligations under the Secured Convertible Notes. If we default on these obligations, and the collateral is sold, we will lose our primary source of operating income, which would have a material adverse effect on our business and would severely jeopardize our ability to continue operations.

If we do not receive an adequate amount of additional financing in the future or such financing does not occur on a timely basis, we will be required to curtail our expenses by reducing research and/or marketing or by taking other steps that could hurt our future performance, including but not limited to, the premature sale of some or all of our assets or product lines on undesirable terms, merger with or acquisition by another company on unsatisfactory terms or the cessation of operations. If we raise funds on unfavorable terms, we may provide rights and preferences to new investors that are not available to our current stockholders or debt holders. For example, we granted license rights to portions of our patent portfolio to a collateral agent, on

behalf of the holders of Secured Convertible Notes, and we have granted preferences upon liquidation to holders of our Series A Preferred Stock. These types of rights and preferences provide a more secure investment position to the holders of these securities than some of our longer term investors enjoy.

Any future equity financings will dilute the ownership interest of our existing investors and may have an adverse impact on the price of our common stock. As of December 31, 2005, our fully diluted capitalization (assuming conversion to common stock of outstanding convertible or exercisable securities) was as follows:

Security	Common Shares	Conversion or Exercise Price Low	Conversion or Exercise Price High
Common stock outstanding	47,498,000	—	—
Stock reserved for converting debentures	777,000	$.99	$ .99
Stock reserved for warrant exercises	9,991,000	.88	2.70
Stock reserved for outstanding stock options	3,116,000	.55	13.13
Stock reserved for Series A Preferred Stock	5,692,000	.88	.88
Total	67,074,000		

The above table includes shares for converting the Convertible Debentures and the Series A Preferred Stock. We plan to use our common stock to pay interest on the Convertible Debenture and to redeem the Convertible Debenture if it is not converted, and these uses of our common stock will result in further dilution, particularly if our share price declines significantly.

Our January 2006 financing was deemed to be a dilutive issuance under the terms of our Convertible Debentures and our Series A Preferred Stock. Accordingly, the holders of the Convertible Debentures and the Series A Preferred Stock received adjustments in conversion prices and warrant exercise prices as a result of the January 2006 financing and the shares we were required to reserve for obligations under the Convertible Debentures and the Series A Preferred Stock were increased as set forth in the table below.

The following table shows our fully diluted capitalization (assuming conversion to common stock of outstanding convertible or exercisable securities) after the January 2006 financing:

Security	Common Shares	Conversion or Exercise Price Low	Conversion or Exercise Price High
Common stock outstanding	47,498,000	—	—
Stock reserved for converting debentures	1,054,000	$.73	$ .73
Stock reserved for secured convertible notes (January 2006 financing)	10,766,000	.65	.65
Stock reserved for warrant exercises	17,487,000	.65	2.70
Stock reserved for outstanding stock options	3,116,000	.55	13.13
Stock reserved for Series A Preferred Stock	7,156,000	.70	.70
Total	87,077,000		

The above table does not include additional shares which we are required to reserve and keep available under the terms of our Convertible Debenture as well as stock options available for grant. Since our authorized common stock is 90 million shares, if our shareholders do not approve an amendment to our certificate of incorporation authorizing additional shares of common stock, we will have fewer than 700,000 shares available to satisfy any future obligations triggered by a dilutive issuance, to pay principal and interest on our Secured Convertible Notes and the Convertible Debentures or to raise additional capital to finance our operations.

Financings

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

share. We ascribed a premium of approximately $500,000 to the value of this license agreement and we recognize as revenue the amounts attributable to this license agreement over the fourteen-year term of the related patents.

In December 2002, we completed a private placement of 222,077 units, at a purchase price of $5.31 per unit. Each unit consists of three shares of common stock and a warrant to purchase one share of common stock at a price of $2.30 per share. We received net proceeds of approximately $1,155,000. These warrants were exercisable until December 9, 2005 and none was exercised and thus all have expired.

In March 2003, we completed a private placement of $5 million of 7.5% Convertible Debentures ("the Convertible Debentures") and Warrants (the "March 2003 Warrants") to purchase 784,314 shares of common stock (including a warrant for 98,039 shares issued to a placement agent in connection with the transaction) at an initial exercise price of $2.278 per share. The Convertible Debentures are convertible into shares of our common stock and require quarterly payments for interest on December 1, March 1, June 1 and September 1 of each year, as well as monthly redemption payments of principal beginning March 1, 2004. Interest and redemption payments may be made in shares of common stock at a discount to valuation, but only if (i) we are not in default under the terms of the debentures, (ii) there is an effective registration statement covering such shares of our common stock, (iii) our common stock is listed on one of American Stock Exchange, New York Stock Exchange, Nasdaq Global Market or Nasdaq Capital Market, (iv) we have provided proper notice of our election to make payments in stock and have made payment of all other amounts then due under the debentures, (v) the issuance of shares of our common stock would not cause the holders to own more than 9.999% of the outstanding shares of our common stock, (vi) no public announcement of a change of control or other reclassification transaction has been made and (vii) we have sufficient authorized but unissued and unreserved shares to satisfy all share issuance obligations under our March 2003 financing. The Convertible Debentures may become immediately due and payable at a premium of 120% of the outstanding principal amount plus accrued interest and damages in the event we default on certain covenants. In addition, the Convertible Debentures obligate us to pay damages and interest upon certain events. Events of default under the Convertible Debentures include, among other things, failure to remain listed on any of the Nasdaq Global Market, New York Stock Exchange, American Stock Exchange or the Nasdaq Capital Market, sale or disposition of our assets in excess of 33% of our total assets, failure to timely deliver stock certificates upon conversion, and default on our existing or future liabilities in excess of $150,000. In addition, we are prohibited from entering into obligations that are senior to the Convertible Debentures without the consent of the holders of the Convertible Debentures. We received net proceeds of approximately $4.5 million in connection with this financing.

On October 15, 2003 and on November 6, 2003, we completed private placements of 3,593,893 and 299,402 shares respectively of our common stock at a price of $1.67 and warrants to purchase 1,257,861 and 104,790 shares respectively of our common stock at a price of $2.45 per share for an aggregate consideration of $6,501,802 (before cash commissions and expenses of approximately $853,000). In addition, we issued warrants to various placement agents for a total of 546,553 shares at exercise prices ranging from $1.67 to $2.70. These warrants are exercisable until October 15, 2008 and November 6, 2008, respectively. Securities included in the November 6, 2003 private placement were purchased by a distributor of our products in the Far East as part of a strategic investment in Matritech. These sales have been deemed to be a dilutive issuance under the terms of the Convertible Debentures and our March 2003 Warrants. As a result, the Convertible Debentures became convertible into 2,673,797 shares of our common stock at a price of $1.87 per share, representing an increase of 713,012 shares from the conversion terms of the debenture at March 31, 2003, and the March 2003 Warrants became exercisable to purchase shares of our common stock at a price of $1.67 per share. The value of these additional shares will be treated as additional interest expense over the term of the Convertible Debentures.

On March 19, 2004, we completed a private placement of 4,858,887 shares of our common stock at a price of $1.35 and warrants to purchase 1,214,725 shares of our common stock at a price of $2.00 per share for aggregate consideration of $6,559,500 (before cash commissions and expenses of approximately $713,000). In addition we issued warrants to various placement agents for a total of 434,475 shares at an exercise price of $2.00 per share. The warrants issued as part of this private placement are exercisable until March 19, 2009.

This sale has also been deemed to be a dilutive issuance under the terms of the Convertible Debentures and our March 2003 Warrants. As a result, the Convertible Debentures became convertible into 3,183,902 shares of our common stock at a price of $1.51 per share, representing an increase of 612,944 shares from the conversion terms of the debenture at November 6, 2003, and the March 2003 Warrants became exercisable to purchase shares of our common stock at a price of $1.35 per share. We recorded an additional beneficial conversion charge totaling approximately $1,340,000 as a debt discount in the first quarter of 2004 and we are amortizing that amount over the remaining life of the Convertible Debentures.

On March 4, 2005, we entered into a purchase agreement (the "Purchase Agreement") which provided for the sale through a private placement of an aggregate of 1,426,124 shares of our Series A Preferred Stock and the issuance to the investors of warrants to purchase 4,991,434 shares of our common stock at a price of $1.47 per share (the "March 2005 Warrants"). The Purchase Agreement provided for two closings (the "First Closing" and the "Second Closing") because we could not issue all shares of the Series A Preferred Stock that we agreed to sell without obtaining stockholder approval because the resulting conversion shares would exceed 20% of our outstanding common stock. On March 4, 2005, we completed the First Closing which consisted of 670,272 shares of Series A Preferred Stock and all of the March 2005 Warrants for aggregate consideration of $5,898,394 (before cash commissions and expenses of approximately $610,000). In addition, we issued warrants to a placement agent for a total of 656,920 shares of common stock. Both the March 2005 Warrants and the placement agent warrants (collectively the "Warrants") have an exercise price of $1.47 per share, became exercisable on September 5, 2005 and expire on March 4, 2010. On June 20, 2005, we entered into a Mutual Termination and Release Agreement with the investors who were parties to the Purchase Agreement to terminate the obligations of all parties to consummate and complete the Second Closing. Accordingly, no additional shares of Series A Preferred Stock or warrants to purchase shares of our common stock were or will be issued in this private placement.

The holders of Series A Preferred Stock are entitled to a liquidation preference and have the benefit of covenants by us not to liquidate, merge, sell control or substantially all our assets, or amend the charter in any way adverse to the holders. We are obligated not to issue other capital stock that would be senior to or on a parity with the Series A Preferred Stock as to dividends or upon liquidation, not to have indebtedness in excess of $7,500,000 except in limited forms, and not to enter into or consummate a transaction which would result in the holders of all the voting power of our outstanding capital stock having less than a majority of voting power of a surviving entity after a merger, consolidation, share exchange or sale. Some of the holders of the Series A Preferred Stock may have the right to participate in subsequent financings completed on or before December 20, 2006. We are further required to reserve sufficient shares of common stock for issuance of all shares issuable upon conversion of the Series A Preferred Stock (the "Conversion Shares") and the exercise of the warrants and to use commercially reasonable efforts to continue the listing and trading of such common shares with the American Stock Exchange or another national stock exchange or stock market. The holders of Series A Preferred Stock are entitled to 6.56 votes for each share of Series A Preferred Stock held by them. The holders of Series A Preferred Stock shall vote together with the holders of common stock, except when our Certificate of Designations or Delaware law provide for a separate class vote.

Each share of Series A Preferred Stock was initially convertible into ten shares of our common stock. Both the Series A Preferred Stock and the March 2005 Warrants have anti-dilution protection provisions. This means that if we issue any shares (subject to limited exceptions) at a price that is less than the initial conversion price of the Series A Preferred Stock ($0.88 per common stock share) in the case of the Preferred Stock or less than the initial exercise price ($1.47 per common stock shares) in the case of the March 2005 Warrants (a "Dilutive Issuance"), the conversion price of the Series A Preferred Stock or the exercise price of the March 2005 Warrants, as applicable, will be adjusted downwards. There is a floor on the new conversion price and the new exercise price that could result from a Dilutive Issuance, in the case of the Preferred Stock the conversion price floor is $0.70 and in the case of the Warrants, the floor on the exercise price floor is $1.34. Our January 2006 financing was deemed to be a Dilutive Issuance resulting in an adjustment of the conversion price of the Series A Preferred Stock to $0.70 per share and an adjustment in the exercise price of the March 2005 Warrants to $1.34 per share. At the time of this Dilutive Issuance, there were 569,251 shares of Series A Preferred Stock outstanding and an additional 1,463,788 shares of our common stock were

reserved for conversion at the new conversion price. Because our stockholders did not approve a proposal which would have removed the floor on conversion and exercise prices for the Series A Preferred Stock and March 2005 Warrants, there will be no further adjustment to these conversion or exercise prices.

We allocated the net cash proceeds of $5,288,000 from the First Closing, further reduced by the fair value of the placement agent warrants totaling $562,000, between the Series A Preferred Stock (approximately $844,000) and the March 2005 Warrants (approximately $3,881,000). We allocated the value of the March 2005 Warrants using the Black-Scholes pricing model with the following assumptions: dividend yield of zero percent; expected volatility of 85%; risk free interest rate of approximately 4% and a term of five years.

In connection with the issuance of the Series A Preferred Stock, we recorded a beneficial conversion feature of $1,627,000. A beneficial conversion feature is recorded when the consideration allocated to the convertible security, divided by the number of common shares into which the security converts, is below the fair value of the common stock into which the Series A Preferred Stock can convert on the date of issuance. The amount of the beneficial conversion feature has been immediately accreted as a deemed dividend because the Series A Preferred Stock is immediately convertible. The value of the beneficial conversion feature has been reflected as an adjustment to the net loss attributable to common stockholders on our Consolidated Statement of Operations.

As part of our March 2005 financing, we entered into a Registration Rights Agreement committing to timely file a registration statement covering the resale of the shares into which the Series A Preferred Stock may be converted and the shares for which the March 2005 Warrants may be exercised (the "Warrant Shares"). If we failed to timely file a registration statement, if the registration statement had not been declared effective within certain time limits or if the registration statement does not remain effective, we would be obligated to pay liquidated damages in an amount equal to 1.5% of the consideration paid for the Series A Preferred Stock for each thirty day period during which the failure persists. In accordance with Emerging Issues Task Force ("EITF") Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled in a Company's Own Stock*, ("EITF 00-19"), a transaction which includes a potential for net cash settlement, including liquidated damages, of a derivative instrument, including warrants, requires that such derivative financial instruments be recorded at fair value as a liability and that subsequent changes in fair value be reflected in the statement of operations. We concluded that the Registration Rights Agreement liquidated damages provision applicable to the Warrant Shares met the definition of net cash settlement under EITF 00-19. In accordance with EITF 00-19, we accounted for the fair value of the Warrants of $4,271,000 as a liability incurred on March 4, 2005 the date of the First Closing, and the subsequent changes in the fair value of the Warrants were reflected on our Consolidated Statement of Operations as mark-to-market warrant adjustments. We allocated transaction costs of $390,000 to the warrants and expensed, upon closing of the transaction, offsetting subsequent mark-to-market warrant adjustments.

On April 18, 2005, we amended the Registration Rights Agreement to eliminate any obligation to pay liquidated damages with respect to a failure to maintain the effectiveness of a registration statement covering resale of the Warrant Shares. On May 9, 2005, the registration statement covering resale of the Warrant Shares became effective and the March 2005 Warrants were reclassified as equity because there is no future potential for a net cash settlement with regard to them. The resulting mark-to-market adjustments (approximately $1,900,000) and the reclassification of the March 2005 Warrants as equity are presented in our financial statements.

The sale of the Series A Preferred Stock and the March 2005 Warrants was deemed to be a dilutive issuance under the terms of our Convertible Debentures and our March 2003 Warrants. As a result, as of March 4, 2005, the Convertible Debentures became currently exercisable into 2,525,253 shares of our common stock at a price of $0.99 per share, representing a current increase of 869,623 shares from the conversion terms of the Convertible Debentures at December 31, 2004, and the March 2003 Warrants became exercisable to purchase shares of our common stock at a price of $0.88 per share. We have calculated an additional beneficial conversion charge totaling approximately $442,000, which was recorded as a debt discount in the first quarter of 2005 and we are amortizing that amount over the remaining life of the Convertible Debentures.

During the year ended December 31, 2005, 101,021 shares of Series A Preferred Stock were converted into common stock. At December 31, 2005, 569,251 shares of Series A Preferred Stock remained outstanding.

On January 13, 2006, we entered into a purchase agreement and related documents, pursuant to which we sold 15% Secured Convertible Promissory Notes maturing January 13, 2009 (the "Secured Convertible Notes"), which are currently convertible into 10,766,092 shares of our common stock, par value $.01 per share, and accompanying warrants to purchase up to 6,459,655 shares of our common stock, for an aggregate consideration of $6,997,960 (before cash commission and expenses of approximately $748,000). The Secured Convertible Notes are convertible into shares of our common stock at an initial conversion price of $0.65 per share of common stock. The warrants, which become exercisable on July 14, 2006 and expire on January 13, 2011, have an exercise price of $0.67 per share. Both the conversion price and the exercise price are subject to adjustment in the event of subsequent dilutive issuances.

The Secured Convertible Notes allow for payment of both principal and interest in shares of our common stock, so long as we satisfy certain conditions. The effective conversion price for payments to be made in stock is the lower of the then conversion price, currently $0.65, or 85% of the 10 day volume weighted average price of common stock (the "10-day VWAP") on AMEX at the time any payment is due. No payments are due on the Secured Convertible Notes prior to January 2007, when interest is due for the period from January 13, 2006 to January 13, 2007. Thereafter, interest is payable quarterly, in arrears, and principal payments of $291,582 per month (assuming no prepayment or conversion by any Note holder) are due monthly beginning in January 2007. We cannot issue any shares in conversion of Secured Convertible Notes, whether for a conversion initiated by the holders of the Secured Convertible Notes or a repayment of a portion of the Secured Convertible Notes by us, at a price below $0.61 per share until after stockholder approval is received for payments below that price. The Secured Convertible Notes provide anti-dilution protection for the holders, but this protection is limited to a floor of the $0.61 per share closing sale price of our common stock on January 12, 2006, until after stockholder approval is obtained for any payments in stock at a lower price.

We must meet all of the following conditions in order to make interest and principal payments on the Secured Convertible Notes in shares of common stock instead of cash: (i) one or more registration statements is effective and available for the resale of the shares required to be registered by the terms of a Registration Rights Agreement entered into in connection with the January 2006 financing; (ii) the shares of our common stock are designated for quotation or listed on the Nasdaq Capital Market, Nasdaq Global Market or AMEX and have not been suspended from trading on any of such exchanges or markets and no written notice of delisting by any of such exchanges or markets have been received and not resolved; (iii) issuance of the shares will not result in a Secured Convertible Note holder and its affiliates owning more than 9.99% of the outstanding shares of our common stock, unless waived by the holder; (iv) the number of shares to be issued to all holders on a specific payment date shall not exceed 10% of the trading volume (as reported by Bloomberg) of our common stock for the period of 20 consecutive trading days ending on the trading day immediately prior to such payment date; (v) our common stock is not selling at a price below $0.50 per share; (vi) the current price per share of the common stock delivered in payment is equal to or greater than $0.61, or we receive stockholder approval to allow issuances below that price; (vii) prior to receipt of that stockholder approval, the 10-day VWAP of our common stock is equal to or greater than the then-effective conversion price, which is $0.65 as of March 15, 2006; and (viii) we have not issued any notice relating to the redemption of any warrant(s) during the 30 day period immediately prior to the payment date. If we are unable to make payments due in stock because we have not received stockholder approval of payments below $0.61 per share, the interest rate on the Secured Convertible Notes will be increased to 17% for the affected payments.

While the Secured Convertible Notes are outstanding, we have restrictions on incurring additional indebtedness (other than receivables financing not to exceed 80% of receivables and equipment purchase or lease financing not to exceed $200,000), as well as restrictions on payment of cash dividends and redemption of securities. Our obligations under the Secured Convertible Notes are secured by first priority liens, effective April 1, 2006, against certain assets related to our NMP22 product line. The security interest covers cell lines, equipment, inventory and general intangibles related to the NMP22 product line, as well as proceeds from the sale of the product line. We also entered into a contingent license agreement with the Collateral Agent, SDS Capital Group SPC, Ltd., granting license rights in the field of bladder cancer detection to some of our patents

related to the NMP22 products, sublicense rights to patents licensed to us and used in connection with the NMP22 product line, and license rights to trademarks used exclusively in connection with the NMP22 product line.

We have granted the holders of Secured Convertible Notes or shares of our common stock issued upon conversion of the Secured Convertible Notes valued at or in excess of $250,000 the right to participate in future financing transactions. These rights are subject to the prior right of holders of at least $495,000 of our Series A Convertible Preferred Stock ("Series A Preferred Stock") to participate in future financings closed on or before December 20, 2006. The holders of the Secured Convertible Notes who qualify for participation rights in our future financing transactions also have the right to exchange up to 50% of the then-held principal value of their Secured Convertible Notes for participation in the transaction, subject to an overall restriction for all holders that limits them to an aggregate of 50% of each future financing transaction.

The Secured Convertible Notes require us to pay interest and liquidated damages and may become immediately due and payable in cash at a premium of 120% of the outstanding principal amount plus accrued interest and damages in the event we default under their terms. Potential defaults would include, among other things:

- our failure to make payments as they become due;
- our failure to remain listed on any of the Nasdaq Capital Market, New York Stock Exchange, AMEX or the Nasdaq Global Market;
- our failure to have an effective registration statement available for resale of the shares upon conversion of the Secured Convertible Notes;
- failure to timely remove restrictive legends from any stock certificates delivered upon conversion;
- our written notice or public announcement of the intention not to issue shares upon conversion;
- our making an assignment for the benefit of creditors, or applying for or consenting to the appointment of a receiver or trustee for a substantial portion of our property or business or that of any subsidiary;
- bankruptcy, insolvency or similar proceedings being filed by or against us or any subsidiary;
- a sale or disposition of substantially all our assets;
- our failure to pay our 2003 Convertible Debentures when due;
- our default on our existing or future liabilities in excess of $250,000; and
- a breach of any material term of any other transaction document we entered into with the purchasers of the Secured Convertible Notes.

In conjunction with the sale of the Secured Convertible Notes, we issued accompanying warrants (the "Purchaser Warrants") exercisable beginning on July 14, 2006 and expiring on January 13, 2011 to purchase up to 6,459,655 shares of our common stock at an exercise price of $0.67 per share. The Purchaser Warrants also provide anti-dilution protection for the holders, but this protection is limited to a floor of the $0.61 until after stockholder approval is obtained for issuances below that price. We also issued warrants to two placement agents in connection with the January 2006 financing to purchase up to 1,036,609 shares of our common stock at an exercise price of $0.65 per share (the "Agent Warrants"). These Agent Warrants are exercisable beginning on July 14, 2006 and expiring on January 13, 2011 and have the same anti-dilution provisions as the Purchaser Warrants.

Under the terms of the transaction documents, we were obligated to file a registration statement covering the shares into which the Secured Convertible Notes may be converted and the shares for which the warrants may be exercised , which we filed on February 10, 2006. The registration statement was declared effective on February 21, 2006, and we are obligated to keep it available for resale of these shares. We are also obligated to keep our stock listed for trading on AMEX, NYSE or Nasdaq. If we fail to timely register the shares we have committed to register, we may be subject to penalties, including payment of 1.5% of the consideration

paid for the Secured Convertible Notes for each thirty day period of delay in registration. Further, we agreed to seek stockholder approval of an increase in authorized shares of our common stock and of the issuance of our common stock in satisfaction of our obligations under the Secured Convertible Notes or the Warrants at a conversion price or exercise price below the $0.61 closing price of our common stock on the last trading day before the closing of the January 2006 financing. We intend to present these matters to our stockholders at our Annual Meeting of Stockholders to be held prior to June 15, 2006.

The sale of the Secured Convertible Notes and the Purchaser Warrants has been deemed to be a dilutive issuance under the terms of our Convertible Debentures and accompanying March 2003 Warrants, our Series A Preferred Stock and accompanying March 2005 Warrants, and some warrants previously issued to a placement agent. As a result, as of January 13, 2006 the Convertible Debentures became convertible at a price of $0.73 per share, and we reserved an additional 269,822 shares for payment of these Convertible Debentures. The exercise price of our March 2003 Warrants was also adjusted to $0.65 per share. As of January 13, 2006, our Series A Preferred Stock became convertible at a price of $0.70 per share, resulting in an increase of number of shares issuable upon conversion to 1,463,788, and the exercise price of the accompanying March 2005 Warrants was adjusted to $1.34 per share. The exercise price of warrants granted in October 2003 and March 2004 to a placement agent to purchase an aggregate of 105,821 shares of our common stock were adjusted from $1.67 and $2.00 per share to $0.65 per share.

Contractual Obligations

Our future commitments are described in further detail in the Notes to Consolidated Financial Statements. Our future commitments are as follows:

	Payment Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating Lease Arrangements(1) . . .	$2,714,000	$ 579,000	$1,617,000	$518,000	$—
Capital Lease Arrangements(1)	7,000	2,000	5,000	—	—
Debt Obligations(2)	794,000	788,000	6,000	—	—
Total	$3,515,000	$1,369,000	$1,628,000	$518,000	$—

(1) See Note 4 to the Consolidated Financial Statements.

(2) See Note 6 to the Consolidated Financial Statements.

The above table excludes obligations under our Secured Convertible Notes. We have no material capital expenditure commitments.

Our intention is to pay the interest and principal on our remaining Convertible Debentures in stock and to pay the interest and principal on our Secured Convertible Notes in stock so long as we meet the applicable stock payment conditions.

Off-Balance Sheet Arrangements

We have not created, and are not party to, any special-purpose or off-balance sheet entities for purpose of raising capital, incurring debt or opening parts of our business that are not consolidated (to the extent of our ownership interest therein) into our financial statements. However, since inception, we have raised capital through issuance of Convertible Debentures, issuance of common stock, issuance of preferred stock and recently issuance of convertible debt. All those arrangements include issuance of warrants. Warrants are instruments that qualify as off-balance sheet arrangements. We have provided further details about those arrangements in Item 7 — Management's Discussion and Analysis of Financial Conditions and Results of Operations — Liquidity and capital resources.

Critical Accounting Policies and Estimates

The preparation of our Consolidated 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, we have made our best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality and assuming that we will continue as a going concern. However, since application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties actual results could differ, potentially materially, from these estimates.

We believe that the accounting policies described below are critical to understanding our business, results of operations and financial condition because they involve significant judgments and estimates used in the preparation of our Consolidated Financial Statements. An accounting policy is deemed to be critical if it requires a judgment of accounting estimate to be made based on assumptions about matters that are highly uncertain, and if different estimates that could have been used, or if changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact our Consolidated Financial Statements.

The following critical accounting policies affect our more significant judgments and estimates used in the preparation of our Consolidated Financial Statements:

Revenue Recognition

We recognize revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition* ("SAB 104") and the Emerging Issues Task Force Issue No. 00-21 (EITF 00-21) "Revenue Arrangements with Multiple Deliverables." We recognize revenue when the following criteria have been met:

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

When determining whether risk of loss has transferred to customers on product sales, we evaluate both the contractual terms and conditions of our sales agreements as well as our business practices. With regard to our sales to distributors, business practices such as agreeing to product exchanges may indicate the existence of an implied right to return the product even if there are no such contractual provisions for product returns. We treat such practices, whether contractual or implied, as conveying a right of return and will establish provisions for returns when reasonable and reliable estimates can be made. In accordance with SAB 104, where we do not have sufficient history to make reasonable and reliable estimates of returns, we defer revenue associated with such practices until the return period lapses or until we can make a reasonable estimate. We then recognize this deferred revenue as revenue when the distributor reports to us that it has either utilized the product or the product shelf life has expired (indicating that the possibility of return is remote).

When determining whether collectibility is reasonably assured, we evaluate the facts and circumstances associated with the individual transaction. Factors we consider differ depending on the nature of the customer (end user versus distributor), size of the transaction, whether we have a past history with the customer and the geographic location of the customer. For sales transactions to customers who are not end users, we evaluate our prior collection history with the customer and obtain credit reports from external sources, particularly for customers expected to have credit balances in excess of $10,000. We closely monitor our accounts receivable aging for these customers and establish reserves for significantly aged accounts if we believe the account is uncollectible. Our collection history has been favorable and we have not been required to establish material bad debt provisions for our significant customers.

For sales transactions to our end user customers, we generally do not perform credit checks due to the high volume and small size of the transactions. Alternatively, we establish credit limits and closely monitor the aging of our receivable balances. If a customer account ages beyond 90 days, the customer will be put on credit hold and no further revenue will be recognized related to that customer until the outstanding balances are paid in full. At the time of product shipment, we establish reserves for customer allowances based on our collection history, which reserves we record as a reduction of revenue. We regularly adjust the reserves based on our actual experience. To date, our historical calculations of the size of required reserves have been in line with our expectations.

We generate alliance and collaboration revenue primarily through collaborative license and development agreements with strategic partners for the development and commercialization of our product candidates. The terms of these agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones, payments for product manufacturing and royalties on net product sales. We examine revenue arrangements where multiple products or services are sold together under one contract to determine if each element represents a separate unit of accounting as defined in (EITF) 00-21. EITF 00-21 requires the following criteria to be met for an element to represent a separate unit of accounting:

1. The delivered items have value to a customer on a stand-alone basis;

2. There is objective and reliable evidence of the fair value of the undelivered items; and

3. Delivery or performance is probable and within the control of the vendor for any delivered items that have a right of return.

In the event that an element of a multiple element arrangement does not represent a separate earnings process and a separate unit of accounting, we recognize revenue from that element over the term of the related contract or as the undelivered items are delivered.

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

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

Valuation Allowances

Inventory. We value our inventory account balances at the lower of cost or net realizable value. We analyze inventory levels quarterly, review inventory account balances and compare those amounts with sales forecasts and projections, historical revenue trends and shelf life of items in inventory. This analysis involves our estimates of future cash flows which are highly judgmental and may differ from actual cash flows. We dispose of inventory with a life in excess of its shelf life and we write the related costs off. If actual market conditions are less favorable than those we project, additional inventory writedowns may be required.

Accounts Receivable. We periodically review outstanding balances in accounts receivable to determine future collections. Management determines an allowance for uncollectible accounts based on our historical experience, current business conditions and expected future collections. In the event circumstances change that

affect the assumptions underlying this allowance, we might be required to take additional write-offs of our accounts receivable balances. With the transition in our U.S. operations to a direct sales force, we have been exposed to a greater volume of transactions which we expect to improve our concentration of credit risk but this benefit has been offset by an extended collection cycle.

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

Income Tax. We record deferred tax assets and liabilities based on the net tax effects of tax credits, operating loss carryforwards, and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. We then assess the likelihood that deferred tax assets will be recovered from future taxable income and, to the extent that we determine that recovery is not likely, a valuation allowance is established. The valuation allowance is based on estimates of taxable income by jurisdiction in which we operate and the period over which deferred tax assets will be recoverable. Through December 31, 2005, we believe it is more likely than not that all of our deferred tax assets will not be realized and, accordingly, have recorded a valuation allowance against all deferred tax assets. If results of operations in the future indicate that some or all of the deferred tax assets will be recovered, the reduction of the valuation allowance will be recorded as a tax benefit during one or over many periods.

Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), *Share-Based Payment*, which is a revision of FASB Statement No. 123 ("Statement 123R"), *Accounting for Stock-Based Compensation.* Statement 123R supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows.* Generally, the approach in Statement 123R is similar to the approach described in Statement No. 123. However, Statement 123R requires all share-based payments to employees, including grants of employee stock options, to be expensed based on their fair values. Pro forma disclosure is no longer an alternative. As required by Statement 123R, we will begin to comply with the pronouncement on January 1, 2006.

Statement 123R permits public companies to adopt its requirements using one of two methods: a "modified prospective method" in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123R for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123R that remain unvested on the effective date or a "modified retrospective" method, which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. We intend to apply the modified prospective method of adoption in our application of Statement 123R.

As permitted by Statement 123, we historically accounted for share-based payments to employees using APB Opinion No. 25's intrinsic value method and, as such, generally recognized no compensation cost for employee stock options. Accordingly, the adoption of Statement 123R's fair value method, effective on January 1, 2006, will have a significant impact on our result of operations, although it will have no impact on our overall financial position. We cannot, however, predict the impact of adoption of Statement 123R because it will depend on levels of share-based payments granted in the future. However, had we adopted

Statement 123R in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net loss per share in the Stock-Based Compensation Note to our Consolidated Financial Statements.

Research and Development

We are engaged in the research, production and marketing of cancer diagnostic technologies and we record all of our research and development expenditures, whether conducted by our own staff or by external scientists on our behalf and at our expense, as expenses as incurred. Since our inception in October of 1987, and through December 31, 2005, expenses related to research and development activities amounted to approximately $48.3 million. Research and development expenses include the salaries and related overhead of our research personnel, laboratory supplies, payments to third parties to help us execute clinical trials, depreciation of research related equipment, legal expenses related to filing and prosecuting patents, other direct expenses and an allocation of our occupancy and related expenses based on the square footage occupied by our research and development staff and their laboratories.

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

Discovery Research

Our primary research focus is on the identification of proteins in the body which are associated with or created by cancerous processes and which, when measured, can provide useful medical information to physicians. Previously, our research focused on discovering the characteristics of these substances using low-throughput research mass spectrometry. Because the cost of research mass spectrometry technology was determined to be too high to create commercially viable products or services, in the last three years we have focused our research on applying high-throughput mass spectrometry methods to measure the proteins characterized as clinical candidates during discovery research and to improving the controls and reproducibility of our mass spectrometry technology. In addition, since 2003, we have been working on programs to adapt ligand binding based technology to measure these proteins, particularly NMP66 proteins. Since the development of core test methods applicable to all cancer types has been a major activity of our staff, we have not tried to track spending by product or to allocate our total research costs to individual products.

Product and Service Development

To develop products which will provide physicians medically useful information, we utilize our technology in four different ways: Lab Test Kits, Point-Of-Care Tests, Cellular Analysis Systems and Proprietary Laboratory Procedures. Product development can also involve activities which resemble discovery research because it may be necessary to identify a fraction of the target protein (such as an antibody binding site) or to separate two similar proteins (or two forms of the same protein), or to select an alternative protein in order to complete this stage. Therefore, the risks of discovery may extend into product development in completing a service or a product which delivers useful information to physicians.

We are investigating opportunities to utilize NMP66 technology in a Proprietary Laboratory Procedure. We have entered into an agreement with MKI whereby they or their designees will serve as our Japanese lab partner for further validation of our NMP66 technology. Pursuant to our agreement with MKI, we may negotiate the terms for distribution rights for the Japanese market for products and services incorporating the NMP66 technology. Our scientists believe they understand the general biological structure of the NMP66 protein complex identified by research mass spectrometry. We are working on an immunoassay and a RT-PCR test and we may develop a Lab Test Kit and/or a Point-Of-Care Test using our NMP66 technology. We have

elected to concentrate our development resources on our NMP66 technology to increase the likelihood of the completion of this project for MKI, as well as for a potential U.S. lab partner. To accomplish this, we have diverted product development resources from our other programs. We have given our NMP66 program priority over the NMP48 program, and we do not intend to begin development of a product for our NMP35 technology until at least development for our NMP66 or NMP48 technology has been successfully completed.

We also intend to ultimately develop Lab Test Kits and/or Point-Of-Care Tests based upon our new, not yet commercialized, technologies. While we have successfully configured our NMP22 technology in these formats, there are always uncertainties involved in successfully creating products which perform reproducibly in every laboratory. Because our newer technologies detect different markers and because they are measured in blood not in urine, we plan not only to apply several of the techniques used in developing our NMP22 products but also to employ additional outside resources to complete the development of these products successfully. Depending on the ongoing results of our development work in our NMP66 breast cancer program and with our other, currently deferred, programs, we will make decisions on how to proceed with our other programs and will consider options including, but not limited to, terminating certain activities, licensing technology to third parties or selling technology to third parties.

Clinical Trials

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

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

Program	Technology Format (Current or Proposed)	Clinical Application	Stage of Development	FDA Status
NMP22 Bladder	Lab Test Kit	Monitoring	Commercialized	Approved
NMP22 Bladder	Lab Test Kit	Diagnosis	Commercialized	Approved
NMP22 Bladder	Point-Of-Care Test	Monitoring	Commercialized	Cleared
NMP22 Bladder	Point-Of-Care Test	Diagnosis	Commercialized	Approved
NMP179 Cervical	Non-Slide-Based Cellular Analysis System	Screening	Licensee Sysmex is conducting pre-clinical trials	*
NMP66 Breast	Proprietary Laboratory Procedure	Not Determined	Development Agreement with Mitsubishi Kagaku Iatron, Inc.	**
NMP66 Breast	Lab Test Kit	Not Determined	Research & Development	*
NMP66 Breast	Point-Of-Care Test	Not Determined	Research & Development	*
NMP48 Prostate	Proprietary Laboratory Procedure	Not Determined	Deferred	**
NMP48 Prostate	Lab Test Kit	Not Determined	Deferred	*
NMP48 Prostate	Point-Of-Care Test	Not Determined	Deferred	*
NMP35 Colon	All	Not Determined	Inactive	***

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

** If offered (as intended) as a service, a FDA submission may not be required. If the service includes a reagent such as an antibody provided by a party other than the laboratory conducting the test, the FDA will likely require an Analyte Specific Reagent notification at a minimum.

In May 2004, Sysmex announced its commencement of preclinical trials of a non-slide-based cellular analysis system incorporating our NMP179 technology. If Sysmex's preclinical and anticipated clinical trials are successful, it is Sysmex's goal to make this technology commercially available in the U.S.

Spending on Research and Development Projects. Total research and development spending in 2005 was approximately $2.9 million. We expect research and development expenditures to be less than $3.5 million in 2006 and to be devoted to our various programs as discussed below.

NMP22 — Bladder. Except for sponsoring additional clinical trials to demonstrate different ways to use the information generated by the products, we do not currently plan to incur any significant additional research spending on any of these products. We do expect to spend, from time to time, funds for product support and manufacturing improvement which are not expected to exceed $750,000 in 2006 and 2007.

NMP179 — Cervical. We completed discovery research on this product prior to 2000 and our expenditures in 2004 and 2005 were principally for technical support of our licensing activity. We expect that substantially all future costs to support additional research and development of this product to be paid by Sysmex. If we incur any additional costs in connection with this program, we expect those costs to be aimed at licensing this technology to a company with a slide-based cervical cancer detection system.

Breast Cancer. Over the next two years, we will spend research and development funds principally to develop products and services for breast cancer, to improve our mass spectrometry technology, and to further develop our ligand binding based technology for Lab Test Kits and/or Point-Of-Care Tests.

Prostate Cancer. The amount of research and development resources we devote to our prostate cancer program depends in large part on the requirements and success of our NMP66 breast cancer program which we plan to give priority in 2006. Because of uncertainty of when we will more actively pursue our prostate cancer program, we cannot reasonably estimate the likelihood or timeframe for reaching any commercialization goals.

Other existing programs. We will make decisions on how and when to proceed with our other existing programs based on our progress with the breast cancer program and the availability of appropriate resources for our remaining programs. We are not able to predict the nature, timing and costs of the efforts that will be required to reach our commercialization goals, nor the amount or timing of the net cash inflows of our individual programs.

Marketing, Supply and Distribution Agreements

In November, 1994, we entered into a supply and distribution agreement with Konica Corporation (now Konica Minolta Medical & Graphic, Inc., "Konica") granting Konica the exclusive right to sell the NMP22 Test Kit in Japan. The term of this agreement was originally six years from the date of Japanese regulatory approval and was amended and restated in December, 2001, to extend the term for additional two year periods until timely notice of termination is given by either party. Under the terms of this agreement, Konica paid a non-refundable exclusivity fee of $255,000 at the time of execution which we have previously recognized as income.

In 2001, we entered into an eight-year, non-exclusive product supply and marketing agreement with DPC enabling DPC to develop and market an automated version of our NMP22 Test Kit. We terminated this agreement effective December 31, 2005. During the term of this agreement, we received royalty payments, which were recognized as revenue when earned based upon the receipt of reports from DPC supporting the amount of and basis for royalty payments to us.

In March 2002, we entered into a supply and distribution agreement with MBL granting MBL the exclusive right in Japan to sell the NMP22 BladderChek Test. Under the agreement, MBL is responsible for conducting clinical trials and securing the necessary regulatory approvals in Japan, MBL received regulatory approval and commenced sales of the NMP22 BladderChek Test during the summer of 2005. Under the terms of this agreement, MBL paid us a non-refundable license fee which is being recognized as revenue over the eight-year term of the agreement.

In October 2002, we entered into a distribution agreement with Cytogen, granting Cytogen the exclusive right to market and sell our NMP22 BladderChek Test in the United States to urologists and oncologists. This agreement was amended in November 2003 to provide Cytogen a non-exclusive right to sell our NMP22 BladderChek Test to urologists only until December 31, 2003 and an exclusive right to continue to sell our NMP22 BladderChek Test to oncologists through December 31, 2004. Under the terms of the agreement, Cytogen paid a non-refundable license fee which was recognized as revenue over the term of the agreement. This agreement expired on December 31, 2004.

In November 2002, we entered into an exclusive license and supply agreement with Sysmex, which granted Sysmex the use of our NMP179 technology for automated non-slide-based laboratory instruments. Under the terms of the agreement, Sysmex purchased shares of our common stock at a premium of approximately $500,000, which amount we are recognizing as revenue over the fourteen-year term of the related patents. This agreement also contains future royalty, milestone and research and development payments. We are recognizing milestone payments over the remaining life of the related patents and will recognize future royalty payments when they are determinable.

In March 2003, we entered into a collaboration and commercialization agreement with MKI whereby they or their designees will serve as our Japanese clinical laboratory partner for further validation of our NMP66 technology and pursuant to which we may negotiate the terms for distribution rights for the Japanese market for products and services incorporating our NMP66 technology. Under the terms of this agreement, MKI paid

us an upfront fee and several milestone payments may become due in the future. We will recognize these payments over the term of the agreement.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk.***

Investment Portfolio. We own financial instruments that are sensitive to market and interest rate risks as part of our investment portfolio. We use this investment portfolio to preserve our capital until it is required to fund operations including our research and development activities. We do not hold any of these market-risk sensitive instruments for trading purposes. Our investment policy prohibits investing in derivatives and limits the amount of credit exposure due to any one issue, issuer, and type of instrument. See Note 1 of Notes to Consolidated Financial Statements — "Operations and Significant Accounting Policies."

We invest our cash in securities classified as cash and cash equivalents. At December 31, 2004 and 2005, these securities totaled $4.9 million and $1.8 million, respectively, and included money market accounts and certificates of deposit. Changes in interest rates affect the investment income we earn on our investments and, therefore, impact our cash flows and results of operations. A hypothetical 50 basis point decrease in interest rates would result in a decrease in annual interest income and a corresponding increase in net loss of approximately $17,000 for the year ended December 31, 2005.

Foreign Exchange. We translate the financial statements of Matritech GmbH in accordance with SFAS No. 52, *Foreign Currency Translation.* The functional currency of our foreign subsidiary is the local currency (Euro). Accordingly, we translate all assets and liabilities of our foreign subsidiary using the applicable exchange rate at the balance sheet date except for intercompany receivables which are of long-term-investment nature, and capital accounts which are translated at historical rates. We translate revenues and expenses at average rates during the period to which they relate. We exclude adjustments resulting from the translation of the financial statements of Matritech GmbH into U.S. Dollars from the determination of net income and we accumulate them in a separate component of stockholders' equity. We report foreign currency transaction gains and losses in the accompanying consolidated statements of operations and they are immaterial to the current results of operations. We had sales denominated in foreign currency of approximately $5,622,000, $4,348,000, and $3,046,000 for the periods ended December 31, 2005, 2004 and 2003, respectively.

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

The information required by this item is contained in the financial statements set forth in Item 15(a) under the caption "Consolidated Financial Statements" as a part of this Annual Report on Form 10-K.

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

Not applicable.

Item 9A. ***Controls and Procedures.***

As of December 31, 2005, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2005, our disclosure controls and procedures were effective to provide reasonable assurance that material information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such material information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. During the period covered by this report, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information.***

There was no information required to be disclosed in a Periodic Report on Form 8-K in the fourth quarter of 2005 which was not reported.

PART III

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2005 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 our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2005.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2005.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2005.

Item 14. ***Principal Accountant Fees and Services.***

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2005.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules.***

(a) 1. Consolidated Financial Statements.

- Reports of Independent Registered Accounting Firm.
- Consolidated Balance Sheets as of December 31, 2004 and 2005.
- Consolidated Statements of Operations for the Years Ended December 31, 2003, 2004 and 2005.
- Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the Years Ended December 31, 2003, 2004 and 2005.
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2003, 2004 and 2005.
- Notes to Consolidated Financial Statements.

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

3. List of Exhibits

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant (originally filed as Exhibits 3, 4.1 to our Registration Statement No. 33-46158 on Form S-1 and re-filed in electronic form as Exhibit 3.1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
3.2	Amended and Restated By-Laws of the Registrant (originally filed as Exhibits 3.2, 4.1 to our Registration Statement No. 33-46158 on Form S-1 and re-filed in electronic form as Exhibit 3.2 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
3.3	Certificate of Amendment dated June 16, 1994, of Amended and Restated Certificate of Incorporation of the Registrant (originally filed as Exhibit 3.2 of our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1995 and re-filed in electronic form as Exhibit 3.3 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
3.4	Certificate of Amendment dated June 5, 1995, of Amended and Restated Certificate of Incorporation of the Registrant (originally filed as Exhibit 3.3 of our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1995 and re-filed in electronic form as Exhibit 3.4 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
3.5	Certificate of Amendment dated June 26, 2002, of Amended and Restated Certificate of Incorporation of the Company (filed as Exhibit 4.6 to our Registration Statement No. 333-96701 on Form S-8, filed on July 18, 2002 and incorporated herein by reference).
3.6	Certificate of Amendment, dated June 11, 2004, of Amended and Restated Certificate of Incorporation (filed as Exhibit 3.5 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2004 and incorporated herein by reference).
3.7	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock, dated March 4, 2005 (filed as Exhibit 4.1 to our Current Report on Form 8-K filed on March 8, 2005 and incorporated herein by reference).
3.8	Certificate of Correction of Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock (filed as Exhibit 4.1 to our Form 8-K/A filed March 25, 2005 and incorporated herein by reference)
3.9	Amendment to Certificate of Designations, Preferences and Rights of Series A Preferred Stock (filed as Exhibit 4.1 to our Current Report on Form 8-K filed January 17, 2006 and incorporated herein by reference).
4.1	Description of Capital Stock contained in the Registrant's Amended and Restated Certificate of Incorporation, filed as Exhibits 3.1, 3.3 and 3.4.
4.5	Purchase Agreement dated June 28, 2000, by and among Petra Urban, on behalf of Franz Maier, Eva Heidt and Joachim Hevler, the shareholders of ADL, and Stephan Schmidt, on behalf of the Company (filed as Exhibit 4.1 to our Form 8-K, filed on July 10, 2000 and incorporated herein by reference).
4.6	Form of Common Stock and Warrant Purchase Agreement (including form of Warrant) between the Company and Several Investors (filed as Exhibit 4.1 to our 8-K, filed on January 4, 2002 and incorporated herein by reference).
4.7	Form of Common Stock and Warrant Purchase Agreement between the Company and each of the Purchasers (filed as Exhibit 4.1 to our 8-K, filed on December 9, 2002 and incorporated herein by reference).
4.8	Securities Purchase Agreement dated March 31, 2003 between the Company and several investors (filed as Exhibit 4.1 to our Form 8-K filed on April 1, 2003 and incorporated herein by reference).

Exhibit Number	Description of Exhibit
4.9	Registration Rights Agreement dated March 31, 2003 between the Company and several investors (filed as Exhibit 4.2 to our Form 8-K filed on April 1, 2003 and incorporated herein by reference).
4.10	Form of 7.5% Convertible Debenture (filed as Exhibit 4.3 to our Form 8-K filed on April 1, 2003 and incorporated herein by reference).
4.11	Form of Stock Purchase Warrant between the Company and several investors (filed as Exhibit 4.4 to our Form 8-K filed on April 1, 2003 and incorporated herein by reference).
4.12	Securities Purchase Agreement dated October 15, 2003 between the Company and several investors (filed as Exhibit 4.1 to our Form 8-K filed on October 16, 2003 and incorporated herein by reference).
4.13	Registration Rights Agreement dated October 15, 2003 between the Company and several investors (filed as Exhibit 4.2 to our Form 8-K filed on October 16, 2003 and incorporated herein by reference).
4.14	Form of Stock Purchase Warrant between the Company and several investors (filed as Exhibit 4.3 to our Form 8-K filed on October 16, 2003 and incorporated herein by reference).
4.15	Securities Purchase Agreement dated October 17, 2003 between the Company and a purchaser of common stock and warrants (filed as Exhibit 4.4 to our Form 10-Q filed on November 12, 2003 and incorporated herein by reference) .
4.16	Registration Rights Agreement dated October 15, 2003 between the Company and a purchaser of common stock and warrants (filed as Exhibit 4.5 to our Form 10-Q filed on November 12, 2003 and incorporated herein by reference).
4.17	Common Stock Purchase Warrant dated November 6, 2003 between the Company and a purchaser of common stock and warrants (filed as Exhibit 4.6 to our Form 10-Q filed on November 12, 2003 and incorporated herein by reference).
4.18	Securities Purchase Agreement dated March 19, 2004 between the Company and several investors (filed as Exhibit 4.1 to our Form 8-K filed on March 22, 2004 and incorporated herein by rherein by reference).
4.19	Registration Rights Agreement dated March 19, 2004 between the Company and several investors (filed as Exhibit 4.2 to our Form 8-K filed on March 22, 2004 and incorporated herein by reference).
4.20	Form of Stock Purchase Warrant between the Company and several investors (filed as Exhibit 4.3 to our Form 8-K filed on March 22, 2004 and incorporated herein by reference).
4.21	Investor Relations Warrant Agreement dated July 14, 2000, by and among the Company and the individuals set forth on Exhibit A thereto (filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2000 and incorporated herein by reference).
4.22	Form of Purchase Agreement dated March 4, 2005 between Matritech, Inc. and various Investors (filed as Exhibit 4.2 to our Current Report on Form 8-K filed on March 8, 2005 and incorporated herein by reference).
4.23	Registration Rights Agreement dated March 4, 2005 between Matritech, Inc. and various Investors (filed as Exhibit 4.3 to our Current Report on Form 8-K filed on March 8, 2005 and incorporated herein by reference).
4.24	Form of Warrant to Purchase Shares of Common Stock (filed as Exhibit 4.4 to our Current Report on Form 8-K filed on March 8, 2005 and incorporated herein by reference).
4.25	Placement Agent Warrant to Purchase Shares of Common Stock (filed as Exhibit 4.5 to our Current Report on Form 8-K filed on March 8, 2005 and incorporated herein by reference).
4.26	Amended Registration Rights Agreement (filed as Exhibit 4.1 to our Current Report on Form 8-K filed April 20, 2005 and incorporated herein by reference).

Exhibit Number	Description of Exhibit
4.27	Revised Form of Common Stock Warrant (filed as Exhibit 4.2 to our Current Report on Form 8-K filed April 20, 2005 and incorporated herein by reference).
4.28	Form of Mutual Termination and Release Agreement between Matritech, Inc. and various Investors (field as Exhibit 4.1 to our current Report on Form 8-K filed June 23, 2005 and incorporated herein by reference).
4.29	Form of Purchase Agreement dated January 13, 2006 between Matritech, inc. and various Purchasers (filed as Exhibit 4.1 on our Current Report on Form 8-K filed January 18, 2006 and incorporated herein by reference).
4.30	Form of Note dated January 13, 2006 issued to various Purchasers (filed as Exhibit 4.2 on our Current Report on Form 8-K filed January 18, 2006 and incorporated herein by reference).
4.31	Form of Registration Rights Agreement dated January 13, 2006 between Matritech, inc. and various Purchasers (filed as Exhibit 4.3 on our Current Report on Form 8-K filed January 18, 2006 and incorporated herein by reference).
4.32	Form of Purchaser Warrant to Purchase Shares of Common Stock (filed as Exhibit 4.4 on our Current Report on Form 8-K filed January 18, 2006 and incorporated herein by reference).
4.33	Form of Placement Agent Warrant to Purchase Shares of Common Stock (filed as Exhibit 4.5 on our Current Report on Form 8-K filed January 18, 2006 and incorporated herein by reference).
4.34	Security Agreement dated January 13, 2006 between Matritech, Inc. and SDS Capital Group SPC, Ltd. as Collateral Agent (filed as Exhibit 4.6 on our Current Report on Form 8-K filed January 18, 2006 and incorporated herein by reference).
4.35	Contingent License Agreement dated January 13, 2006 between Matritech, Inc. and SDS Capital Group SPC, Ltd. as Collateral Agent (filed as Exhibit 4.7 on our Current Report on Form 8-K filed January 18, 2006 and incorporated herein by reference).
10.1@	License Agreement between the Company and the Massachusetts Institute of Technology dated December 14, 1987, as amended March 15, 1988, December 20, 1989 and March 4, 1992 (originally filed as Exhibit 10.1 to our Registration Statement No. 33-46158 on Form S-1 and re-filed in electronic form as Exhibit 10.1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.2#	1992 Stock Plan as amended June 16, 2000 (filed as Exhibit 4.6 to our Registration Statement No. 333-51116 on Form S-8, filed on December 1, 2000 and incorporated herein by reference).
10.3#	Amended and Restated 1992 Non-Employee Director Stock Plan as amended June 16, 2000 (filed as Exhibit 4.7 to our Registration Statement No. 333-51116 on Form S-8, filed on December 1, 2000 and incorporated herein by reference).
10.4	Form of Indemnity Agreement with directors (originally filed as Exhibit 10.14 to our Registration Statement No. 33-46158 on Form S-1 and re-filed in electronic form as Exhibit 10.6 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.5	Fourth Amendment dated March 18, 1993 to License Agreement between the Company and the Massachusetts Institute of Technology dated December 14, 1987, as amended (originally filed as Exhibit 10.9 to our Annual Report on Form 10-K for the fiscal year ended December 31, 1997 and re-filed in electronic form as Exhibit 10.7 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.6	Fifth Amendment dated April 14, 1994 to License Agreement between the Company and the Massachusetts Institute of Technology dated December 14, 1987, as amended (originally filed as Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended March 31, 1994 and re-filed in electronic form Exhibit 10.8 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).

Exhibit Number	Description of Exhibit
10.7@	Exclusive Distribution Agreement between the Company and Konica Corporation dated as of November 9, 1994 (originally filed as Exhibit 10.26 to our Annual Report on Form 10-K for the fiscal year ended December 31, 1994 and re-filed in electronic form as Exhibit 10.9 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.8	First Amendment to Agreement of Lease between the Company and One Nevada Realty Trust dated June 22, 2000 (filed as Exhibit 10.10 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2000 and incorporated herein by reference).
10.9	Sixth Amendment dated March 1, 1996 to License Agreement between the Company and the Massachusetts Institute of Technology dated December 14, 1987, as amended (originally filed as Exhibit 10.26 to our Annual Report on Form 10-K for the fiscal year ended December 31, 1995 and re-filed in electronic form as Exhibit 10.11 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference).
10.10	Senior Loan and Security Agreement No. 0096 between the Company and Phoenix Leasing, Incorporated dated August 29, 1997 including form of Senior Secured Promissory Note between the Company and Phoenix Leasing, Incorporated (filed as Exhibit 10.20 to our Annual Report on Form 10-K for the fiscal year ended December 31, 1997 and incorporated herein by reference).
10.11@	Distributorship Agreement by and between the Company and Curtin Matheson Scientific, a division of Fisher Scientific Company, L.L.C. dated March 19, 1998 (filed as Exhibit 10.21 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1997 and incorporated herein by reference).
10.12	Bank Loan between Matritech GmbH and Sparkasse Freiburg, dated May 7, 1999 (filed as Exhibit 10.17 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2000 and incorporated herein by reference).
10.13@	Distributorship Agreement by and between Matritech GmbH and Hitachi Chemical Diagnostics, Inc., dated October 1, 2000 (filed as Exhibit 10.18 to our Annual Report on Form 10-K for the year ended December 31, 2000 and incorporated herein by reference).
10.14#	2002 Stock Option and Incentive Plan (filed as Appendix B to our Definitive Proxy Statement, filed April 22, 2002 on Form 14A and incorporated herein by reference).
10.15#	2002 Non-Employee Director Stock Option Plan (filed as Appendix C to our Definitive Proxy Statement, filed April 22, 2002 on Form 14A and incorporated herein by reference).
10.16#	2002 Employee Stock Purchase Plan (filed as Appendix D to our Definitive Proxy Statement filed April 22, 2002 on Form 14A and incorporated herein by reference).
10.17@	Exclusive License and Supply Agreement between Matritech, Inc. and Sysmex Corporation, dated November 20, 2002 filed as Exhibit 10.22 with our Form 10-K filed on March 31, 2003 and incorporated herein by reference).
10.18@	Amended and Restated Distribution Agreement dated October 31, 2003 between Cytogen Corporation and Matritech, Inc. (filed as Exhibit 10.21 to our Annual Report on Form 10-K for the year ended December 31, 2003 and incorporated herein by reference).
10.19	Second Amendment to Agreement of Lease dated May 12, 2004 between the Company and Francis L. Biotti as trustee of One Nevada Realty Trust (filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2004 and incorporated herein by reference).
10.20#	2002 Employee Stock Purchase Plan as amended effective June 11, 2004 (filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2004 and incorporated herein by reference).
10.21@	Sublicense Agreement between the Company and Abbott Laboratories, dated as of April 1, 2004 (filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2004 and incorporated herein by reference).

Exhibit Number	Description of Exhibit
10.22@	Letter Agreement regarding Contract Manufacturing Arrangement between the Company and Unotech Diagnostics, Inc. executed in April 2001 (filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2004 and incorporated herein by reference).
10.23#	Management Bonus Plan adopted February 18, 2005 (filed as Exhibit 99.1 to our Current Report on Form 8-K filed February 23, 2005 and incorporated herein by reference).
10.24#	Form of Stock Option Agreement for stock option grants made in February 2005 to executive officers (filed as Exhibit 4.1 to our Current Report on Form 8-K filed February 16, 2005 and incorporated herein by reference).
10.25#	Amended and Restated Management Bonus Plan as of December 9, 2005 (filed as Exhibit 10.1 to our Current Report on Form 8-K filed December 9, 2005 and incorporated herein by reference).
10.26#	Form of Restricted Stock Award Agreement for restricted stock used for bonus awards under Amended and Restated Management Bonus Plan as of December 9, 2005 (filed as Exhibit 10.1 to our Current Report on Form 8-K filed March 10, 2006 and incorporated herein by reference).
10.27#	Form of Restricted Stock Unit Award Agreement for restricted stock units used for bonus awards under Amended and Restated Management Bonus Plan as of December 9, 2005 (filed as Exhibit 10.2 to our Current Report on Form 8-K filed March 10, 2006 and incorporation herein by reference).
10.28#	Form of Restricted Stock Award Agreement in lieu of stock option grants to US based executive officers (filed as Exhibit 10.3 to our Current Report on Form 8-K filed March 10, 2006 and incorporated herein by reference).
10.29#	Form of Restricted Stock Unit Award Agreement in lieu of stock option grants to non-US based executive officer (filed as Exhibit 10.4 to our Current Report on Form 8-K filed March 10, 2006 and incorporated herein by reference).
10.30#	Form of Performance-Based Restricted Stock Award Agreement (filed as Exhibit 10.5 to our Current Report on Form 8-K filed March 10, 2006 and incorporated herein by reference).
10.31#	Form of Change of Control Agreement (filed as Exhibit 10.1 to our Current Report on Form 8-K filed March 20, 2006 and incorporated herein by reference).
10.32#	Form of Amended Restricted Stock Award Agreement for restricted stock awards used for bonus awards under Amended and Restated Management Bonus Plan as of December 9, 2005 (filed as Exhibit 10.1 to our Current Report on Form 8-K filed March 21, 2006 and incorporated herein by reference).
10.33#	Form of Amended Restricted Stock Unit Award Agreement for restricted stock unit awards used for bonus awards under Amended and Restated Management Bonus Plan as of December 9, 2005 (filed as Exhibit 10.2 to our Current Report on Form 8-K filed March 21, 2006 and incorporated herein by reference).
10.34#	Form of Amended Performance-Based Restricted Stock Award Agreement (filed as Exhibit 10.3 to our Current Report on Form 8-K filed March 21, 2006 and incorporated herein by reference).
14.1	Code of Business Conduct and Ethics (filed as Exhibit 14.1 to our Annual Report on Form 10-K for the year ended December 31, 2004 and incorporated herein by reference).
14.2	Amended and Restated Code of Business Conduct and Ethics dated May 25, 2005 (filed as Exhibit 14.1 to our Current Report on Form 8-K filed May 26, 2005 and incorporated herein by reference)
23**	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm.
31.1	Certification of the Chief Executive Officer under Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer under Section 302 of Sarbanes-Oxley Act of 2002
32.1^	Certification of the Chief Executive Officer under Section 906 of Sarbanes-Oxley Act of 2002
32.2^	Certification of the Chief Financial Officer under Section 906 of Sarbanes-Oxley Act of 2002.

@ 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.

^ Furnished as exhibits

(c) Exhibits. The Company hereby files as exhibits to this Form 10-K those exhibits listed in Item 15(a)(3), 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 21st day of March, 2006.

Matritech, Inc.

By: /s/ Stephen D. Chubb
Stephen D. Chubb
Director, Chairman and
Chief Executive Officer

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

Signature	Title	Date
/s/ Stephen D. Chubb Stephen D. Chubb	Director, Chairman, and Chief Executive Officer (Principal Executive Officer)	March 21, 2006
/s/ David L. Corbet David L. Corbet	Director, President and Chief Operating Officer	March 21, 2006
/s/ Richard A. Sandberg Richard A. Sandberg	Director, Vice President, Chief Financial Officer and Treasurer (Principal Accounting and Financial Officer)	March 21, 2006
/s/ Walter O. Fredericks Walter O. Fredericks	Director	March 21, 2006
/s/ Judith Kurland Judith Kurland	Director	March 21, 2006
/s/ Jonathan M. Niloff Jonathan M. Niloff	Director	March 21, 2006
/s/ T. Stephen Thompson T. Stephen Thompson	Director	March 21, 2006
/s/ C. William Zadel C. William Zadel	Director	March 21, 2006

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MATRITECH, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, stockholders' equity and comprehensive loss and cash flows present fairly, in all material respects, the financial position of Matritech Inc. and its subsidiary at December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 21, 2006

MATRITECH, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2004	December 31, 2005
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,906,178	$ 1,789,792
Accounts receivable less allowance of $85,123 in 2004 and $110,059 in 2005	884,057	1,534,096
Inventories	878,804	756,079
Prepaid expenses and other current assets	347,245	323,660
Total current assets	7,016,284	4,403,627
Property and equipment, at cost:		
Laboratory equipment	2,499,519	2,287,161
Office equipment	505,792	582,798
Laboratory furniture	62,739	62,739
Leasehold improvements	141,267	141,267
Automobiles	48,933	18,896
	3,258,250	3,092,861
Less — Accumulated depreciation and amortization	2,343,673	2,211,618
	914,577	881,243
Goodwill	132,615	132,615
Other assets	166,416	206,948
Receivable from related party	16,104	3,551
Total assets	$ 8,245,996	$ 5,627,984
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Current maturities of notes payable	$ 13,534	$ 13,571
Current maturities of convertible debt	1,390,887	634,971
Accounts payable	475,342	523,742
Accrued expenses	1,570,588	1,301,719
Deferred revenue	386,188	286,186
Total current liabilities	3,836,539	2,760,189
Notes payable, less current maturities	13,534	9,979
Convertible debt, less current maturities	364,236	—
Deferred revenue	636,775	641,725
Other long term liabilities	—	132,852
Total liabilities	4,851,084	3,544,745
Commitments and Contingencies (Note 4)		
Series A Convertible Preferred Stock, $1.00 par value		
Authorized — 4,000,000 shares		
Designated as Series A Convertible Preferred — 1,426,124 shares		
Issued and outstanding — 0 shares in 2004 and 569,251 shares of Series A in 2005	—	729,495
Liquidation preference of $0 and $5,009,409 for Series A in 2004 and 2005, respectively	—	729,495
Stockholders' Equity:		
Common stock, $0.01 par value		
Authorized — 90,000,000 in 2004 and 2005		
Issued and outstanding — 43,014,543 shares in 2004 and 47,498,008 shares in 2005	430,145	474,979
Additional paid-in capital	92,944,400	98,800,393
Accumulated other comprehensive income	142,399	65,367
Accumulated deficit	(90,122,032)	(97,986,995)
Total stockholders' equity	3,394,912	1,353,744
Total liabilities and stockholders' equity	$ 8,245,996	$ 5,627,984

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

MATRITECH, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2003	2004	2005
Revenue:			
Product sales, net of allowances	$ 4,017,896	$ 7,274,789	$10,290,097
Alliance and collaboration revenue	357,315	208,306	125,373
Total revenue	4,375,211	7,483,095	10,415,470
Expenses:			
Cost of product sales	2,008,954	2,579,581	3,085,465
Research & development and clinical & regulatory expense	2,647,716	2,726,030	2,862,744
Selling, general and administrative expense	6,574,088	10,545,268	12,196,962
Total operating expenses	11,230,758	15,850,879	18,145,171
Gain on sale of fixed assets	—	—	60,091
Loss from operations	(6,855,547)	(8,367,784)	(7,669,610)
Interest income	76,629	97,741	120,051
Interest expense	1,099,372	2,853,112	2,215,102
Mark-to-market adjustment from warrants	—	—	1,899,698
Net loss	$ (7,878,290)	$(11,123,155)	$ (7,864,963)
Beneficial conversion feature related to series A convertible preferred stock	—	—	(1,627,232)
Net loss attributable to common shareholders	$ (7,878,290)	$(11,123,155)	$ (9,492,195)
Basic and diluted net loss attributable to common shareholders per common share	$ (0.24)	$ (0.27)	$ (0.21)
Basic and diluted weighted average number of common shares outstanding	32,956,888	40,686,755	45,002,662

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

MATRITECH, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

	Common Stock		Additional		Accumulated Other		Total
	Number of shares	Par Value	Paid-in Capital	Deferred Compensation	Comprehensive Income/(Loss)	Accumulated Deficit	Stockholders' Equity
Balance, December 31, 2002	32,128,243	$321,282	$74,694,619	$(35,710)	$(20,619)	$(71,120,587)	$ 3,838,985
Net Loss	—	—	—	—	—	(7,878,290)	(7,878,290)
Cumulative translation adjustment	—	—	—	—	139,738	—	139,738
Total comprehensive loss							(7,738,552)
Issuance of warrants in connection with convertible debt			1,112,357	—	—	—	1,112,357
Sale of common stock and warrants, net of issuance costs of $853,220	3,893,295	38,933	5,609,649	—	—	—	5,648,582
Beneficial conversion feature associated with convertible debt			1,696,125				1,696,125
Exercise of common stock options	250	3	333	—	—	—	336
Issuance of common stock for interest on convertible debt	93,146	931	191,506	—	—	—	192,437
Issuance of common stock under employee stock purchase plan	7,000	70	12,180	—	—	—	12,250
Amortization of deferred compensation	—	—	—	35,710	—	—	35,710
Balance, December 31, 2003	36,121,934	$361,219	$83,316,769	$ —	$119,119	$(78,998,877)	$ 4,798,230
Net Loss	—	—	—	—	—	(11,123,155)	(11,123,155)
Cumulative translation adjustment	—	—	—	—	23,280	—	23,280
Total comprehensive loss							(11,099,875)
Sale of common stock and warrants, net of issuance costs of $712,530	4,858,887	48,589	5,798,380	—	—	—	5,846,969
Beneficial conversion feature associated with convertible debt	—	—	1,338,669	—	—	—	1,338,669
Exercise of common stock options	100,000	1,000	83,000	—	—	—	84,000
Issuance of common stock for interest on convertible debt	257,728	2,577	326,203	—	—	—	328,780
Issuance of common stock for redemption payments on convertible debt	1,669,994	16,700	2,072,439	—	—	—	2,089,139
Issuance of common stock under employee stock purchase plan	6,000	60	8,940	—	—	—	9,000
Balance, December 31, 2004	43,014,543	$430,145	$92,944,400	$ —	$142,399	$(90,122,032)	$ 3,394,912
Net Loss	—	—	—	—	—	(7,864,963)	(7,864,963)
Cumulative translation adjustment	—	—	—	—	(77,032)	—	(77,032)
Total comprehensive loss							(7,941,995)
Issuance of warrants to a placement agent	—	—	562,125	—	—	—	562,125
Beneficial conversion feature associated with convertible debt	—	—	442,027	—	—	—	442,027
Conversion of preferred stock into common stock	1,010,210	10,102	119,357	—	—	—	129,459
Issuance of common stock for interest on convertible debt	198,927	1,989	161,262	—	—	—	163,251
Issuance of common stock for redemption payments on convertible debt	3,268,102	32,681	2,598,116	—	—	—	2,630,797
Issuance of common stock under employee stock purchase plan	6,226	62	6,164	—	—	—	6,226
Reclassification of warrants from a liability to equity	—	—	1,966,942	—	—	—	1,966,942
Balance, December 31, 2005	47,498,008	$474,979	$98,800,393	$ —	$ 65,367	$(97,986,995)	$ 1,353,744

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

MATRITECH, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2003	2004	2005
Cash Flows from Operating Activities:			
Net loss	$(7,878,290)	$(11,123,155)	$(7,864,963)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	225,646	256,289	250,222
Amortization of deferred compensation	35,710	—	—
Amortization of debt discount	644,202	2,149,943	1,629,569
Amortization of deferred charges	145,549	210,917	111,937
Issuance of common stock for interest on debt	192,437	328,781	163,250
Noncash interest expense	—	166,059	323,104
Mark-to-market adjustment on warrants	—	—	(1,899,698)
Gain on sale of fixed assets	—	—	(60,091)
Noncash expense related to bonus plan	—	—	66,426
Provision for bad debts	—	61,532	96,609
Changes in assets and liabilities:			
Accounts receivable	179,658	(358,690)	(768,356)
Inventories	(111,298)	(248,582)	75,496
Prepaid expenses and other assets	(19,073)	(87,782)	(128,884)
Accounts payable	(151,383)	187,023	59,168
Accrued expenses and other liabilities	132,850	582,598	(162,813)
Deferred revenue	(58,167)	(145,412)	(95,052)
Net cash used in operating activities	(6,662,159)	(8,020,479)	(8,204,076)
Cash Flows from Investing Activities:			
Purchases of property and equipment	(182,349)	(229,969)	(221,022)
Proceeds from sale of fixed assets			60,091
Net cash used in investing activities	(182,349)	(229,969)	(160,931)
Cash Flows from Financing Activities:			
Payments on notes payable	(160,515)	(295,212)	(6,120)
Proceeds from sale of preferred stock and warrants, net	—	—	5,287,721
Proceeds from convertible debentures and warrants, net	4,556,083	—	—
Proceeds from sale of common stock and warrants, net	5,648,582	5,846,969	—
Proceeds from exercise of common stock options	336	84,000	—
Proceeds from issuance of common stock under employee stock purchase plan	12,250	9,000	6,226
Net cash provided by financing activities	10,056,736	5,644,757	5,287,827
Effect of foreign exchange on cash and cash equivalents	133,883	(6,255)	(39,206)
Increase (decrease) in cash and cash equivalents	3,346,111	(2,611,946)	(3,116,386)
Cash and cash equivalents, beginning of year	4,172,013	7,518,124	4,906,178
Cash and cash equivalents, end of year	$ 7,518,124	$ 4,906,178	$ 1,789,792
Supplemental Cash Flow Information:			
Cash paid during the year for interest	$ 85,767	$ 8,444	$ 1,668
Supplemental Disclosure of Noncash Financing and Investing Activities:			
Non-cash dividends to preferred stockholders arising from the beneficial conversion feature	—	—	$ 1,627,232
Additional beneficial conversion feature on Convertible Debentures	$ 1,497,326	$ 1,338,669	$ 442,027
Issuance of common stock as payment on debt:			
Number of shares issued	93,146	1,927,722	3,467,029
Payment on debt in dollars	$ 187,500	$ 2,231,971	$ 2,459,135
Conversion of 101,021 shares of preferred stock to 1,010,210 shares of common stock	—	—	$ 129,459
Purchase of fixed assets through capital lease	—	—	$ 5,791

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. We initially licensed nuclear matrix protein technology from the Massachusetts Institute of Technology ("MIT"), and have since obtained an additional 18 U.S. patents relating to our products and nuclear matrix protein technology.

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

We have incurred losses from operations since our inception. We have an accumulated deficit of $98 million at December 31, 2005. Based on our current forecast of cash utilization, we believe that our existing capital resources combined with our recent financing completed in January 2006 will be sufficient to fund operations into the first quarter of 2007, provided we pay interest and principal on our Convertible Debentures and our Secured Convertible Notes in stock. We will, as we deem necessary or prudent, continue to seek to raise additional capital and will consider various financing alternatives, including equity or debt financings, issuance of securities convertible into equity and corporate partnering arrangements. However, we may not be able to raise needed capital on terms that are acceptable to us, or at all.

We will not be able to raise significant additional capital unless we receive stockholder approval of an increase in our authorized common stock. Currently, we have fewer than 700,000 shares of our common stock available to sell in future financings. The balance of our authorized common stock, 90,000,000 shares, is outstanding or reserved for other existing obligations. If we cannot repay our Secured Convertible Notes in stock because of a failure of the stock payment conditions, we must repay them in cash. However, without further stockholder action to approve an increase in our authorized shares, we are unlikely to be able to raise sufficient additional cash to cover for the required repayments of the Secured Convertible Notes. If we do not receive an adequate amount of additional financing in the future or such financing does not occur on a timely basis, we will be required to curtail our expenses by reducing research and/or marketing or by taking other steps that could hurt our future performance, including but not limited to, the premature sale of some or all of our assets or product lines on undesirable terms, merger with or acquisition by another company on unsatisfactory terms or the cessation of operations.

Our existing securities restrict our future financing options. For example, our Convertible Debenture has a prohibition against any debt having a ranking senior to the Convertible Debenture and our Series A Preferred Stock imposes a limitation on indebtedness not outstanding on March 4, 2005 in excess of $7,500,000 except in limited forms. While our Secured Convertible Notes are outstanding, we have restrictions on incurring additional indebtedness (other than receivables financing not to exceed 80% of receivables and equipment purchase or lease financing not to exceed $200,000), as well as restrictions on payment of cash dividends and redemption of securities. Moreover, we have granted to a collateral agent on behalf of the holders of the Secured Convertible Notes a security interest in collateral including some cell lines, equipment, inventory and general intangibles related to our NMP22 product line, as well as proceeds from any sale of the product line. We also granted license rights to the collateral agent in the field of bladder cancer detection to some of our patents related to the NMP22 products, sublicense rights to patents licensed to us and used in connection with the NMP22 product line, and license rights to trademarks used exclusively in connection with the NMP22 product line. The NMP22 product line, portions of which serve as collateral for the Secured Convertible Notes,

includes all of our currently commercialized products. The agreements reflecting the collateral and license arrangements contain restrictions on our sale or abandonment of the collateral and the patent rights. Further, these agreements afford the collateral agent the right to assume control of and sell the collateral and to use the license rights exclusively within the field of bladder cancer detection in the event of our default in our obligations under the Secured Convertible Notes. If we default on these obligations, and the collateral is sold, we will lose our primary source of operating income, which would have a material adverse effect on our business and would severely jeopardize our ability to continue operations.

If we raise funds on unfavorable terms, we may provide rights and preferences to new investors which are not available to current shareholders. In addition, our existing financing arrangements contain anti-dilutive provisions which may require us to issue additional securities if certain conditions are met. Any future equity financings or retirements of debt with common stock will dilute the ownership interest of our existing investors and may have an adverse impact on the price of our common stock. Any of the foregoing steps may have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that capital will be available on terms acceptable to us, if at all. These financial statements do not include any adjustments that would be necessary if the company was unable to continue as a going concern entity.

(a) Principles of Consolidation

The consolidated financial statements include the accounts of Matritech, Inc., a Delaware corporation and our wholly-owned subsidiary Matritech GmbH based in Freiburg, Germany. All intercompany balances and transactions have been eliminated at consolidation level.

(b) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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) Foreign Currency Translation

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

(d) Cash and Cash Equivalents

We consider all highly liquid investments with maturities of 90 days or less at the date of purchase to be cash equivalents. We follow the provisions of SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, in accounting for our marketable securities. Securities held at December 31, 2004 and 2005, include only cash and cash equivalents and money market accounts.

(e) Concentration of Credit Risk and Significant Customers

Financial instruments that potentially expose us to concentrations of credit risk consist primarily of cash and cash equivalents and trade accounts receivable. We limit credit risk in cash and cash equivalents by investing only in short-term, investment grade securities with financial institutions of high credit standing. To reduce credit risk associated with our trade accounts receivable, we routinely assess the financial strength of our customers and utilize credit limits and, as a consequence, we believe that our trade accounts receivable credit risk exposure is limited. We do not require collateral from our customers.

No customer accounted for more than 10% of our total revenues in fiscal 2003, 2004, and 2005 respectively. One customer accounted for 10% of our total accounts receivable balance at December 31, 2003. No customer accounted for more than 10% of our accounts receivable balance at December 31, 2004 and December 31, 2005.

(f) 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,	
	2004	2005
Raw materials	$169,708	$206,200
Work-in-process	7,975	22,117
Finished goods	655,739	462,732
Consignment inventory	45,382	65,030
	$878,804	$756,079

(g) Depreciation

We provide for depreciation using straight-line methods by recording 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	2-5 years
Laboratory furniture	5 years
Leasehold improvements	Shorter of useful life or lease term
Automobiles	5 years

(h) Capital leases

Assets acquired under capital lease agreements are recorded at the present value of the future minimum rental payments using interest rates appropriate at the inception of the lease. Property and equipment subject to capital lease agreements are amortized over the shorter of the life of the lease or the estimated useful life of the asset unless the lease transfers ownership or contains a bargain purchase option, in which case the leased asset is amortized over the estimated useful life of such asset.

(i) Disclosure of Fair Value of Financial Instruments

Our financial instruments consist mainly of cash and cash equivalents, accounts receivable, accounts payable, convertible debt and notes payable. The carrying amounts of our financial instruments, excluding the

Convertible Debt, approximate their estimated fair values at December 31, 2004 and 2005. The estimated fair values have been determined through information obtained from market sources and management estimates.

The fair value of the Convertible Debt at December 31, 2004 and 2005 as estimated by management is approximately $2.8 million and $769,000, respectively. The carrying value of the Convertible Debt in our financial statements reflects discounts related to beneficial conversion charges calculated in accordance with EITF Issue No. 00-27.

(j) Goodwill and Long-lived Assets

We have completed the annual impairment tests as required by SFAS No. 142, *Goodwill and Other Intangible Assets* ("SFAS 142") and, based on the results of these tests, no impairment of goodwill was identified.

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

(k) Revenue Recognition

We recognize revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition* ("SAB 104"). Revenue is recognized when the following criteria have been met:

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

When determining whether risk of loss has transferred to customers on product sales, we evaluate both the contractual terms and conditions of our sales agreements as well as our business practices. Business practices such as agreeing to product exchanges may indicate the existence of an implied right to return the product even if there are no such contractual provisions for product returns. We treat such practices, whether contractual or implied, as conveying a right of return and will establish provisions for returns when reasonable and reliable estimates can be made. In accordance with SAB 104, where we do not have sufficient history to make reasonable and reliable estimates of returns, revenue associated with such practices is deferred until the return period lapses or a reasonable estimate can be made. This deferred revenue will be recognized as revenue when the distributor reports to us that it has either shipped or disposed of the units (indicating that the possibility of return is remote).

Alliance and collaboration revenue is primarily generated through collaborative license and development agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones, payments for product manufacturing and royalties on

net product sales. Revenue arrangements where multiple products or services are sold together under one contract are evaluated to determine if each element represents a separate unit of accounting as defined in Emerging Task Issues Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). EITF 00-21 requires the following criteria to be met for an element to represent a separate unit of accounting:

1. The delivered items have value to a customer on a stand-alone basis;

2. There is objective and reliable evidence of the fair value of the undelivered items; and

3. Delivery or performance is probable and within the control of the vendor for any delivered items that have a right of return.

In the event that an element of such multiple element arrangement does not represent a separate earnings process and a separate unit of accounting, we recognize revenue from this element over the term of the related contract or as the undelivered items are delivered.

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

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

Deferred revenue consists of the following:

	December 31,	
	2004	2005
Collaboration fees	$ 737,885	$715,608
Deferred product revenue	285,078	212,303
	$1,022,963	$927,911

(l) Research and Development Costs

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

(m) Cost of Products Sold

Cost of product sales includes payroll-related expenses, product materials, rent and related expenses, supplies, depreciation of fixed assets used in production as well as royalties paid to third parties. Gross profit is calculated by deducting the cost of product sales from product sales.

(n) Significant Risks and Uncertainties

We do not currently have alternative suppliers for certain key components and processes which are provided by some subcontractors for our NMP22 Test Kits and our NMP22 BladderChek Tests. If the components from these suppliers or the services of these assemblers become unavailable for any reason, including their failure to comply with FDA regulations, or should any of our suppliers or assemblers be unable to provide the quantity of products or services we require, we would need to seek alternative or additional sources of supply or assembly. In order to maintain the FDA acceptance of our manufacturing process, we would have to demonstrate to the FDA that other sources of supply are equivalent to our current sources, which is likely to involve a submission and approval process. Although we attempt to maintain an adequate level of inventory to provide for these and other contingencies, if our manufacturing processes are disrupted because key components are unavailable, because new components must be revalidated or because an assembler fails to meet our requirements, we may be forced to modify our products to enable another subcontractor to meet our sales requirements or we may be required to cease production of such products altogether until we are able to establish an adequate replacement supplier. Disruptive changes of this nature may make us unable to meet our sales commitments to customers.

(o) Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and foreign currency translation adjustments related to our GmbH subsidiary.

(p) Stock-Based Compensation

We have elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25") and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation,* ("SFAS 123"). Under APB 25, when the exercise price of options granted under these plans is greater than or equals the market price of the underlying stock on the date of grant, no compensation expense is recognized.

In December, 2005, the Compensation Committee of our Board of Directors approved the acceleration of vesting of approximately 574,000 unvested stock options granted between January 2002 and December 2004 to employees of the Company. These options had exercise prices greater than the market value of our stock at that time. The exercise price and number of shares underlying each affected stock option were unchanged. The acceleration of these options was primarily done in connection with our impending adoption of Statement No. 123 (revised 2004), *Share-Based Payment*, ("SFAS 123R") effective January 1, 2006 in order to avoid the recognition of compensation expense in 2006 and thereafter with respect to the vesting of these options. As a result of this acceleration, we will not be required to recognize share-based compensation, net of related tax effects, of $450,000 in future years, based on valuation calculations using the Black-Scholes methodology. Total 2005 stock-based compensation expense under SFAS 123 would have been approximately $1,102,000 including approximately $450,000 of expense as a result of the acceleration of the 574,000 unvested options in December 2005.

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

	2003	2004	2005
Net loss attributable to common shareholders	$(7,878,290)	$(11,123,155)	$ (9,492,195)
Add: employee stock based compensation expense included in net loss attributable to common shareholders	35,710	—	—
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(1,075,669)	(701,434)	(1,102,437)
Pro forma net loss attributable to common shareholders	$(8,918,249)	$(11,824,589)	$(10,594,632)
Net loss attributable to common shareholders per common share:			
Basic and diluted — as reported	$ (0.24)	$ (0.27)	$ (0.21)
Basic and diluted — pro forma	$ (0.27)	$ (0.29)	$ (0.24)

The weighted-average per share fair value of grants during 2003, 2004 and 2005 was $1.82, $0.85 and $0.58, respectively.

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

	2003	2004	2005
Risk-free interest rate	2.27 - 4.07%	3.74 - 4.69%	3.61 - 4.34%
Expected dividend yield	—	—	
Expected life	7 years	5 years	5 years
Expected volatility	110%	85%	68%

The effects on 2003, 2004 and 2005 pro forma net loss attributable to common shareholders and net loss attributable to common shareholders per share of expensing the estimated fair value of stock options and common shares issued pursuant to the stock option and stock purchase plans are not necessarily representative of the effects on reported results of operations for future years as options vest over several years and we intend to grant varying levels of stock options in future periods.

(q) Net Loss per Common Share

We compute earnings per share in accordance with Statement of Financial Accounting Standards ("SFAS") No. 128, *Earnings per Share*. Basic net loss per common share is computed by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding during the year. Diluted loss per share is the same as basic loss per share as the effects of our potential dilutive common shares are anti-dilutive. Potential common stock equivalents consist of stock options, warrants, convertible preferred stock and convertible debentures. The number of anti-dilutive securities excluded from the computation of diluted loss per share were 8,317,864, 9,391,336 and 19,576,067 for the years ended December 31, 2003, 2004 and 2005, respectively. In January 2006 we entered into a purchase agreement pursuant to which we sold 15% Secured Convertible Promissory Notes (futher described in footnote 12). This transaction would add approximately 19,996,000 shares to the number of anti-dilutive securities.

(r) Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued SFAS 123R which is a revision of SFAS 123. SFAS 123R supersedes APB 25, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be expensed based on their fair values. Pro forma disclosure is no longer an alternative. SFAS 123R must be adopted in the first annual period beginning after June 15, 2005, irrespective of the entity's fiscal year. We must adopt SFAS 123R on January 1, 2006.

SFAS 123R permits public companies to adopt its requirements using one of two methods: a "modified prospective method" in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date or a "modified retrospective" method, which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. We intend to apply the modified prospective method of adoption in our application of SFAS 123R.

As permitted by SFAS 123, we currently account for share-based payments to employees using APB 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss per share in this note to our consolidated financial statements.

(2) Agreements

In March 2001, we entered into an eight-year, non-exclusive product supply and marketing agreement with Diagnostic Products Corporation ("DPC") enabling DPC to develop and market an automated version of our NMP22 Test Kit. This agreement was terminated effective December 31, 2005. During the term of this agreement, we received royalty payments which were recognized when earned based upon the receipt of data from DPC supporting the amount of and basis for royalty payments to us.

In March 2002, we entered into a supply and distribution agreement with Medical and Biological Laboratories Group of Nagoya, Japan ("MBL") granting MBL the exclusive right in Japan to sell the NMP22 BladderChek Test. MBL is responsible for conducting clinical trials and securing the necessary regulatory approvals in Japan and it received regulatory approval and commenced sales of the NMP22 BladderChek Test during the summer of 2005. Under the terms of this agreement MBL paid us a non-refundable license fee which is being recognized as revenue over the eight-year term of the agreement.

In October 2002, we entered into a distribution agreement with Cytogen Corporation ("Cytogen"), granting Cytogen the exclusive right to market and sell the NMP22 BladderChek Test in the United States to the urology and oncology marketplace. This agreement was amended in November 2003 to provide Cytogen a non-exclusive right to sell NMP22 BladderChek Tests to urologists until December 31, 2003 and an exclusive right to continue to sell NMP22 BladderChek Tests to oncologists through December 31, 2004. Under the terms of the agreement, Cytogen paid a non-refundable license fee which was recognized as revenue over the term of the agreement.

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

In March 2003, we entered into a collaboration and commercialization agreement with Mitsubishi Kagaku Iastron, Inc., a division of Mitsubishi Chemical ("MKI"), whereby they or their designees will serve as our Japanese clinical laboratory partner for further validation of our NMP66 technology and pursuant to which we and they may negotiate the terms for distribution rights for the Japanese market for products and services incorporating the NMP66 technology. Under the terms of this agreement, MKI paid Matritech an upfront fee and several milestone payments may become due in the future. These payments will be recognized over the term of the agreement.

(3) Valuation and Qualifying Accounts

The following table sets forth activity in our accounts receivable reserve account:

	Balance at Beginning of Year	Provision Charged to Income	Write-offs	Balance at End of Year
2003	23,591	—	—	23,591
2004	23,591	61,532	—	85,123
2005	85,123	96,609	71,673	110,059

The following table sets forth activity in our valuation allowance against deferred tax assets account:

	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
2003	28,901,000	2,803,000	—	31,704,000
2004	31,704,000	3,228,000	—	34,932,000
2005	34,932,000	1,209,000	—	36,141,000

(4) Commitments and Contingencies

In 2004, we extended our lease agreement for our corporate headquarters in Newton, Massachusetts. The lease expires on December 31, 2010, with the right to renew for an additional five-year period at the then market rate.

In 2005, we entered into a new lease agreement for our office in Freiburg, Germany. This lease commences in January 2006 and continues through January 2011 with the right to renew for an additional five-year period.

In December 2005, we entered into a capital lease agreement, totaling approximately $5,800, to provide us with office equipment. The lease term is three years. Capital lease obligations are recorded as notes payable in our balance sheet.

We lease office and laboratory facilities and certain equipment under operating and capital leases that expire through 2011. Total commitments are due as follows:

	Operating Lease	Capital Lease
2006	$ 579,000	$3,000
2007	573,000	2,000
2008	532,000	2,000
2009	512,000	—
2010	509,000	—
Thereafter	9,000	—
Total	$2,714,000	$7,000

Rent expense, including facility and equipment rentals, for the years ended December 31, 2003, 2004 and 2005 was approximately $568,000, $601,000 and $592,000, respectively.

In December 2003, a third party complaint was filed against us by the lessor of the property we occupy in Newton, Massachusetts in a suit brought against the lessor by a former employee of ours. The action was filed in Middlesex County Superior Court, Massachusetts under the caption Kira Shapiro et al v. Francis Biotti as Trustee of One Nevada Street Realty Trust, Civil Action No. 02-05439. In the underlying action, the plaintiff sought damages for personal injuries allegedly sustained as a result of the negligence of the lessor in maintaining the interior of the leased premises. Our lessor sought reimbursement from us for any amounts for which he may be held liable. The plaintiffs' action was dismissed by the court on January 25, 2005, and a stipulation of dismissal covering the third party claims against us was filed with the court on January 28, 2005. These dismissals conclude the case.

During 2003, we received reports from customers that one of the products we sell through our German subsidiary failed to perform correctly and provided false readings on patients' conditions. We believe the product performance problems have been addressed by the manufacturer of the products and that the manufacturer has accepted responsibility for defective products. Accordingly, we have no liabilities recorded for, nor any accruals made with respect to, these matters as of December 31, 2004 or 2005.

Guarantees

As permitted under Delaware law, we have agreements whereby we indemnify our officers and directors for certain events or occurrences while the officer or director is, or was, serving at our request in such capacity. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited; however, we have a Director and Officer insurance policy that may enable us to recover a portion of any future amounts paid. As a result of our insurance policy coverage, we believe the estimated fair value of these indemnification agreements is minimal.

We enter into standard indemnification agreements in our ordinary course of business. Pursuant to these agreements, we indemnify, hold harmless, and agree to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally our business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to our products. The term of these indemnification agreements vary. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the estimated fair value of these agreements is minimal.

Intellectual Property Rights

Our NMP22 BladderChek Test is a point-of-care device which may infringe the intellectual property rights of third parties. In August 2004, we entered into a license agreement, effective as of April 1, 2004, with one holder of such patent rights, Abbott Laboratories, and we are continuing to investigate other licensing arrangements covering our BladderChek Tests. We do not know whether we will be successful in securing licenses or waivers from all third parties that may claim rights to point-of-care device technology. If we are required to obtain additional licenses, we can not currently estimate the extent of any liabilities we may incur or whether future profit margins will be significantly affected by the arrangements we may negotiate.

License Agreements

a. MIT License Agreement

MIT has granted us a worldwide exclusive license to certain technology, which was extended when we obtained FDA approval of our first cancer diagnostic product in 1996, until the expiration of all patent rights. Pursuant to the license agreement, we pay royalties on the sales of products incorporating the licensed technology. We paid $34,764, $76,638 and $163,770 in royalties in the years ended December 31, 2003, 2004 and 2005, respectively.

b. Hybritech License Agreement

In August 1994, we entered into a non-exclusive license agreement with Hybritech, Inc. for the manufacture and sale of certain patented technology for immunometric assays using monoclonal antibodies. We are required to pay a royalty equal to 8% of net sales of licensed products subject to the license in countries where Hybritech, Inc. has a valid patent in effect. The last Hybritech, Inc. patent expires in 2008. We paid $0, $2,976 and $0 royalties in the years ending December 31, 2003, 2004, and 2005, respectively.

c. Abbott Laboratories License Agreement

In August 2004, we entered into a sublicense agreement with Abbott Laboratories, effective as of April 1, 2004, to license certain United States and foreign patent rights covering our BladderChek Test point-of-care product. We paid $227,538 and $363,721 in royalties in the years ended December 31, 2004 and 2005, respectively.

(5) Stockholders' Equity

(a) Sale of Common Stock, Preferred Stock and Warrants

In March 2003, we completed a private placement of 7.5% Convertible Debentures (the "Convertible Debentures") in aggregate subscription amount equal to $5 million and accompanying Warrants (the "March Warrants"). In connection with this private placement we issued warrants to purchase 784,314 shares of our common stock at an exercise price of $2.278 including a warrant to purchase 98,039 shares of common stock to a placement agent in connection with this transaction (see Note 6). These warrants are exercisable until March 2008. The exercise price of the warrants is adjustable down to the deemed issuance price of any subsequent dilutive issuances (subject to certain limited exceptions), and after the Convertible Debentures are no longer outstanding, the exercise price of the Warrants will be adjustable downward on a weighted-average basis upon any such subsequent dilutive issuance. On October 15, 2003 we sold common stock in a transaction which has been deemed to be a dilutive issuance under the terms of the March Warrants. As a result, the exercise price of the March Warrants was adjusted downward, and at December 31, 2003 these warrants were exercisable to purchase shares of our common stock at a price of $1.67 per share. On March 19, 2004 we sold common stock in a transaction which has been deemed to be a dilutive issuance under the terms of the March Warrants. As a result, the exercise price of the March Warrants was adjusted downward, and at

December 31, 2004 these warrants were exercisable to purchase shares of our common stock at a price of $1.35 per share. On March 4, 2005, we sold shares of Series A Convertible Preferred Stock in a transaction which has been deemed to be a dilutive issuance under the terms of the March Warrants. As a result, the exercise price of the March Warrants was again adjusted downward, and at December 31, 2005, these warrants were exercisable to purchase shares of our common stock at a price of $0.88 per share.

On October 15, 2003 we completed a private placement of 3,593,893 shares of our common stock at a price of $1.67 and warrants to purchase 1,257,861 shares of our common stock at a price of $2.45 per share for an aggregate consideration of $6,001,801 (before cash commissions and expenses of approximately $840,000). In addition, we issued warrants to various placement agents for a total of 546,553 shares at exercise prices ranging from $1.67 to $2.70. These warrants are valued at approximately $839,000. The warrants issued as part of this private placement are exercisable until October 15, 2008. None of these warrants has been exercised. The values of the warrants and common stock in excess of par value have been reflected in additional paid-in-capital.

On November 6, 2003, a distributor of our products in the Far East acquired our common stock and warrants as part of a strategic investment in Matritech. The transaction included 299,402 shares of our common stock at a price of $1.67 and warrants to purchase 104,790 shares of our common stock at a price of $2.45 per share for an aggregate consideration of $500,000 (before expenses of approximately $13,000). The warrants issued as part of this private placement are exercisable until November 6, 2008. None of these warrants has been exercised. The values of the warrants and common stock in excess of par value have been reflected in additional paid-in-capital. The terms of this private placement were essentially the same as those of the private placement that we completed on October 15, 2003.

On March 19, 2004 we completed a private placement of 4,858,887 shares of our common stock at a price of $1.35 per share and warrants to purchase 1,214,725 shares of our common stock at a price of $2.00 per share for aggregate consideration of $6,559,500 (before cash commissions and expenses of approximately $713,000). In addition we issued warrants to various placement agents for a total of 434,475 shares at an exercise price of $2.00 per share. These warrants are valued at approximately $560,000. The warrants issued as part of this private placement are exercisable until March 19, 2009. None of these warrants has been exercised. The values of the warrants and common stock in excess of par value have been reflected in additional paid-in-capital.

On March 4, 2005, we entered into a purchase agreement (the "Purchase Agreement") which provided for the sale through a private placement of an aggregate of 1,426,124 shares of our Series A Convertible Preferred Stock, par value $1.00 per share (the "Series A Preferred Stock") and the issuance to the investors of warrants to purchase 4,991,434 shares of our common stock at a price of $1.47 per share (the "2005 Warrants"). The Purchase Agreement provided for two closings (the "First Closing" and the "Second Closing") because we could not issue all shares of the Series A Preferred Stock that we agreed to sell without obtaining stockholder approval because the resulting Conversion Shares would exceed 20% of our outstanding common stock. On March 4, 2005, we completed the First Closing which consisted of 670,272 shares of Series A Preferred Stock and the 2005 Warrants to purchase 4,991,434 shares of our common stock, for an aggregate consideration of $5,898,394 (before cash commissions and expenses of approximately $610,000). In addition, we issued warrants to a placement agent for a total of 656,920 shares of common stock (with a value of approximately $562,000). Both the 2005 Warrants and the placement agent warrants (collectively the "Warrants") have an exercise price of $1.47 per share, became exercisable on September 5, 2005 and expire on March 4, 2010.

On June 20, 2005, we entered into a Mutual Termination and Release Agreement with the investors who were parties to the Purchase Agreement to terminate the obligations of all parties to consummate and complete the Second Closing. Accordingly, no additional shares of Series A Preferred Stock or warrants to purchase shares of our common stock will be issued in this private placement.

The holders of Series A Preferred Stock are entitled to a liquidation preference of $8.80 per share and have the benefit of covenants by us not to liquidate, merge, sell control or substantially all its assets, or amend the charter in any way adverse to the holders. We are obligated not to issue other capital stock that would be senior to or on a parity with the Series A Preferred Stock as to dividends or upon liquidation, not to have indebtedness in excess of $7,500,000 except in limited forms, and not to enter into or consummate a transaction which would result in the holders of all the voting power of our outstanding capital stock having less than a majority of voting power of a surviving entity after a merger, consolidation, share exchange or sale. Some of the holders of the Series A Preferred Stock may have the right to participate in subsequent financings completed on or before December 20, 2006. We are further required to reserve sufficient shares of common stock for issuance of all shares issuable upon conversion of the Series A Preferred Stock (the "Conversion Shares") and the exercise of the warrants and to use commercially reasonable efforts to continue the listing and trading of such common shares with the American Stock Exchange or another national stock exchange or stock market. The holders of Series A Preferred Stock are entitled to 6.56 votes for each share of Series A Preferred Stock held by them. The holders of Series A Preferred Stock shall vote together with the holders of common stock, except when our Certificate of Designations or Delaware law provide for a separate class vote.

Each share of Series A Preferred Stock was initially convertible into ten shares of our common stock. Both the Series A Preferred Stock and the 2005 Warrants have anti-dilution provisions. This means that if we issue any shares (subject to limited exceptions) at a price that is less than the initial conversion price of the Series A Preferred Stock ($.88 per common stock share) in the case of the Preferred Stock or less than the initial exercise price ($1.47 per common stock shares) in the case of the 2005 Warrants (a "Dilutive Issuance"), the conversion price of the Series A Preferred Stock or the exercise price of the 2005 Warrants, as applicable, will be adjusted downwards. There is a floor on the new conversion price and the new exercise price that could result from a Dilutive Issuance, in the case of the Preferred Stock a conversion price floor of $0.70 and in the case of the 2005 Warrants an exercise price floor of $1.34. As of December 31, 2005, 101,021 shares of Series A Preferred Stock had been converted into 1,010,210 shares of common stock. Our January 2006 financing was deemed to be a dilutive issuance resulting in an adjustment of the conversion price of the Series A Preferred Stock to $0.70 per share and an adjustment in the exercise price of the 2005 Warrants to $1.34 per share. At the time of this dilutive issuance, there were 569,251 shares of Series A Preferred Stock outstanding and an additional 1,463,788 shares of our common stock were reserved for conversion at the new conversion price. Because our stockholders did not approve a proposal which would have removed the floor on conversion and exercise prices for the Series A Preferred Stock and 2005 Warrants, there will be no further adjustment to these conversion or exercise prices.

The net cash proceeds of $5,288,000 from the First Closing, further reduced by the fair value of the placement agent warrants totaling $562,000, were allocated between the Series A Preferred Stock (approximately $844,000) and the 2005 Warrants (approximately $3,881,000). The value of the 2005 Warrants was calculated using the Black-Scholes pricing model with the following assumptions: dividend yield of zero percent; expected volatility of 85%; risk free interest rate of approximately 4% and a term of five years.

In connection with the issuance of the Series A Preferred Stock, we recorded a beneficial conversion feature of $1,627,000. A beneficial conversion feature is recorded when the consideration allocated to the convertible security, divided by the number of common shares into which the security converts, is below the fair value of the common stock into which the Series A Preferred Stock can convert at the date of issuance. The amount of the beneficial conversion feature has been immediately accreted as a deemed dividend because the preferred stock is immediately convertible. The value of the beneficial conversion feature has been reflected as an adjustment to the net loss attributable to common shareholders on our Consolidated Statement of Operations.

As part of the private placement, we entered into a Registration Rights Agreement committing to timely file a registration statement covering the resale of the conversion shares into which the Series A Preferred

Stock may be converted and the shares for which the 2005 Warrants may be exercised (the "Warrant Shares"). If we failed to timely file a registration statement, if the registration statement was not declared effective within certain time limits or if the registration statement does not remain effective, we would be obligated to pay liquidated damages in an amount equal to 1.5% of the consideration paid for the Series A Preferred Stock for each thirty day period during which the failure persists. In accordance with Emerging Issues Task Force ("EITF") Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled in a Company's Own Stock*, ("EITF 00-19"), a transaction which includes a potential for net cash settlement, including liquidated damages, of a derivative instrument, including warrants, requires that such derivative financial instruments be recorded at fair value as a liability and that subsequent changes in fair value be reflected in the statement of operations. We concluded that the Registration Rights Agreement liquidated damages provision applicable to the Warrant Shares met the definition of net cash settlement under EITF 00-19. In accordance with EITF 00-19, the fair value of the warrants of $4,271,000 was accounted for as a liability at March 4, 2005, the date of the First Closing, and the subsequent changes in the fair value of the 2005 Warrants were reflected on our Consolidated Statement of Operations as mark-to-market warrant adjustments. Transaction costs of $390,000 were allocated to the warrants and expensed upon closing of the transaction, offsetting subsequent mark-to-market warrant adjustments.

On April 18, 2005, we amended the Registration Rights Agreement to eliminate any obligation to pay liquidated damages with respect to a failure to maintain the effectiveness of a registration statement covering resale of the Warrant Shares. On May 9, 2005 the registration statement covering resale of the Warrant Shares became effective and the 2005 Warrants were reclassified as equity because there is no future potential for a net cash settlement with regard to the 2005 Warrants. The resulting mark-to-market adjustments (approximately $1,900,000) and the reclassification of the 2005 Warrants as equity are presented in our financial statements for the year ended December 31, 2005.

This sale has been deemed to be a dilutive issuance under the terms of our Convertible Debentures and our March 2003 Warrants. As a result, as of March 4, 2005, the Convertible Debentures became currently exercisable into 2,525,253 shares of our common stock at a price of $.99 per share, representing a current increase of 869,623 shares from the conversion terms of the Debentures at December 31, 2004, and the March 2003 Warrants became exercisable to purchase shares of our common stock at a price of $0.88 per share. We have calculated an additional debt discount in the first quarter of 2005 of approximately $442,000 based on the beneficial conversion feature of this debt. This charge is being amortized as interest expense over the remaining life of the Convertible Debentures.

A rollforward of warrant activity for 2004 is as follows:

Balance January 1, 2004	Additions	Balance December 31, 2004	Expiration Date	Exercise Price
200,000		200,000	July 2005	$2.50
222,077		222,077	December 2005	$2.30
784,314		784,314	March 2008	$1.35
1,257,861		1,257,861	October 2008	$2.45
61,377		61,377	October 2008	$1.67
359,390		359,390	October 2008	$1.84
125,786		125,786	October 2008	$2.70
104,790		104,790	November 2008	$2.45
	1,649,200	1,649,200	March 2009	$2.00
3,115,595	1,649,200	4,764,795		

A rollforward of warrant activity for 2005 is as follows:

Balance January 1, 2005	Additions	Subtractions	Balance December 31, 2005	Expiration Date	Exercise Price
200,000		(200,000)	—	July 2005	$2.50
222,077		(222,077)	—	December 2005	$2.30
784,314			784,314	March 2008	$0.88
1,257,861			1,257,861	October 2008	$2.45
61,377			61,377	October 2008	$1.67
359,390			359,390	October 2008	$1.84
125,786			125,786	October 2008	$2.70
104,790			104,790	November 2008	$2.45
1,649,200			1,649,200	March 2009	$2.00
	5,648,354		5,648,354	March 2010	$1.47
4,764,795	5,648,354	(422,077)	9,991,072		

(b) Stock Option and Purchase Plans

We have granted incentive and nonqualified options under our 1988, 1992 and 2002 option plans and the 1992 and 2002 Directors' Plans. All option grants, prices and vesting periods are determined by the Board of Directors. Incentive stock options must be granted at a price not less than the fair market value on the date of grant. Options vest at various rates over periods of up to four years and all options issued prior to mid-February 2005 expire ten years from the date of grant. In February 2005, the form of option agreement was changed to reduce the option term to seven years. 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 1,618,231 common shares available for future grants under existing option plans at December 31, 2005. The following table summarizes stock option activity:

	Number of Options	Exercise Price per Share	Weighted Average Exercise Price Per Share
Options outstanding, December 31, 2002	2,533,865	0.84 - 13.13	$4.52
Granted	237,500	1.75 - 2.54	2.08
Exercised	(250)	1.34	1.34
Terminated	(242,643)	1.44 - 7.88	2.27
Options outstanding, December 31, 2003	2,528,472	0.84 - 13.13	3.36
Granted	594,112	0.95 - 1.90	1.46
Exercised	(100,000)	0.84	0.84
Terminated	(433,738)	1.30 - 7.88	2.04
Options outstanding, December 31, 2004	2,588,846	$0.95 - $13.13	3.24
Granted	609,486	0.55 - 1.13	.88
Exercised	—	—	—
Terminated	(82,748)	0.89 - 3.63	1.80
Options outstanding, December 31, 2005	3,115,584	$0.55 - $13.13	$2.82
Options exercisable, December 31, 2005	2,523,431	$0.67 - $13.13	$3.27
Options exercisable, December 31, 2004	1,549,173	$1.16 - $13.13	$4.15
Options exercisable, December 31, 2003	1,388,307	$0.84 - $13.13	$4.26

	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
$ 0.55 - $ 0.84	115,700	6.60	$ 0.69	12,500	$ 0.67
0.85 - 1.16	536,786	8.58	$ 0.94	55,333	$ 1.08
1.17 - 2.00	635,766	7.56	$ 1.54	633,266	$ 1.54
2.01 - 2.85	1,071,494	5.98	$ 2.31	1,066,494	$ 2.31
2.86 - 4.34	292,219	4.82	$ 3.40	292,219	$ 3.40
4.35 - 6.69	42,325	3.84	$ 6.28	42,325	$ 6.28
6.70 - 10.63	391,294	1.00	$ 7.89	391,294	$ 7.89
10.64 - 13.13	30,000	0.44	$13.13	30,000	$13.13
Total	3,115,584	5.96	$ 2.82	2,523,431	$ 3.27

As discussed in Note 1, we accelerated the vesting of approximately 574,000 unvested stock options in December, 2005. This vesting acceleration has been reflected in the table above for number of options exercisable.

At December 31, 2004 we had accumulated payroll deductions of $6,226 for the issuance of 6,226 shares of common stock which were issued to employees under the Employee Stock Purchase Plan. Under this plan stock is sold at 85% of fair market value, as defined. Effective June 30, 2005 we terminated this plan.

(c) Reserved Shares

As of December 31, 2005 the following shares of common stock were reserved and available for future issuance:

Stock Option Plans	4,733,815
Exercise of warrants outstanding	10,226,366
Stock reserved for converting debentures	1,010,101
Stock reserved for preferred stock conversions	5,692,410
	21,662,692

The table above includes additional warrant and converting debenture shares which we are required to reserve and keep available under the terms of our Convertible Debenture.

(6) Convertible Debt and Notes Payable

Convertible Debt

On March 31, 2003, we completed a private placement of 7.5% Convertible Debentures in an aggregate subscription amount equal to $5 million and accompanying March Warrants for an aggregate of 784,314 shares of our common stock, including a Warrant for 98,039 shares issued to a placement agent in connection with this transaction (the "March Private Placement").

Upon issuance, the Convertible Debentures were convertible into 1,960,784 shares of our common stock at a conversion price of $2.55, but the conversion price is subject to downward adjustment (with certain limited exceptions) upon any dilutive issuances of our securities to an amount equal to 112% of the price at which such dilutive issuance is deemed to be made. These terms create the potential for issuance of additional shares of our common stock upon conversion of the Convertible Debentures. On October 15, 2003 we sold common stock in a transaction which has been deemed to be a dilutive issuance under the terms of the Convertible Debentures. As a result, at December 31, 2003, the Convertible Debentures were convertible into 2,673,797 shares of our common stock at a price of $1.87 per share, representing an increase of 713,012 shares from the conversion terms of the Convertible Debenture at March 31, 2003. We have calculated an additional benificial conversion charge totaling approximately $1,497,000 which is being treated as additional interest expense over the term of the debentures. On March 19, 2004 we sold common stock in a transaction which has been deemed to be a dilutive issuance under the terms of the Convertible Debentures. As a result, at December 31, 2004, the Convertible Debentures became convertible into 3,183,902 shares of our common stock at a price of $1.51 per share, representing an increase of 612,944 shares from the conversion terms of the debenture immeidately prior to the transaction. At December 31, 2004, the Convertible Debentures were convertible into 2,037,695 shares of our common stock at a price of $1.51 per share. At December 31, 2004, the March 2003 Warrants were exercisable to purchase shares of our common stock at a price of $1.35 per share representing a decrease in purchase price of $0.32 per share. We have calculated an additional beneficial conversion charge totaling approximately $1,339,000 which was recorded as an additional debt discount in the first quarter of 2004 and is being amortized over the remaining life of the debt. On March 4, 2005, we sold of Series A Convertible Preferred Stock in a transaction which has been deemed to be a dilutive issuance under the terms of the Convertible Debentures. As a result, the Convertible Debentures became convertible into 2,525,253 shares of our common stock at a price of $0.99 per share, representing an increase of 869,623 shares from the conversion terms of the debenture immedately prior to the transaction. At December 31, 2005, the

Convertible Debentures were convertible into 777,000 shares of our common stock at a price of $0.99 per share. We have calculated an additional debt discount in the first quarter of 2005 of approximately $442,000 based on the beneficial conversion feature of this debt. This charge is being amortized as interest expense over the remaining life of the Debentures. On January 13, 2006, we sold Secured Convertible Notes which were convertible into shares of our common stock at a conversion price of $0.65 per share and this transaction has been deemed to be a dilutive issuance under the terms of the Convertible Debentures. As a result, the Convertible Debentures became convertible into 790,305 shares of our common stock at a price of $0.73 per share (as of January 13, 2006), representing an increase of 207,555 shares from the conversion terms of the debenture immedately prior to the transaction.

The Convertible Debentures bear interest at the rate of 7.5% per annum, payable quarterly, and permit us, in certain circumstances, to make such interest payments in shares of common stock based on a 5% discount to the valuation of the common stock. The Convertible Debentures are redeemable in monthly installments equal to 1/26th of the aggregate subscription amounts paid for such Convertible Debentures, commencing March 1, 2004. The monthly redemption payments, subject to certain conditions, may also be made in shares of common stock based on a 10% discount to valuation.

The Convertible Debentures may become immediately due and payable at a premium of 120% of the outstanding principal amount plus accrued interest and damages in the event of default by us of certain covenants and also obligate us to pay damages and interest upon certain events. Events of default under the Convertible Debentures include, among other things, failure to remain listed on any of the Nasdaq Capital Market, New York Stock Exchange, American Stock Exchange or the Nasdaq Global Market, sale or disposition of our assets in excess of 33% of our total assets, failure to timely deliver stock certificates upon conversion, and default on our existing or future liabilities in excess of $150,000. In addition, we are prohibited from entering into obligations that are senior to the Convertible Debentures.

The proceeds of $5 million, less closing costs, were allocated between the Convertible Debentures (approximately $3,450,000) and the warrants (approximately $950,000) based on their relative fair values. The value of the warrants was calculated using the Black-Scholes pricing model with the following assumptions: dividend yield of zero percent; expected volatility of 110%; risk free interest rate of approximately 3% and a term of five years. The initial carrying value of the Convertible Debentures is being accreted ratably, over the term of the notes, to the $5 million amount due at maturity using the effective interest method. Total closing costs were approximately $600,000 and included a warrant issued to the placement agent valued at approximately $162,000 using the Black-Scholes pricing model with the same assumptions as the warrants above. The closing costs were allocated between the debt and the warrants resulting in $475,000 being ascribed to the debt as deferred offering costs and such costs included $132,000 related to the placement agent warrant. In addition, the difference between the effective conversion price of the debentures into common stock and the fair value of our common stock on the date of issuance of the debentures resulted in a beneficial conversion feature totaling approximately $199,000, which was calculated in accordance with EITF 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments.* This beneficial conversion feature was recorded as a debt discount and is being amortized using the effective interest rate over the life of the debt.

A summary of the Convertible Debt accounting is as follows:

Proceeds at closing in March 2003	$ 5,000,000
Less:	
Fair value ascribed to the warrants and recorded as debt discount	(950,000)
Fair value ascribed to placement agent warrant and recorded as debt discount	(131,000)
Beneficial conversion feature calculated on date of closing and recorded as debt discount	(199,000)
Additional beneficial conversion feature recorded in the fourth quarter of 2003 as debt discount	(1,497,000)
Additional beneficial conversion feature recorded in the first quarter of 2004 as debt discount	(1,339,000)
Additional beneficial conversion feature recorded in the first quarter of 2005 as debt discount	(442,000)
Cumulative principal payments made in stock	(4,231,000)
Add back:	
Cumulative amortization of debt discount and beneficial conversion features	4,424,000
Balance, December 31, 2005	$ 635,000

The debt discount is being amortized to interest expense using the effective interest method over the term of the debt. For the years ended December 31, 2003, 2004 and 2005, $644,000, $2,150,000 and $1,630,000, respectively, representing amortization of these costs is included in interest expense.

Debt issuance costs attributable to the Convertible Debentures, which totaled approximately $475,000, have been capitalized as other assets and other current assets on the consolidated balance sheet and will be amortized based on the effective interest method over the term of the debt. For the years ended December 31, 2003, 2004 and 2005, $146,000, $210,000 and $112,000, respectively representing amortization of these costs is included in interest expense. As of December 31, 2003, 2004 and 2005, unamortized debt issuance costs totaled $329,000, $119,000 and $7,000, of which $210,000, $112,000 and $7,000 is included in other current assets, respectively.

Minimum future payments on the debt are as follows:

Total payments	$ 776,000
Less: Portion related to periodic interest payments	(7,000)
Non-cash interest related to debt discount	(134,000)
Balance, December 31, 2005	635,000
Less current portion	635,000
Long-term portion	—

The Convertible Debentures allow the interest and principal to be paid in common stock at a discount to value, but only if (i) we are not in default under the terms of the Convertible Debentures, (ii) there is an effective registration statement covering such shares, (iii) our common stock is listed on one of American Stock Exchange, New York Stock Exchange, Nasdaq Global Market or Nasdaq Capital Market, (iv) we have provided proper notice of our election to make payments in stock and have made payment of all other amounts then due under the Convertible Debentures, (v) the issuance of such shares would not cause the holders to own more than 9.999% of the outstanding shares of our common stock, (vi) no public announcement of a change of control or other reclassification transaction has been made and (vii) we have sufficient authorized but unissued and unreserved shares to satisfy all share issuance obligations under the March 2003 financing. The

2004 and 2005 quarterly interest payments totaling $309,000 and $151,000 respectively, were made in stock and the monthly principal repayments of $192,000 each commencing in March 2004 (totaling $1,920,000 and $2,308,000 at December 31, 2004 and 2005) were made in stock and unless a default occurs, the remaining payments scheduled for both interest and principal are expected to be made in stock. Common stock issued during the years ended December 31, 2004 and 2005 was 1,927,722 and 3,467,029, respectively.

Notes Payable

In connection with the acquisition of ADL, we assumed certain debt obligations. At December 31, 2005, these obligations consisted of an $18,000 third-party demand note. The note bears interest at 5.2%, is due in monthly installments of $4,000 and is secured by trade receivables and inventory. A key Matritech GmbH employee will pay us all amounts due under the demand note and we will repay the demand note using those funds over the next year. We have recorded a corresponding asset for this employee receivable.

In July 2002, we entered into a term note for $410,000 with Citizens Bank of Massachusetts to finance an equipment purchase. The term note was payable over four years, bore interest at 1% plus the bank's prime rate (4% at December 31, 2003) and contained a covenant which required us to maintain a cash balance of $250,000 at all times. This note was collateralized by the capital equipment. This note was repaid in full during 2004.

In December 2005, we entered into a capital lease agreement to provide us with office equipment. The lease term is three years. The balance at December 31, 2005 was $5,800. Capital lease obligations are recorded as notes payable in our balance sheet.

Maturities of debt obligations are as follows:

2006	$649,000
2007	8,000
2008	2,000
Total	$659,000

(7) Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2004	2005
Payroll and related costs	$1,006,134	$ 747,625
Professional fees	193,089	222,057
Other	371,365	332,037
	$1,570,588	$1,301,719

(8) Income Taxes

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

	December 31,		
	2003	2004	2005
Income tax provision at federal statutory rate	(34.0)%	(34.0)%	(34.0)%
Permanent differences	4.00	8.49	3.00
Increase in tax resulting from State tax provision, net of Federal benefit	(6.0)	(5.15)	(5.0)
Increase in valuation allowance	36.0	27.23	15.0
Expiration of carryforwards	3.00	4.20	25.0
Other	(3.00)	(0.77)	(4.0)
Effective tax rate	0%	0%	0%

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

At December 31, 2005, we had federal and state tax net operating loss carryforwards ("NOL") of approximately $73,614,000 and $34,433,000, which will, if not used, expire at various dates from 2006 through 2025. Approximately, $5,607,000 of state NOLs and $2,335,000 of federal NOLs expired in 2005. We also have a NOL from our operation in Germany of approximately $1,795,000, which carries forward indefinitely. At December 31, 2005, we had federal and state research and experimentation credit carryforwards of approximately $1,641,000 and $1,070,000, respectively, which will, if not used, expire at various dates from 2006 through 2025. Based upon the Internal Revenue Code Section 382, changes in our ownership could limit the utilization of our tax attributes.

Our net deferred tax asset consists of the following:

	December 31,	
	2004	2005
Net operating loss carryforwards	$ 26,168,000	$ 27,870,000
Capitalized research and development expenses	5,728,000	5,452,000
Tax credits	2,392,000	2,347,000
Deferred revenue	411,000	374,000
Other temporary differences	233,000	98,000
Deferred tax asset	34,932,000	36,141,000
Valuation allowance	(34,932,000)	(36,141,000)
Net deferred tax asset	$ —	$ —

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

(9) Related Party Transactions

On November 6, 2003, a distributor of our products in the Far East acquired $500,000 of our common stock and warrants (see Note 5). We shipped approximately $130,000, $108,000 and $164,000 of product to this distributor during 2003, 2004 and 2005.

(10) Segment and Geographic Information

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

	Revenue					
	2003		2004		2005	
	$	%	$	%	$	%
	($ in 000's)					
Germany	$3,011	75%	$4,271	59%	$ 5,414	53%
United States	583	15	2,413	33	3,932	38
Japan	175	4	203	3	301	3
Europe (excluding Germany)	35	1	154	2	251	2
Rest of world	214	5	234	3	392	4
Total sales	$4,018	100%	$7,275	100%	$10,290	100%
Alliance and collaboration revenue (United States)	357		208		125	
Total revenue	$4,375		$7,483		$10,415	

Product sales by type are as follows:

	Revenue					
	2003		2004		2005	
	$	%	$	%	$	%
	($ in 000's)					
NMP22 products	$2,176	54%	$5,369	74%	$ 8,543	83%
Other products	1,842	46	1,906	26	1,747	17
Total sales	$4,018	100%	$7,275	100%	$10,290	100%

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

	Total Net Fixed Assets			
	2004		2005	
	$	%	$	%
	($ in 000's)			
United States	$854	93%	$805	91%
Germany	61	7	76	9
Total	$915	100%	$881	100%

(11) Supplemental Financial Disclosure

	Q1-04	Q2-04	Q3-04	Q4-04
	Unaudited ($ in 000's, except per share amounts)			
Revenue	$ 1,434	$ 1,682	$ 1,935	$ 2,432
Loss from operations	(2,090)	(2,437)	(1,988)	(1,853)
Net loss	(2,692)	(3,221)	(2,720)	(2,490)
Basic/diluted net loss per share	$ (0.07)	$ (0.08)	$ (0.06)	$ (0.06)

	Q1-05	Q2-05	Q3-05	Q4-05
	Unaudited ($ in 000's, except per share amounts)			
Revenue	$ 2,174	$ 2,644	$ 2,780	$ 2,818
Loss from operations	(2,165)	(2,035)	(1,675)	(1,795)
Net loss attributable to common shareholders	(3,723)	(1,384)	(2,168)	(2,218)
Basic/diluted net loss per share	$ (0.09)	$ (0.03)	$ (0.05)	$ (0.05)

(12) Subsequent Events

On January 13, 2006, we entered into a purchase agreement and related documents, pursuant to which we sold 15% Secured Convertible Promissory Notes maturing January 13, 2009 (the "Secured Convertible Notes"), which were initially convertible into 10,766,092 shares of our common stock, par value $.01 per share, and accompanying warrants to purchase up to 6,459,655 shares of our common stock ("Purchaser Warrants"), for an aggregate consideration of $6,997,960 (before cash commission and expenses of approximately $748,000). The Secured Convertible Notes are convertible into shares of our common stock at an initial conversion price of $0.65 per share of common stock. The Purchaser Warrants, which become exercisable on July 14, 2006 and expire on January 13, 2011, have an exercise price of $0.67 per share. Both the conversion price and the exercise price are subject to adjustment in the event of subsequent dilutive issuances. In addition we issued warrants to two placement agents for a total of 1,036,609 shares of our common stock ("Agent Warrants"). The Agent Warrants, which become exercisable on July 14, 2006 and expire on January 13, 2011, have an exercise price of $0.65 per share.

The Secured Convertible Notes allow for payment of both principal and interest in shares of our common stock, so long as stock payment conditions are satisfied. The effective conversion price for payments to be made in stock is the lower of the then conversion price, currently $0.65, or 85% of the 10 day volume weighted average price of common stock (the "10-day VWAP"). No payments are due on the Secured Convertible Notes prior to January 2007. Interest is payable quarterly, in arrears, after the initial first year's interest payment is made in January 2007, and principal payments of $291,582 per month (assuming no prepayment or conversion by any Note holder) are due monthly beginning in January 2007. We cannot issue any shares in conversion of Secured Convertible Notes, whether for a conversion initiated by the holders of the

Secured Convertible Notes or a repayment of a portion of the Secured Convertible Notes by us, at a price below $0.61 per share until after stockholder approval is received for payments below that price. The Secured Convertible Notes provide anti-dilution protection for the holders, but such protection is limited to a floor of the $0.61 closing sale price of the stock on the day before the closing until after stockholder approval is obtained.

We must meet all of the following stock payment conditions in order to make interest and principal payments on the Secured Convertible Notes in shares of common stock instead of cash: (i) one or more registration statements is effective and available for the resale of the shares required to be registered by the terms of a Registration Rights Agreement entered into in connection with the January 2006 financing; (ii) the shares of our common stock are designated for quotation or listed on the Nasdaq Capital Market, Nasdaq Global Market or AMEX and have not been suspended from trading on any of such exchanges or markets and no written notice of delisting by any of such exchanges or markets have been received and not resolved; (iii) issuance of the shares will not result in a Secured Convertible Note holder and its affiliates owning more than 9.99% of the outstanding shares of our common stock, unless waived by the holder; (iv) the number of shares to be issued to all holders on a specific payment date shall not exceed 10% of the trading volume (as reported by Bloomberg) of our common stock for the period of 20 consecutive trading days ending on the trading day immediately prior to such payment date; (v) our common stock is not selling at a price below $0.50 per share; (vi) the current price per share of the common stock delivered in payment is equal to or greater than $0.61, or we receive stockholder approval to allow issuances below that price; (vii) prior to receipt of that stockholder approval, the 10-day VWAP of our common stock is equal to or greater than the then-effective conversion price, which is $0.65 as of March 1, 2006; and (viii) we have not issued any notice relating to the redemption of any warrant(s) during the 30 day period immediately prior to the payment date. If we are unable to make payments due in stock because we have not received stockholder approval of payments below $0.61 per share, the interest rate on the Secured Converible Notes will be increased to 17% for the affected payments.

While the Secured Convertible Notes are outstanding, we have restrictions on incurring additional indebtedness (other than receivables financing not to exceed 80% of receivables and equipment purchase or lease financing not to exceed $200,000), as well as restrictions on payment of cash dividends and redemption of securities. Our obligations under the Secured Convertible Notes are secured by first priority liens, effective April 1, 2006, against certain assets related to our NMP22 product line. The security interest covers cell lines, equipment, inventory and general intangibles related to the NMP22 product line, as well as proceeds from the sale of the product line. We also entered into a contingent license agreement with the Collateral Agent, SDS Capital Group SPC, Ltd., granting license rights in the field of bladder cancer detection to some of our patents related to the NMP22 products, sublicense rights to patents licensed to us and used in connection with the NMP22 product line, and license rights to trademarks used exclusively in connection with the NMP22 product line.

We have granted the holders of the Secured Convertible Notes the right to participate in our future financing transactions if the holder has $250,000 or more of value of Secured Convertible Notes or shares into which the Secured Convertible Notes have been converted. These rights are subject to the prior right of holders of at least $495,000 of our Series A Convertible Preferred Stock ("Series A Preferred Stock") to participate in future financings closed on or before December 20, 2006. The holders of the Secured Convertible Notes who qualify for participation rights in our future financing transactions also have the right to exchange up to 50% of then-held principal value of their Secured Convertible Notes for participation in the transaction, subject to an overall restriction for all holders that limits them to an aggregate of 50% of each future financing transaction.

The Secured Convertible Notes require us to pay interest and liquidated damages and may become immediately due and payable in cash at a premium of 120% of the outstanding principal amount plus accrued

interest and damages in the event we default under their terms. Potential defaults would include, among other things:

- our failure to make payments as they become due;
- our failure to remain listed on any of the Nasdaq Capital Market, New York Stock Exchange, AMEX or the Nasdaq Global Market;
- our failure to have an effective registration statement available for resale of the shares;
- failure to timely remove restrictive legends from any stock certificates delivered upon conversion;
- our written notice or public announcement of the intention not to issue shares upon conversion;
- our making an assignment for the benefit of creditors, or applying for or consenting to the appointment of a receiver or trustee for a substantial portion of our property or business or that of any subsidiary;
- bankruptcy, insolvency or similar proceedings being filed by or against us or any subsidiary;
- a sale or disposition of substantially all our assets;
- our failure to pay our 2003 Convertible Debentures when due;
- our default on our existing or future liabilities in excess of $250,000; and
- a breach of any material term of any other transaction document we entered into with the purchasers of the Secured Convertible Notes.

In conjunction with the sale of the Secured Convertible Notes, we issued accompanying warrants (the "Purchaser Warrants") exercisable beginning on July 14, 2006 and expiring on January 13, 2011 to purchase up to 6,459,655 shares of our common stock at an exercise price of $0.67 per share. The Purchaser Warrants also provide anti-dilution protection for the holders, but such protection is limited to a floor of $0.61 until after stockholder approval is obtained for issuances below that price. We also issued warrants to two placement agents in connection with the January 2006 financing to purchase up to 1,036,609 shares of our common stock at an exercise price of $0.65 per share (the "Agent Warrants"). These Agent Warrants are exercisable beginning on July 14, 2006 and expiring on January 13, 2011 and have the same anti-dilution provisions as the Purchaser Warrants.

Under the terms of the transaction documents, we are obligated to file a registration statement covering the shares into which the Secured Convertible Notes may be converted and the shares for which the Purchaser and Agent warrants may be exercised and, once the registration statement is declared effective, to keep it available for resale of these shares ("Registration Rights"). We are also obligated to keep our stock listed for trading on AMEX, NYSE or Nasdaq. If we fail to timely register the shares we have committed to register, we may be subject to penalties, including payment of 1.5% of the consideration paid for the Secured Convertible Notes for each thirty day period of delay in registration. Further, we agreed to seek stockholder approval of an increase in authorized shares of our common stock and of the issuance of our common stock in satisfaction of our obligations under the Secured Convertible Notes or the Purchaser and Agent Warrants at a conversion price or exercise price below the $0.61 closing price of our common stock on the last trading day before the closing of the January 2006 financing. We intend to present these matters to our stockholders at our Annual Meeting of Stockholders to be held prior to June 15, 2006.

This sale has been deemed to be a dilutive issuance under the terms of our Convertible Debentures, accompanying March 2003 warrants, our Series A Preferred Stock and accompanying March 2005 warrants and some warrants previously issued to a placement agent. As a result, as of January 13, 2006 the Convertible Debentures became convertible at a price of $0.73 per share, and we reserved an additional 207,555 shares for payment of these Convertible Debentures. The exercise price of our March 2003 warrants was also adjusted to

$0.65 per share. As of January 13, 2006, our Series A Preferred Stock became convertible at a price of $0.70 per share, resulting in an increase of shares issuable upon conversion of 1,463,788, and the exercise price of the accompanying March 2005 warrants was adjusted to $1.34 per share. The exercise price of warrants granted in October 2003 and March 2004 to a placement agent to purchase an aggregate of 105,821 shares of our common stock were adjusted from $1.67 and $2.00 per share to $0.65 per share.

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.

The proceeds of $6,997,960, less closing costs, were allocated between the Secured Convertible Notes (approximately $4,019,000), the Purchaser and Agent Warrants ("Warrants") (approximately $1,488,000 based on relative fair value) and a registration rights liability (approximately $270,000 based on its full fair value). The value of the Warrants was calculated using the Black-Scholes pricing model with the following assumptions: dividend yield of zero percent; expected volatility of 68%; risk free interest rate of 4.14% and a term of five years. The registration rights liability represents the value associated with the potential cash penalty if we fail to register the shares into which the Secured Convertible Notes may be converted and for which the Warrants may be exercised and, once the registration statement is declared effective, to keep it available for resale of these shares and/or if our Common Stock is not listed or included for quotation on the Nasdaq Capital Market, the Nasdaq Global Market, the New York Stock Exchange or the American Stock Exchange ("Registration Rights Liability"). The Registration Rights Liability was recorded at its fair value as a liability with subsequent changes in fair value reflected in the statement of operations. The fair value of the Registration Rights Liability was determined using a probability weighted discounted cash flow technique based on the potential cash penalties. The initial carrying value of the Secured Convertible Notes is being accreted ratably, over its 3 year term, to the $7 million amount due at maturity using the effective interest method. Total closing costs were approximately $1,220,000 and included the Agent Warrants issued to the placement agents valued at approximately $472,000 using the Black-Scholes pricing model with the same assumptions as above. The closing costs were allocated between the Secured Convertible Notes, Warrants and Registration Rights Liability resulting in $866,000 being ascribed to the Secured Convertible Notes as deferred offering costs and such costs included $320,000 related to the Agent Warrants. Transaction costs of $34,000 were allocated to the Registration Rights Liability and expensed upon the closing of this transaction. In addition, the difference between the effective conversion price of the Secured Convertible Notes into common stock and the fair value of our common stock on the date of issuance of the Secured Convertible Notes resulted in a beneficial conversion feature totaling approximately $2,974,000 which was calculated in accordance with EITF 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments.* This beneficial conversion feature was recorded as a debt discount and is being amortized using the effective interest rate over the life of the Secured Convertible Notes.

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C. WILLIAM ZADEL (1,2,3)
FORMER CHAIRMAN AND CEO, MYKROLIS CORPORATION

1 Compensation Committee
2 Audit Committee
3 Nominating and Corporate Governance Committee

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PricewaterhouseCoopers LLP
125 High Street
Boston, MA 02110-1707
617-530-5000

TRANSFER AGENT

Registrar and Transfer Company
10 Commerce Drive
Cranford, NJ 07016
800-368-5948

LEGAL COUNSEL

Choate, Hall & Stewart LLP
Two International Place
Boston, MA 02110
617-248-5000

ANNUAL MEETING

June 9, 2006
9:00 a.m.
Sheraton Newton Hotel
320 Washington Street
Newton, MA 02458

FINANCIAL INFORMATION REQUESTS

Our Annual Report on Form 10-K, including financial statements, other financial and general information are available without cost. Such information can be obtained either by accessing the EDGAR database on the Securities and Exchange Commission website at www.sec.gov, on the Matritech website at www.matritech.com; or by writing to:

Investor Relations
Matritech, Inc.
330 Nevada Street
Newton, MA 02460

This Annual Report contains other forward-looking statements which are made pursuant to the safe harbor provisions of the Private Litigation Reform Act of 1995. Any statements in this Annual Report that are not statements of historical fact are forward-looking statements. These forward-looking statements are based on a number of assumptions, including our assessment of whether they are material, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, or developments in our business or industry, to differ materially from those indicated or anticipated in or implied by any forward-looking statement. Factors that may cause such differences or otherwise affect our business, results of operations and financial condition include, but are not limited to, those discussed in this Annual Report and in our other reports filed with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future results, but rather are based on management's current plans, estimates, opinions and projections. We assume no obligation to update forward-looking statements if assumptions or these plans, estimates, opinions or projections should change.

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