



THIRD WAVE<sup>®</sup>  
TECHNOLOGIES

ANNUAL  
REPORT **05**



# THIRD WAVE TECHNOLOGIES



Third Wave is a growing leader in molecular diagnostics—the use of advanced tools to directly detect DNA and RNA. We provide DNA and RNA analysis products to an expanding list of clinical, research and agricultural customers. We are dedicated to continuing to create value for our customers and shareholders by maximizing our key competitive advantages.

## CHEMISTRY

The Invader® chemistry is one of the few chemistries capable of performing molecular diagnostic testing. It provides accurate, scalable and simple analysis of nucleic acids—DNA and RNA—across a broad range of applications. We are continually translating new applications and enhanced capabilities of the Invader chemistry into further growth for Third Wave.

## PRODUCTS

We take the time to clearly understand the needs of our customers throughout our product development process. We work closely with thought leaders in molecular diagnostics to ensure that our products address unmet needs in the most valuable markets. By enabling earlier, more targeted patient interventions, our products produce better and more cost-effective health care outcomes.

## PEOPLE

We have a passion for making the best molecular diagnostic products and providing our customers with the best possible service. Extraordinarily talented and experienced people contribute in every area of our business. All of us are focused on creating the maximum value for our customers and shareholders.

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We are excited about our prospects for growth and value creation—for our customers and our shareholders. Our ability to create value is founded on an incredibly valuable asset: the Invader chemistry. It is one of the very few chemistries capable of performing molecular diagnostic testing—the use of advanced tools to directly detect DNA or RNA.

As we have built our product menu, the Invader chemistry has proven its broad applicability to a wide range of unmet needs in the molecular diagnostics market. As a result, our core business, clinical molecular diagnostics, continued to grow in 2005 and has grown at a compound annual rate of 30% since 2001. We launched two new products during 2005—our CFTR InPlex™ reagents and our Invader® UGT1A1 Molecular Assay, which received FDA clearance last summer. Third Wave is focused in 2006 on delivering best-in-class products to highest growth markets, the most valuable of which is the HPV market.

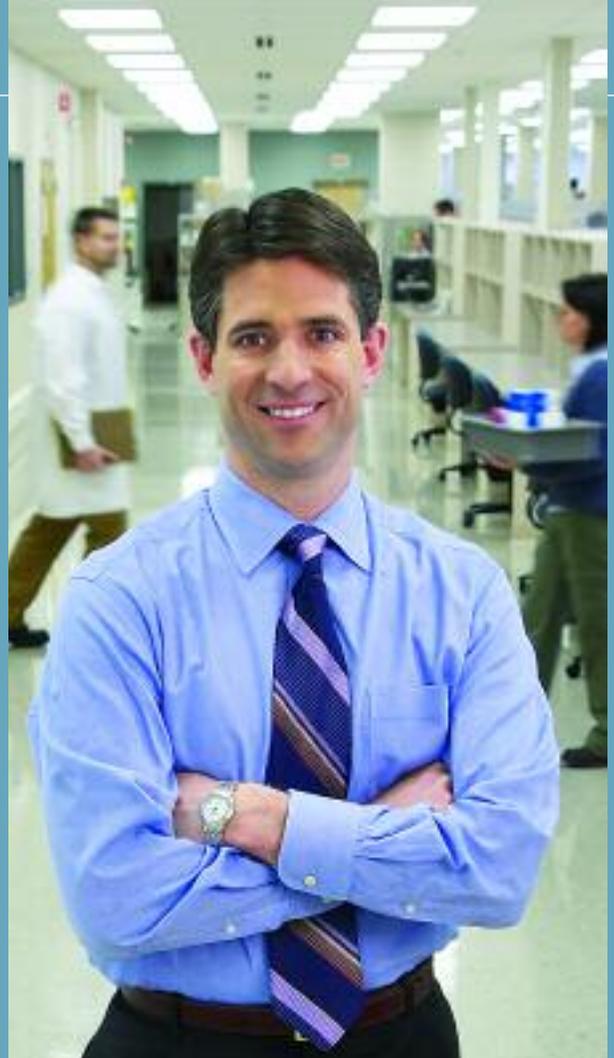
Because our Invader chemistry gives Third Wave unique access to these and other markets, we have worked diligently to protect it. In 2005, we won our patent infringement suit against Stratagene Corporation that resulted in an award of more than \$20 million to the company, another strong indicator of the value of our chemistry.

#### A WORLD OF OPPORTUNITIES

Our Invader chemistry, current product menu and focused pipeline all position Third Wave well to take advantage of the emerging market for molecular diagnostic testing.

The global molecular diagnostics market, currently estimated to be \$1.6 billion, is the fastest-growing segment of the \$29-billion global IVD market and is expanding at an annual rate of 15% to 25%. A key driver of the future growth of molecular diagnostic testing is the cost-effective means it provides to help control health care costs. Diagnostic testing represents 3% of all health care costs, but influences up to 70% of health care decisions, according to a report commissioned by the Advanced Medical Technology Association\*. Molecular diagnostic testing can improve health care quality and help control costs because of its ability to facilitate earlier, more precise patient interventions. As health care costs continue to rise—they are expected to double to \$4 trillion by 2015 in the United States alone—molecular diagnostic testing will play an increasingly important role in the delivery of cost-effective health care. Third Wave's Invader chemistry is one of just a few chemistries that enables molecular diagnostics, giving us a unique and enviable position from which to address this high-value, rapidly growing market.

\*The Lewin Group, Inc., *The Value of Diagnostics: Innovation, Adoption and Diffusion into Health Care*. July 2005.



**“There is a renewed energy at Third Wave and I am more confident than ever that Third Wave has a bright future ahead of it.”**

**kevin conroy**

PRESIDENT AND CHIEF EXECUTIVE OFFICER

#### DRIVEN BY THREE KEY PRIORITIES

**We aim to maximize our unique position and deliver outstanding value to our customers and shareholders through three key priorities:**

- **Driving sustained, recurring revenue growth from our current product menu**
- **Delivering best-in-class products to the highest growth market segments**
- **Investing in research and development to continually improve the Invader chemistry and enable Third Wave's entry into new markets**

## DRIVING SUSTAINED REVENUE GROWTH

Our clinical molecular diagnostic revenue continued to grow steadily during 2005. Our clinical customer base grew from 120 to 140 in 2005. We expect continued growth in our clinical molecular diagnostic business, as we leverage our market leadership in coagulation and cardiovascular marker testing and continue to drive penetration of our CFTR (cystic fibrosis transmembrane conductance regulator gene) InPlex™ reagents. We also are very pleased with the 2005 performance of our agricultural biotechnology, or Agbio, business, which provides diagnostic products to agricultural customers around the world, including four of the top five seed companies. It generated revenue growth of 66% from a small, but solid base, and we expect it to grow by 15% to 20% during 2006.

## DELIVERING BEST-IN-CLASS NEW PRODUCTS

We are committed to bringing new, high-value products to market as quickly as possible. The most valuable of these products is a human papillomavirus, or HPV, product for which we will seek FDA approval in 2007. The current global HPV market is more than \$150 million and is growing at over 30% a year. The global market opportunity could be \$1 billion a year. The potential market opportunity in the United States alone is more than \$500 million. We see an FDA-approved HPV product as an incredibly valuable opportunity for Third Wave. The financial impact of capturing even a small portion of the HPV market in 2007 would be significant for the company and our shareholders.

We are also working in 2006 to ensure Third Wave's continued leadership in pharmacogenetics. During 2005, we received FDA clearance for the Invader® UGT1A1 Molecular Assay, which identifies patients who may be at increased risk for adverse reactions to the chemotherapeutic Camptosar (irinotecan) by detecting variations in the UGT1A1 gene that have been associated with that risk. The clearance of our UGT1A1 product followed FDA-recommended changes to the Camptosar label to include dosing recommendations based on a patient's UGT1A1 genetic profile.

The FDA has recommended similar changes to the label of the blood thinner warfarin, a drug that is prescribed 22 million times a year in the United States alone. The dosing of warfarin is complex and time consuming, and genetic variations can cause intracranial and intestinal bleeding. Third Wave will submit an application to the FDA for a product that will help doctors determine the right dosage of the drug for their patients, minimizing those harmful drug reactions. We expect to launch a product for warfarin in 2006.

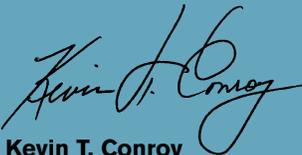
## INVESTING IN RESEARCH AND DEVELOPMENT

One of our most important strategic objectives is to invest aggressively in R&D to continually improve our Invader chemistry and enable our entry into new, high-growth markets like HPV and other women's health and oncology markets. We developed and implemented a 2006 budget that fixes our expense mix and ensures that we are making the necessary investment in the development of our HPV and other high-value products.

## THE FUTURE: RENEWED ENERGY

We have built a strong foundation for success at Third Wave. We have a broad menu of clinical molecular diagnostic products that will continue to drive growth. We aligned our product pipeline to fulfill unmet needs in high-growth markets like the HPV market that can provide maximum value. We are making the investment necessary to ensure that we bring high-quality products to those markets as quickly as possible. We built a strong management team with molecular diagnostic industry leaders from Genzyme, Bayer and Roche who are committed to execution and creating value for our customers and shareholders. Our sales organization is competing successfully against larger competitors.

All of these factors have created a renewed energy at Third Wave. I am more confident than ever that Third Wave has a bright future ahead of it.



**Kevin T. Conroy**

*President and Chief Executive Officer*

## CLINICAL MOLECULAR DIAGNOSTIC REVENUE

in millions of dollars



Third Wave has worked hard to build a strong foundation for success.

The Invader® chemistry is the cornerstone of our company. It was developed here, when the company was run from the end of a borrowed lab bench. Our chemistry gives Third Wave something that only a handful of companies have: a truly unique molecular diagnostic chemistry that provides access to the highest-growth diagnostic markets today. As a result, we have protected our most valuable asset aggressively, building strong patent protection around it and successfully defending it against infringement.

We have developed a broad menu based on our chemistry that includes products that have made Third Wave the market leader for coagulation and cardiovascular marker testing. All of our Invader products continue to earn praise from our customers for their performance, simplicity and ease of use.

Not only have we built a strong product menu for our customers, we continue to enhance the advantages the Invader chemistry provides them. Our Invader Plus chemistry offers all the advantages of the Invader chemistry plus the increased sensitivity and faster time to result provided by basic polymerase chain reaction, or PCR. Invader InPlex™ couples the performance of the Invader chemistry with 3M's microfluidic technology to extend the efficiency and ease of use of our chemistry.

We also have built a solid infrastructure to support the growth of our business as we bring new, high-value applications of the Invader chemistry to market. At the core of our management team are leaders with broad experience in the development, marketing and sales of molecular diagnostics. We have made an investment in

our sales and support organization, and our 35 sales and technical support representatives interact with our customers every day. Our outstanding commercial team has built a base of 140 recurring clinical lab customers, which collectively represent 80% of the molecular diagnostic laboratories in operation today.

Third Wave's unique Invader chemistry, product menu, outstanding commercial team and broad customer base are a strong foundation for the future success of the company.

#### CURRENT PRODUCT MENU

##### Analyte specific reagents (ASRs)\* for the following analytes or markers

- Factor V (Leiden), Factor II (prothrombin) and other coagulation/cardiovascular markers
- CFTR
- HCV
- HPV
- Others

##### Invader® UGT1A1 Molecular Assay IVD

- Identification of patients who may be at increased risk of adverse reaction to the chemotherapy Camptosar (irinotecan), used to treat colorectal cancer
- Preferred marketing relationship with Genzyme Genetics
- UGT1A1 gene is being examined for effect on other drugs
- Irinotecan is being evaluated for use in 15 indications other than colorectal cancer

\*Analyte Specific Reagent. Analytical and performance characteristics are not established.

### [ 2002 ] KEY EVENTS

● **2002:** Third Wave refocuses and begins its transition to the high-value, high-growth clinical molecular diagnostics market. The global molecular diagnostics market is estimated to be \$1.6 billion and growing by more than 15% a year.



● **2003:** Third Wave builds market-leadership position in coagulation and cardiovascular marker testing.

● **2004:** Third Wave launches ASRs for the hepatitis C virus.



● **APRIL 2005:** CFTR InPlex launched in partnership with 3M. Invader InPlex couples all the advantages of the Invader chemistry with the enhanced ease of use and efficiency of 3M's microfluidic technology.

### [ 2005 ]

● **AUGUST 2005:** FDA clears the Invader® UGT1A1 Molecular Assay. The test is used by oncologists to identify cancer patients who may be at increased risk of adverse reaction to the chemotherapy Camptosar (irinotecan).



“I was part of the team that invented the core Invader® chemistry and I still have a personal attachment to that project. It is exciting to see the Invader chemistry out in the marketplace, making an impact in clinical labs. Third Wave has always had talented, genuine people dedicated to delivering quality products. I’m looking forward to working with them to make further enhancements to our chemistry that allow us to enter new markets.”

jeff hall  
PRINCIPAL SCIENTIST

Third Wave is dedicated to utilizing our best-in-class Invader<sup>®</sup> chemistry to be the global leader in molecular diagnostics.

The advancement of our understanding of the connection between genetics and disease has helped give rise to the growth of *molecular diagnostics*—the direct detection and analysis of DNA and RNA. The molecular diagnostics market has evolved from one focused almost exclusively on products for infectious disease detection, which remains the market's largest segment, to one that also includes products to highlight an individual's predisposition to disease and to aid in the selection of the appropriate drug at the right dose.



Molecular diagnostics is the fastest growing segment of the \$29-billion worldwide IVD market, expanding by 15% to 25% a year. An increasing number of physician and other professional organizations are recommending specific molecular diagnostic applications as the standard of patient care.

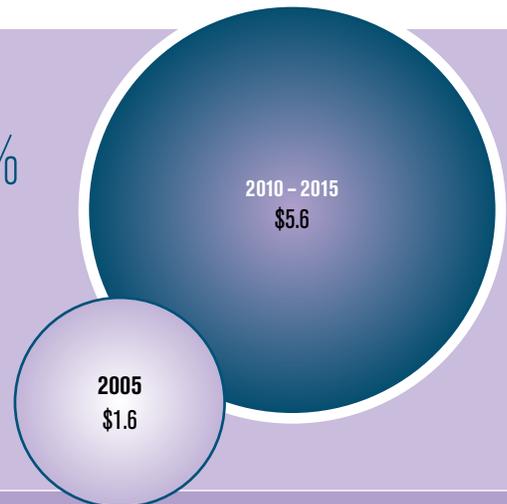
The market is also expected to grow rapidly as molecular diagnostics continue to demonstrate early detection and intervention advantages that lead to improved patient outcomes and reduced health care costs. It will continue to expand as physicians use molecular diagnostics to customize drug therapies for individual patients.

Third Wave owns one of the few chemistries capable of addressing the molecular diagnostics market and we are uniquely positioned to capture value in it. The 30% compound annual growth in our clinical molecular diagnostic revenue since 2001 is a clear demonstration of our ability to do that.

**GLOBAL MARKET: MOLECULAR DIAGNOSTICS**  
in billions of dollars

Molecular diagnostics is the fastest growing segment of the \$29-billion worldwide IVD market.

CAGR  
15 – 25%



A man in a dark suit, white shirt, and patterned tie is smiling. He is standing in front of a blue background with white text. The text reads "THIRD WAVE" at the top, "MOLECULAR DIAGNOSTICS" in the middle, and "SUPERIOR MOLECULAR SOLUTIONS" at the bottom. The text is slightly blurred and has a glowing effect.

THIRD WAVE  
MOLECULAR DIAGNOSTICS  
SUPERIOR MOLECULAR SOLUTIONS

“I hear consistently from our customers that the Invader<sup>®</sup> chemistry provides them with the peace of mind that they are delivering high-quality results to the physicians they serve each and every day. They also tell me that our chemistry is easy to implement in their laboratories. As a result, there is growing excitement within the clinical lab community about our current product menu and the products we have in our pipeline.”

[ john bellano ]  
VICE PRESIDENT, SALES

There are a number of unmet needs in high-value, high-growth segments of the molecular diagnostic market. We have instituted a rigorous, disciplined process for assessing all of these opportunities that focuses resources only on those that have the highest potential value.

The clearance of our Invader® UGT1A1 Molecular Assay by the FDA during 2005 is a testament to our commitment to leadership in pharmacogenetics. Our next product for this emerging market is one that could be used in conjunction with the prescription of warfarin.

Warfarin and other coumarin-based blood thinners are mainstays in managing and preventing blood clotting. Warfarin is prescribed 22 million times a year in the United States alone. But the dosing for the drug is complex and time-consuming, and genetic variation can cause adverse reactions to it, including intracranial and intestinal bleeding. The reagents we are building will help doctors determine the right dosage of warfarin for their patients, decreasing the complexity of dosing and reducing the possibility of adverse drug reactions. While the market for pharmacogenetics products is emerging, we know that there are more than 300,000 new prescriptions written for these blood thinners each year in the United States.

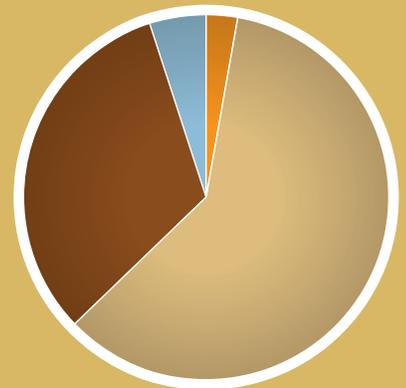
The market for CFTR testing, currently estimated to be \$80 million globally, continues to grow. We plan to submit our CFTR InPlex™ to the FDA for clearance in 2006, as we work to expand the company's presence in this important market. The CFTR InPlex product combines the performance and the ease of use of our Invader chemistry with 3M's microfluidic technology. It will enable our customers to benefit from the resulting speed-to-result, efficiency and ease-of-use advantages.

Another growth opportunity for Third Wave is our new Universal Invader Plus program. This program will enable our customers to design, build and optimize their own Invader Plus assays based on their unique interests. It allows Third Wave to expand access to the Invader chemistry outside of our standard product menu and empower our customers to develop their own Invader assays. We anticipate launching this program by the end of 2006.

We also are excited by opportunities outside the U.S. clinical lab market. Third Wave recently announced the formation of a joint venture with Mitsubishi Corporation, through Mitsubishi's 14% investment in Third Wave Japan, to accelerate the development and commercialization of molecular diagnostics in Japan and throughout the Asia-Pacific region. Products for hepatitis B and C viral load and genotyping, human papillomavirus, and mycobacterium are in planning or development. Third Wave will have worldwide rights outside the Asia-Pacific region to any new product developed by Third Wave Japan.

**MOLECULAR DIAGNOSTICS:  
A HIGH-GROWTH MARKET**

- **Cancer**  
3% of market  
CAGR 50%
- **Infectious Disease**  
60% of market  
CAGR 8%
- **Blood Processing**  
32% of market  
CAGR 20%
- **Genetics**  
5% of market  
CAGR 25%



**PRODUCT CANDIDATES**





“Our management team has established a clear strategic focus for Third Wave. We strive to bring a heightened awareness to our customers’ needs and the highest-growth markets. There are great short- and long-term opportunities to grow our business. Our current product pipeline, including HPV and warfarin, has the potential to influence both present and future patient management strategies. It is a unique experience to be part of building something that will change the practice of medicine, while continuing to expand the company’s product pipeline and revenue potential.”

**jorge garces phd**

VICE PRESIDENT, PLATFORM & PRODUCT DEVELOPMENT

Our most valuable product under development is one for the detection of the human papillomavirus, or HPV—the virus that causes virtually all cases of cervical cancer. We anticipate submitting the product to the FDA in 2007 for approval.

Today's global HPV testing market is more than \$150 million, growing at over 30% a year, with a total global market opportunity of \$1 billion. The potential market opportunity in the United States alone is projected to be \$500 million a year. But only a portion of women who could be tested for HPV receives the test today.

HPV, a double-stranded DNA virus, is the most common sexually-transmitted viral infection in the United States. There are more than 100 unique types of HPV, but less than 20 of them can increase a women's risk of cervical cancer. Cervical disease progresses very slowly to cancer and early, accurate detection of high-risk HPV types allows physicians to identify those women who are at greater risk for progressing to invasive cancer and to manage them more carefully.

The Pap test remains the primary means of screening women for cervical disease. More than 60 million Pap tests are performed each year in the United States alone. Despite its widespread use, the ability of the Pap test to detect precancerous and cancerous cells is limited in some cases. Physicians now routinely use HPV testing to help resolve the roughly 5% of Pap tests with ambiguous results. They also are beginning to use HPV testing as a complement to the Pap test for women age 30 and over. The use of HPV testing in these two settings is now supported by patient management guidelines published by medical professional organizations, including the American College of Obstetricians and Gynecologists, and the American Society for Colposcopy and Cervical Pathology.

Third Wave's top product priority is bringing its best-in-class HPV product to market. We are actively managing our costs to ensure that we are investing as aggressively as we can in the development and clinical trials for this valuable product. We have worked, as we always do, with our customers, collaborators and thought leaders in the field to ensure that our product fills the unmet needs of today's HPV testing market. We are confident and excited about the HPV product that we plan to submit to the FDA.

HPV is an incredibly valuable, long-term opportunity for Third Wave. The financial impact of capturing even a small portion of the HPV market in 2007 would be significant for the company and our shareholders. All of us at Third Wave are focused on completing the submission to the FDA, getting the product to market and maximizing its value.

Today's global HPV testing market is more than \$150 million, growing at over 30% a year, with a total global market opportunity of \$1 billion.

**CURRENT GLOBAL HPV MARKET**  
in millions of dollars

**Market Opportunity**

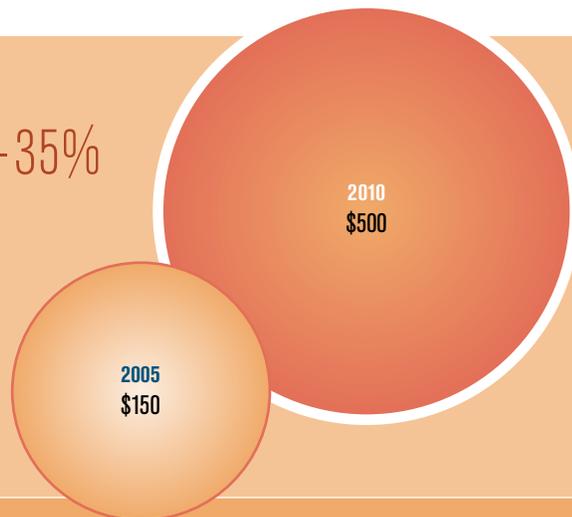
Total global market opportunity: \$1 billion  
Total U.S. market opportunity: \$500 million or ~35 million tests annually  
Market 15 - 20% penetrated

CAGR  
30-35%

**Third Wave Advantages**

- Specificity
- Sensitivity
- Simple workflow
- Significant hands-off time

**FDA submission: 1H 2007**





“As part of the research and development team, I have led the development of multiple products. I know the people at Third Wave are committed to providing new and better solutions for molecular diagnostics. The most recent display of that commitment is the development of our HPV product. There is large revenue potential for this product and it will provide significant value to the company, to our customers and the patients they serve. We are dedicated to bringing this and other valuable products to the marketplace.”

**marilyn olson phd**  
DIRECTOR, PRODUCT DEVELOPMENT

Third Wave is committed to maximizing value for our customers and shareholders.

- Our patented Invader® chemistry, one of the few molecular diagnostic chemistries, gives us unique access to the high-value, rapidly-growing molecular diagnostics market
- Our broad menu of molecular diagnostic products will continue to drive growth. Already the market leader in coagulation and cardiovascular marker testing, we are positioned for leadership in pharmacogenetics
- Our product pipeline is focused on the highest-value molecular diagnostic markets, including HPV and women's health, pharmacogenetics, and infectious disease
- Our growing businesses outside of the U.S. clinical molecular diagnostic market are contributing to overall revenue growth. These businesses include Agbio and Third Wave Japan, a joint venture with Mitsubishi Corporation

Our mission is simple: to utilize our best-in-class Invader chemistry to be a global leader in molecular diagnostics. We have never been so well positioned to accomplish that mission.



[ third wave ]

MADISON, WISCONSIN

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

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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: 000-31745

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THIRD WAVE TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

502 S. Rosa Road, Madison, WI  
(Address of principal executive offices)

39-1791034

(I.R.S. Employer  
Identification No.)

53719

(Zip Code)

(888) 898-2357

(Registrant's telephone number, including area code)

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

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

Common stock, \$.001 par value per share  
preferred stock purchase rights  
(Title of Class)

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 file 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 the 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. Yes  No

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 filer" 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

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate), computed by reference to the last sale price of the common stock of the registrant on June 30, 2005, as reported by the Nasdaq Stock Market, was \$153,941,523.

As of the close of business on March 1, 2006, the registrant had 41,516,877 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on June 13, 2006.

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**THIRD WAVE TECHNOLOGIES**  
**FORM 10-K**  
**FOR THE Year Ended December 31, 2005**  
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## FORWARD-LOOKING STATEMENTS

This Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. When used in this Form 10-K, the words “believe,” “anticipates,” “intends,” “plans,” “estimates,” and similar expressions are forward-looking statements. Such forward-looking statements contained in this Form 10-K are based on management’s current expectations. Forward-looking statements may address the following subjects: results of operations; customer growth and retention; development of technologies; losses or earnings; operating expenses, including, without limitation, marketing expense and technology and development expense; and revenue growth. We caution investors that there can be no assurance that actual results, outcomes or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, among others, our limited operating history, unpredictability of future revenues and operating results, competitive pressures and also the potential risks and uncertainties set forth in the “Overview” section of Item 7 hereof and in the “Risk Factors” section of Item 1A hereof.

You should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission. Except as required by law, we undertake no obligation to update any forward-looking statements.

In this Form 10-K, we refer to information regarding our potential markets and other industry data. We believe that all such information has been obtained from reliable sources that are customarily relied upon by companies in our industry. However, we have not independently verified any such information.

In this Form 10-K, the terms “we,” “us,” “our,” “Company” and “Third Wave” each refer to Third Wave Technologies, Inc. and its subsidiaries, unless the context requires otherwise.

In the United States, our registered trademarks are Third Wave®, Cleavase®, Invader®, InvaderCreator®, Cleavase and Invader are registered in Japan, Germany, the UK and France. Trademark applications are pending in the United States for Invader® Plus™, InPlex™, and Inrange™.

## PART I

### ITEM 1. BUSINESS

#### OVERVIEW

Third Wave Technologies, Inc. develops and markets molecular diagnostics for a variety of DNA and RNA analysis applications, providing our clinical, research and agricultural customers with superior molecular solutions. Third Wave’s products are based on our proprietary Invader® chemistry. It is a novel, molecular chemistry that we believe is easier to use, more accurate and cost-effective, and enables higher throughput compared to other methods of DNA and RNA analysis. Third Wave was incorporated in California in 1993 and reincorporated in Delaware in 2000.

We believe the market of greatest application and commercial opportunity for Third Wave’s Invader chemistry is clinical molecular diagnostics. We estimate that this market is approximately \$1.4 billion worldwide today and will be growing to \$2.4 billion worldwide by 2008. Within this market, there are a number of diverse segments for which the Company’s chemistry is well suited, including genetics and pharmacogenetics, women’s health, infectious disease and oncology. In addition to the molecular diagnostics market, the utility of the Invader chemistry extends to research, agricultural and other applications.

#### THIRD WAVE MISSION AND CORPORATE STRATEGY

Third Wave’s mission is to be a leading provider of superior molecular solutions. The Company seeks to achieve its mission by continuing to convert its proprietary Invader® molecular chemistry into valuable molecular diagnostic products.

We have implemented a strategy to:

- Grow our U.S. clinical molecular diagnostic revenue through our expanding product menu by using our strong U.S. distribution and thought-leader networks.
- Continue to expand our pipeline of molecular diagnostic products and enhance our product capabilities.
- Partner when appropriate to optimize our opportunities in molecular diagnostics and in markets where the Invader chemistry can create unique competitive advantages.

## TECHNOLOGY

### *Invader Chemistry*

Invader chemistry is a simple and scalable DNA and RNA analysis solution designed to provide results more quickly, increase throughput, and lower costs. It is an isothermal, DNA-probe-based reaction that detects specific genomic sequences or variations.

The performance and flexibility of Invader chemistry can be coupled with the sensitivity of a rudimentary form of polymerase chain reaction whose patents have expired. The Company calls this combination Invader Plus and believes that it will bring the advantages of both chemistries to its customers, enabling them to perform molecular testing more easily and more rapidly.

Third Wave has developed, and will to continue to develop, a line of clinical molecular diagnostic products based on its Invader chemistry. Clinical applications of the Invader chemistry include detecting genetic variation associated with inherited conditions such as cystic fibrosis, hemostasis and cardiovascular risk factors, and those associated with drug efficacy and adverse drug reactions. They also include confirming diagnosis, quantifying viral load and genotyping for infectious diseases such as hepatitis B and C, and for detecting human papilloma virus (HPV) strains. We have received in vitro diagnostic device clearance from the U.S. Food and Drug Administration for our Invader UGT1A1 Molecular Assay. The Invader UGT1A1 molecular assay is cleared for use to identify patients who may be at increased risk of adverse reaction to the chemotherapy drug Camptosar® (irinotecan) by detecting and identifying specific mutations in the UGT1A1 gene that have been associated with that risk. Camptosar, marketed in the United States by Pfizer, Inc., is used to treat colorectal cancer and was relabeled recently to include dosing recommendations based on a patient's genetic profile.

In addition to the Company's growing menu of clinical products, there are a number of other Invader chemistry applications, including research, agriculture, and other potential industrial applications, including food and water testing.

## INDUSTRY BACKGROUND

Prior to the late 1990s, many diagnostic testing methods had limited accuracy and served primarily as guides to analysis. This is changing with the emergence of nucleic acid testing, also referred to as NAT or molecular diagnostic testing.

Nucleic acid testing is the direct analysis of DNA or RNA. It is accomplished through genotyping, determining whether a variation or series of variations are present in an individual, or gene expression analysis, determining the level of activity of a specific gene by quantitating the messenger RNA, or mRNA, it is producing. The advantage of this testing method is that it directly detects DNA or RNA rather than monitoring antigens or antibodies. NAT was initially used primarily for HIV and blood screening, but it is rapidly displacing conventional testing methods as the industry standard for a variety of applications. For example, the need to perform accurate and high-throughput blood screening and tests for infectious diseases/viral loads has resulted in NAT replacing immunotechnology (immunoassays) as the solution of choice among many clinical labs.

Ongoing scientific research has helped determine that a majority of human diseases have genetic components. The monumental mapping and sequencing of the entire human genome, through the Human Genome Project and subsequent research initiatives, are being translated into precise clinical applications to diagnose and treat disease. As a result, hundreds of molecular diagnostic tests based on NAT technology are now being used to identify

variations in DNA sequence to detect disease or highlight genetic predispositions. Furthermore, researchers' continuing progress in understanding disease and definitively linking particular diseases to an individual's DNA and RNA have caused key medical thought leaders to introduce new screening guidelines that incorporate NAT.

The availability of the human genome sequence, combined with an ever-growing list of known variations in DNA sequence and advances in our understanding of the cause and progression of disease, will likely result in the emergence of additional NAT applications. As a result, we believe that a significant increase in demand for gene-based tests will occur in the coming years.

**LIMITATIONS OF CONVENTIONAL METHODS VERSUS THE THIRD WAVE SOLUTION**

A limited number of chemistry platforms are presently capable of performing NAT, including the following:

<u>Name</u>	<u>Platform</u>	<u>Status</u>
PCR . . . . .	Target Amplification	Most commonly used technology
TMA/NASBA . . . . .	Target Amplification	Market leader for blood screening
Hybrid Capture . . . . .	Signal Amplification	Currently used primarily for HPV testing
Ligation . . . . .	Signal Amplification	Primarily used in cystic fibrosis testing
INVADER® . . . . .	Signal Amplification	Adoption across multiple applications
Invader Plus™ . . . . .	Target/Signal Amplification	New capability for numerous applications

Many of today's methods for analyzing nucleic acids are based on hybridization in combination with polymerase chain reaction ("PCR").

We believe the Invader and Invader Plus chemistries offer competitive advantages compared to the other forms of NAT, including:

- Increased Accuracy — In the study submitted to the FDA as part of the Company's application for clearance of its Invader UGT1A1 Molecular Assay, it was 100% accurate compared to DNA sequencing, the standard for genotype determination.
- Ease of Use — Invader products are extremely easy to use for technicians of any skill level. Assay setup requires a simple addition of the reagents to the prepared sample and can be completed with minimal hands-on time. During the incubation at a single temperature, technicians are free to perform additional duties.
- Flexibility/Scalability — The Invader chemistry is highly scalable, allowing any Clinical Laboratory Improvement Amendments (CLIA)-high complexity lab, regardless of size, to take advantage of its benefits.
- Throughput — The Invader chemistry offers customers a higher throughput potential than other methods, providing cost and time-saving benefits.

**PRODUCTS AND PRODUCT CANDIDATES**

Third Wave has applied its proprietary Invader® chemistry to a number of molecular diagnostic, research and other applications. The Company has a pipeline of new products under development, which it anticipates releasing during 2006 and beyond, and is assessing the technical feasibility and commercial viability of a number of other applications.

*Molecular Diagnostics*

**PRODUCTS ON THE MARKET — UNITED STATES**

*InVitro Diagnostic (IVD) Devices*

- Invader UGT1A1 Molecular Assay

*Analyte Specific Reagents (ASRs)*

- Hepatitis C virus (HCV)

- Cystic Fibrosis Transmembrane Conductance Regulator gene (CFTR)
- Human Papilloma virus (HPV)
- Connexin 26
- Factor V (Leiden)
- Factor II (prothrombin)
- Methylene tetrahydrofolate reductase (MTHFR gene)
- Apolipoprotein E (ApoE gene)

## **PRODUCTS ON THE MARKET — EUROPEAN ECONOMIC AREA (EEA)**

### ***In Vitro Diagnostic Devices — CE Mark***

- Factor V Leiden (G1691A)
- Factor II (FII G20210A)
- Methylene tetrahydrofolate reductase (MTHFR) (C677T)
- Methylene tetrahydrofolate reductase (MTHFR) (A1298C)
- Apolipoprotein E (ApoE) (C112R)
- Apolipoprotein E (ApoE) (R158C)
- Plasminogen Activator Inhibitor-1 (PAI-1) (4G/5G)
- Platelet Glycoprotein IIIa (PL A1/A2) (Leu 33 Pro, T1565C)
- Connexin 26 (Gap Junction Beta 2 gene; 35delG)
- Connexin 26 (Gap Junction Beta 2 gene 167delT)

## **PRODUCTS IN DEVELOPMENT OR BEING ASSESSED FOR TECHNICAL FEASIBILITY AND COMMERCIAL VIABILITY**

- HCV viral load
- Additional HPV offerings
- Additional CFTR offerings
- Coumarin (drug metabolism markers)
- Chlamydia
- Gonorrhea
- Hepatitis B virus
- Various additional CYP450 products (identification of genes associated with drug response)

The Company also has developed a number of DNA and RNA analysis products for the research and agricultural biotechnology markets.

## **MANUFACTURING**

We currently manufacture products at our facility in Madison, Wisconsin. We have scalable manufacturing systems, and we possess the expertise necessary to manufacture our current products. We currently have sufficient manufacturing capacity to meet our customer requirements. However, key components of our products may be sourced from a single supplier or a limited number of suppliers. Specifically, oligonucleotides for many of our

research use only products are sourced from a single supplier. In addition, some of the components incorporated into our products may be proprietary and unavailable from secondary sources. See Part I, Item 1A — Risk Factors.

We have registered the facility used for manufacturing our clinical products with the U.S. Food and Drug Administration, or FDA, as a Device Manufacturer and we believe we are in substantial compliance with the FDA's quality system requirements or QSRs. We have also achieved ISO 13485:2003 Certification, a stringent, globally-recognized standard of quality management for medical device manufacturers.

We also outsource the manufacture of select components for the microfluidics card format and components of certain assays intended for research applications. We work closely with the vendors of these components to optimize the manufacturing process, monitor quality control and ensure compliance with our product specifications.

## **MARKETING AND SALES**

We currently market and sell our products in the United States through a combination of direct sales personnel who are focused primarily on the clinical market, and through collaborative relationships. Our clinical sales force is comprised of 33 direct sales representatives and technical support personnel. We plan to increase our sales force as market demand requires. The clinical sales force targets high-volume clinical and reference laboratories that meet the criteria for highly-complex CLIA laboratories.

We have more than 130 clinical testing customers in the United States and we serve most major clinical laboratories that perform molecular testing. During 2005, the majority of our product sales were to domestic clinical laboratories.

Our products for the research market are sold primarily through collaborative relationships with research institutions and pharmaceutical companies focused on the life sciences in humans, plants and animals. We also appear at industry trade shows in connection with our marketing efforts.

Third Wave has established a strong and direct presence in Japan. In 2002, we established a wholly-owned subsidiary for the purpose of working more directly with our customers, collaborators and distributors in the Japanese market. We have two employees based in Japan.

Our customer base is dominated by a small number of large clinical-testing laboratories (Quest Diagnostics, Inc., Specialty Laboratories, Inc., Mayo Medical Laboratories, Kaiser Permanente, and Berkeley Heart Laboratories,) and research customers (University of Tokyo/RIKEN and Pioneer Hi-Bred International, Inc.). If we are unable to maintain current pricing levels and/or volumes with these customers, our revenues and business may suffer materially. See Part I, Item 1A — Risk Factors.

We intend to continue to pursue domestic and international market opportunities through a combination of direct sales, distribution arrangements and collaborative relationships. In 2004, Third Wave entered into a limited-term distribution arrangement for a limited number of its products in the European market with Innogenetics, N.V.

For a description of our industry segment and our product revenues by geographic area, see Note 12 of the Notes to the Consolidated Financial Statements included under Item 8 of this Form 10-K. As described in this Note, in 2005 we derived approximately 27% of our product revenues from sales to international end-users. The majority of our international sales were to a major Japanese research institute for use by several end-users. Our international sales are subject to customary risks associated with international transactions. See Part I, Item 1A — Risk Factors.

Our business is generally not seasonal.

## **COLLABORATIVE RELATIONSHIPS**

Our business involves collaborations with clinical laboratory companies, instrument companies, pharmaceutical companies and academic institutions. We have entered into a number of collaboration agreements and continue to assess additional relationships for the supply, distribution and development of our products. The following is a summary of our principal collaborative relationships.

## **BML**

In December 2000, Third Wave entered into a development and commercialization agreement with BML, Inc., (“BML”), one of the two largest clinical reference laboratories in Japan. Through this agreement, the companies are collaborating to develop and commercialize molecular diagnostics for infectious disease, genetic testing and pharmacogenomics. Under the agreement, Third Wave develops mutually agreed upon clinical assays, and BML reimburses development expenses and purchases final product. As provided by the terms of the agreement, Third Wave develops and supplies BML with clinical reagents at preferential prices. Third Wave has certain rights to commercialize the developed assays worldwide; however, such commercialization rights are limited in Japan depending on BML’s intellectual property surrounding the specific assay. Further, BML has the right to negotiate the terms and conditions under which BML would have the right to use the developed assays for providing clinical testing services in Japan. The term of the agreement is until December 31, 2009.

## **MONOGRAM BIOSCIENCES (formerly ACLARA BIOSCIENCES, INC.)**

In October 2002, Third Wave entered into limited license and supply agreements with ACLARA BioSciences, Inc., which was acquired by Monogram Biosciences (formerly Virologics, Inc.) in December 2004. Under this agreement, Monogram has nonexclusive rights to incorporate our proprietary Invader® chemistry and Cleavase® enzyme with Monogram’s eTag™ technology platform for multiplexed gene expression applications for the research market.

In exchange for the license, Monogram made up-front payments and will continue to make royalty payments based on sales of the Monogram product. The license, supply and Invader Creator software access agreements supercede the research, development and collaboration agreement between the parties that was announced and executed in October 2001.

## **UNIVERSITY OF TOKYO/RIKEN**

In 2003, Third Wave entered into a collaboration with the University of Tokyo to support the genetic research efforts directed by Dr. Yusuke Nakamura, group director of the Research Group for Personalized Medicine at RIKEN and director of the Genome Center at the University of Tokyo. Dr. Nakamura is widely regarded as one of the world’s leading genetic researchers and he was the leader of the Japanese portion of the International Haplotype Map (HapMap) Project as well as other large-scale genotyping projects.

The HapMap Project, which concluded in early 2005, was a worldwide initiative to create a map of common patterns of single nucleotide polymorphisms, or SNPs. SNPs are single-base variations scattered throughout the human genome and are believed to be the cause of most genetic variations from hair color to disease susceptibility. Researchers believe that mapping SNPs will assist in the understanding and analysis of human disease and drug response. Third Wave concluded its ongoing support of HapMap-related research in Japan in 2005, but the Company will continue to support Dr. Nakamura for other research projects.

## **INTELLECTUAL PROPERTY**

We have implemented a patent strategy designed to provide us with freedom to operate and facilitate commercialization of our current and future products. We currently own 38 issued U.S. patents, and hold exclusive licenses to two issued patents in the United States, own seven issued patents in Australia, two issued patents in Canada, one issued patent in Japan, and one issued European Cooperative patent. We have received notices of allowance for seven additional U.S. patent applications. We have 68 additional U.S. patent applications pending, including 61 non-provisional applications. In addition, we have licensed rights to patents and patent applications pending in the United States, Japan and other major industrialized nations, covering genetic variations associated with drug metabolism. We have licensed rights to patents and/or patent applications covering genetic variations associated with certain diseases for which we have designed clinical diagnostic products. In 2005, we obtained a nonexclusive license from the Mayo Foundation for a suite of patents related to detection of genetic polymorphisms in the human UGT1A1 gene. We also have licensed rights to patents and/or patent applications covering various nucleic acid amplification or detection platforms, detection methodologies, and the like. In 2005, we obtained a nonexclusive license from Abbott Molecular Diagnostics for a patent related to multiplex PCR amplification in

diagnostic applications. Reflecting our international business strategy, we have foreign filings in major industrialized nations corresponding to each major technology area represented in our U.S. patent and application claims. Currently, we have 68 pending applications in foreign jurisdictions, and 5 international (PCT) applications for which foreign filing designations have not yet been made.

Our issued, allowed and pending patents distinguish us from competitors by claiming proprietary methods and compositions for analysis of DNA and RNA, either genomic or amplified, using structure-specific cleavage processes and compositions. Issued and pending claims are included for assay design methods and compositions, as well as for use of the technology in various read-out formats such as fluorescence resonance energy transfer, mass spectrometry or in conjunction with solid supports such as micro latex beads or chips. We also have issued and pending claims covering oligonucleotide design production systems and methods. These methods also allow multiplexing or analysis of more than one sample in a single reaction, enabling the system to be easily amenable to a wide range of automated and non-automated detection methods.

The Company's issued U.S. patents will expire between 2012 and 2021. Our success depends, to a significant degree, on our ability to develop proprietary products and technologies. We intend to continue to file patent applications, and to license rights to patents and patent applications, as we develop new products, technologies and patentable enhancements. Prosecution practices have been implemented to avoid any applicant delays that could compromise the guaranteed minimum patent term. There can be no guarantee, however, that such procedures will prevent the loss of a potential patent term.

Complex legal and factual determinations and evolving laws make patent protection and freedom to operate uncertain. As a result, we cannot be certain that patents will be issued from any of our pending patent applications or from applications licensed to us or that any issued patents will have sufficient breadth to offer meaningful protection. In addition, our issued patents or patents licensed to us may be successfully challenged, invalidated, circumvented or found unenforceable so that our patent rights would not create an effective competitive barrier. Moreover, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. patent laws.

In addition to patent protection, we rely on copyright and trade secret protection of our intellectual property. We attempt to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants are required to sign agreements to assign to us their interests in discoveries, inventions, patents and copyrights arising from their work for us. They are also required to maintain the confidentiality of our intellectual property, and refrain from unfair competition with us during their employment and for a period of time after their employment with us, including solicitation of our employees and customers. We cannot be certain that these agreements will not be breached or invalidated. In addition, we cannot assure you that third parties will not independently discover or invent competing technologies or reverse engineer our trade secrets or other technologies.

See Part I, Item 1A — Risk Factors.

## **COMPETITION**

The markets for our technologies and products are very competitive, and we expect the intensity of competition to increase. We compete with organizations that develop and manufacture products and provide services for the analysis of genetic information for research and/or clinical applications. These organizations include (1) diagnostic, biotechnology, pharmaceutical, healthcare, chemical and other companies, (2) academic and scientific institutions, (3) governmental agencies, and (4) public and private research organizations. Many of our competitors have greater financial, operational, sales and marketing resources and more experience in research and development than we have. Moreover, competitors may have greater name recognition than we do and may offer discounts as a competitive tactic. These competitors and other companies may have developed or could in the future develop new technologies that compete with our products or render our products obsolete.

We compete with many companies in the United States and abroad engaged in the development, commercialization and distribution of similar products intended for clinical molecular diagnostic applications. These companies may have or develop products competitive with the products offered by us. Clinical laboratories also

may offer testing services that are competitive with our products. Clinical laboratories may use reagents purchased from us or others to develop their own diagnostic tests. Such laboratory-developed tests may not be subject to the same requirements for clinical trials and FDA submission requirements that may apply to our products.

In the clinical market, we compete with several companies offering alternative technologies to the Invader® chemistry. These companies include, among others: Abbott Laboratories; Bayer Corporation; Becton, Dickinson and Company; BioRad Laboratories, Inc.; Digene Corporation; Roche Diagnostics Corporation; Gen-Probe; Applera Corporation companies including Applied Biosystems and Celera; Innogenetics, Inc.; TM Bioscience Corporation; and Ventana Medical Systems Inc.

In the research market, we compete with several companies offering alternative technologies to the Invader® chemistry. These companies include, among others: Affymetrix, Inc.; Perlegen Sciences, Inc.; Illumina, Inc.; and Applied Biosystems.

We believe the primary competitive factors in our markets are performance and reliability, ease of use, standardization, cost, proprietary position, market share, access to distribution channels, regulatory approvals, clinical validation and availability of reimbursement.

See Part I, Item 1A — Risk Factors.

## **GOVERNMENT REGULATION**

We are subject to regulation by the FDA under the Federal Food, Drug and Cosmetic Act and other laws. The Food, Drug and Cosmetic Act requires that medical devices introduced to the U.S. market, unless otherwise exempted, be the subject of either a premarket notification clearance, known as a 510(k), or a premarket approval, known as a PMA. Some of our clinical products may require a PMA, others may require a 510(k). Other products, like analyte specific reagents, or ASRs, may be exempt from regulatory clearance or approval, but still subject to restrictions by FDA.

With respect to products reviewed through the 510(k) process, we may not market a product until an order is issued by the FDA finding our product to be substantially equivalent to a legally marketed product known as a predicate device. A 510(k) submission may involve the presentation of a substantial volume of data, including clinical data, and may require a substantial review. The FDA may agree that the product is substantially equivalent to a predicate device and allow the product to be marketed in the United States. The FDA, however, may determine that the device is not substantially equivalent and require a PMA, or require further information, such as additional test data, including data from clinical studies, before it is able to make a determination regarding substantial equivalence. If, after reviewing the 510(k), the FDA determines there is no predicate device, we may request that the FDA use the process known as de novo classification and then clear the device through that means, rather than a PMA. De novo classification is intended to be used for lower-risk products. By requesting additional information, the FDA can further delay market introduction of our products.

If the FDA indicates that a PMA is required for any of our clinical products, the application will require extensive clinical studies, manufacturing information and likely review by a panel of experts outside the FDA. Clinical studies to support either a 510(k) submission or a PMA application would need to be conducted in accordance with FDA requirements. Failure to comply with FDA requirements could result in the FDA's refusal to accept the data or the imposition of regulatory sanctions. There can be no assurance that we will be able to meet the FDA's requirements or receive any necessary approval or clearance.

Once granted, a 510(k) clearance or PMA approval may place substantial restrictions on how our device is marketed or to whom it may be sold. Even in the case of devices like ASRs, most of which are exempt from 510(k) clearance or PMA approval requirements, the FDA imposes restrictions on marketing. Additionally, our ASR products may be sold only to clinical laboratories certified under CLIA to perform high complexity testing. The FDA is currently in the process of drafting guidelines for ASRs and these guidelines may result in FDA seeking to limit the types of products that can be sold as ASRs. In addition to requiring approval or clearance for new products, the FDA may require approval or clearance prior to marketing products that are modifications of existing products. We cannot be assured that any necessary 510(k) clearance or PMA approval will be granted on a timely basis, or at all. Delays in receipt of or failure to receive any necessary 510(k) clearance or PMA approval or the imposition of

stringent restrictions on the labeling and sales of our products could have a material adverse effect on us. We do not anticipate that our products that will be labeled for research use only, or RUO, (i.e., products used in drug discovery or genomics research) will be subject to additional government regulation of significance. Our products labeled as ASRs or labeled for in-vitro diagnostic use will be regulated as medical devices by the FDA and in certain other countries. We believe most of our products currently marketed pursuant to FDA regulations as ASRs, as well as many products we intend to market in the future as ASRs, are exempt from the 510(k) premarket notification and premarket approval requirements. However, the FDA may require that we obtain, or we may choose to obtain, regulatory clearances or approvals for certain of our products or their applications, as was done for our Invader® UGT1A1 Molecular Assay. We expect that we will apply for FDA clearances or approvals for some of our current and future products.

As a medical device manufacturer, we are also required to register our facility and list our products with the FDA. In addition, we are required to comply with the FDA's quality systems regulations, or QSRs, which require that our devices be manufactured and records be maintained in a prescribed manner with respect to manufacturing, testing and control activities. Further, we are required to comply with FDA requirements for labeling and promotion. For example, the FDA prohibits cleared or approved devices from being promoted for uncleared or unapproved uses. In addition, the medical device reporting regulation requires that we provide information to the FDA whenever there is evidence to reasonably suggest that one of our devices may have caused or contributed to a death or serious injury or that there has occurred a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Under FDA regulatory requirements, we may not make claims about the performance, intended clinical use or efficacy of ASR products. There are also restrictions on the concurrent marketing of components that can be used to develop an assay.

Our manufacturing facility is subject to periodic and unannounced inspections by the FDA for compliance with quality system regulations. Additionally, the FDA often will conduct a preapproval inspection for PMA devices. Although we believe we are in compliance with the FDA's quality system regulations, we have never been inspected by the FDA and cannot assure that we will be able to maintain compliance in the future. If the FDA believes that we are not in compliance with applicable laws or regulations, it can issue a warning letter, detain or seize our products, issue a recall notice or request that a recall be initiated, seek to enjoin future violations and assess civil and criminal penalties against us. In addition, approvals or clearances could be withdrawn under certain circumstances. Failure to comply with regulatory requirements or any adverse regulatory action could have a material adverse effect on us.

Any customers using our products for clinical use in the U.S. will be regulated under CLIA. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA establish three levels of diagnostic tests, namely, waived, moderately complex and highly complex, and the standards applicable to a clinical laboratory depend on the level of the tests it performs. We cannot assure you that the CLIA regulations and future administrative interpretations of CLIA will not have a material adverse impact on us by limiting the potential market for our products.

Medical device laws and regulations are also in effect in many of the countries in which we may do business outside the United States. These range from comprehensive device approval requirements for some or all of our medical device products, to requests for product data or certifications. The number and scope of these requirements are increasing. Medical device laws and regulations are also in effect in some states in which we do business. There can be no assurance that we will obtain regulatory approvals in such countries or that we will not incur significant costs in obtaining or maintaining foreign regulatory approvals. In addition, export of certain of our products that have not yet been cleared or approved for domestic commercial distribution may be subject to FDA export restrictions.

We are also subject to numerous environmental and safety laws and regulations, including those governing the use and disposal of hazardous materials. Any violation of and the cost of compliance with these regulations could have a material adverse effect on our business.

See Part I, Item 1A — Risk Factors.

## RESEARCH AND DEVELOPMENT

Research and development costs associated with our products and technologies, as well as facilities costs, personnel costs, marketing programs and overhead account for a substantial portion of our operating expenses. Research and development expenses for the years ended December 31, 2005, 2004, and 2003 were \$8.4 million, \$11.6 million, and \$12.0 million, respectively.

## EMPLOYEES

As of December 31, 2005, we employed 154 persons, of whom 29 hold doctorate degrees and 105 hold other advanced degrees. Approximately 37 employees are engaged in research and development, 53 in business development, sales and marketing, 27 in operations and manufacturing and 37 in intellectual property, finance and other administrative functions. Our success will depend in large part on our ability to attract and retain qualified employees. We face competition in this regard from other companies, research and academic institutions, government entities and other organizations. We believe that we maintain good relations with our employees.

## AVAILABLE INFORMATION

The Company makes available financial information, news releases and other information on its web site at [www.twt.com](http://www.twt.com). The Company's annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, its Code of Business Conduct (which governs all officers, executives, directors and employees of the Company), and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge on its Web site as soon as reasonably practicable after the Company files such reports and amendments with, or furnishes them to, the Securities and Exchange Commission.

## ITEM 1A. RISK FACTORS

### RISKS RELATED TO OUR BUSINESS

***WE HAD AN ACCUMULATED DEFICIT OF \$158.1 MILLION AT DECEMBER 31, 2005, AND EXPECT TO CONTINUE TO INCUR SUBSTANTIAL OPERATING LOSSES FOR THE FORESEEABLE FUTURE.***

We have had substantial operating losses since our inception in 1993, and we expect our operating losses to continue over the foreseeable future. We experienced net losses of \$22.3 million in 2005, \$1.9 million in 2004, and \$8.1 million in 2003. In order to further develop our products and technologies, including development of new products for the clinical market, we will need to incur significant expenses in connection with our internal research and development and commercialization programs. As a result, we expect to incur annual operating losses for the foreseeable future. In addition, there is no assurance that we will ever become profitable or that we will sustain profitability if we do become profitable. Should we experience protracted or unforeseen operating losses, our capital requirements would increase and our stock price would likely decline.

***FLUCTUATIONS IN OUR QUARTERLY REVENUES AND OPERATING RESULTS MAY NEGATIVELY IMPACT OUR STOCK PRICE.***

Our revenues and results of operations have fluctuated significantly in the past and we expect significant fluctuations to continue in the future due to a variety of factors, many of which are outside of our control. These factors include:

- the volume and timing of orders for our products;
- changes in the mix of our products offered;
- the timing of payments we receive under collaborative agreements, as well as our ability to recognize these payments as revenues;
- the number, timing and significance of new products and technologies introduced by our competitors;

- third-party intellectual property, which may require significant investments in licensing or royalties, or which may materially impede our ability to sell products;
- our ability to develop, obtain regulatory clearance, market and introduce new and enhanced products on a timely basis;
- changes in the cost, quality and availability of equipment, reagents and components required to manufacture or use our products;
- availability of commercial and government funding to researchers who use our products and services, including our single-largest research customer in Japan; and
- availability of third-party reimbursement to users of our clinical products.

Research and development costs associated with our products and technologies, as well as facilities costs, personnel costs, marketing programs and overhead account for a substantial portion of our operating expenses. Research and development expenses for the years ended December 31, 2005, 2004, and 2003 were \$8.4 million, \$11.6 million, and \$12.0 million, respectively. We cannot reduce these expenses quickly in the short term. If our revenues decline or do not grow as anticipated, we may not be able to reduce our operating expenses accordingly. Failure to achieve anticipated levels of revenues could significantly harm our operating results for one or more fiscal periods. Due to the possibility of fluctuations in our revenues and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. In addition, our operating results in a future fiscal quarter may not meet the expectations of stock market analysts and investors. In that case, our stock price would likely decline and investors would experience a decline in the value of their investment.

***OUR TECHNOLOGIES AND COMMERCIAL PRODUCTS MAY NOT BE COMMERCIALY VIABLE OR SUCCESSFUL, WHICH COULD ADVERSELY AFFECT OUR BUSINESS.***

We are currently developing and commercializing a limited number of products based on our technologies. We plan to develop additional products. We cannot assure you that we will be able to complete development of our products that are currently under development or that we will be able to develop additional new products. In addition, for our genetic and pharmacogenetic products, some of the genetic variations for which we develop our products may not be useful or cost effective in assisting therapeutic selection, patient monitoring or diagnostic applications. In this event, our sales of products for these genetic variations would diminish significantly or cease, and we would not be able to recoup our investment in developing these products. Accordingly, if we fail to successfully develop our products and technologies or if our technologies are not useful in the development of commercially successful products, we may not achieve a competitive position in the market. If we fail to do so, our revenues will be seriously harmed and it is unlikely that we will ever achieve profitability. Market acceptance of our products will depend on widespread acceptance of such products by doctors and clinicians. The use of products to assess genetic variation, gene expression or identify infectious diseases is relatively new and remains uncertain. If clinicians and doctors do not adopt our products, our business, financial condition and results of operation could be adversely affected. In these events, our stock price would likely decline.

***WE HAVE LIMITED MANUFACTURING EXPERIENCE AND MAY NEED TO MODIFY, EXPAND OR ESTABLISH NEW MANUFACTURING FACILITIES AS WE COMMERCIALIZE OUR PRODUCTS.***

We have limited experience manufacturing our products and have limited experience manufacturing our products in the volumes that will be necessary for us to achieve significant commercial sales. We may need to establish new manufacturing processes or facilities, modify existing facilities and processes, or outsource product component manufacturing. Facilities expansion and development, process improvements, and outsourcing manufacturing can be delayed by unforeseen circumstances, including inability to obtain needed manufacturing equipment on a timely basis, difficulties with facility construction and completion of improvements and difficulties incorporating new processes and vendor supply issues associated with component outsourcing. If we fail to meet our manufacturing needs, we may not be able to provide our customers with the quantity of products they require, which would damage customer relations and result in reduced revenues. Additionally, some of our products must be

manufactured in accordance with the FDA's QSRs. We have limited experience in manufacturing our products in compliance with QSRs and cannot guarantee that our manufacturing and production systems are in compliance with the QSRs.

Key components of our products may be sourced from a single supplier or a limited number of suppliers. Specifically, oligonucleotides for many of our research use only products are sourced from a single supplier as are certain components of our InPlex microfluidic card format. In addition, some of the components incorporated into our products may be proprietary and unavailable from secondary sources. Finally, to comply with QSRs, we must verify that our suppliers of key components are in compliance with all applicable FDA regulations and meet our standards for quality. If we lose a source of supply due to any of the above reasons or otherwise we may not be able to arrange for alternative supply sources. If our suppliers are unable or unwilling to supply us on commercially acceptable terms with these components, we may be unable to satisfy demand for our product on reasonable terms, if at all, which may have an adverse effect on our business, financial condition and results of operations.

***OUR LIMITED SALES AND MARKETING EXPERIENCE AND CAPACITY MAY ADVERSELY AFFECT OUR ABILITY TO GROW AND TO COMPETE SUCCESSFULLY IN COMMERCIALIZING OUR POTENTIAL PRODUCTS.***

Our sales force consists of 18 individuals focused on direct sales and 15 individuals focused on service and support in the clinical market. We may need to increase the size of our sales force as we further commercialize our products, and we may not be able to recruit, hire and train a sufficient number of sales personnel in a short time frame. We may also market our products through collaborations and distribution agreements with diagnostic, biopharmaceutical and life science companies. We cannot guarantee that we will be able to establish a successful sales force or to establish collaboration or distribution arrangements to market our products. If we are unable to implement an effective marketing and sales strategy, we will be unable to grow our revenues and execute our business plan. This would have an adverse effect on our business, financial condition and results of operations.

We have limited experience with sales of our clinical molecular diagnostics products outside of the U.S. We cannot guarantee that we will successfully develop sales, distribution, product and customer support capabilities internationally that will enable us to generate significant revenue from sales outside the United States. In addition, sales made outside the U.S. are subject to foreign regulations typical to the sale and marketing of our products that may pose an additional risk for us. If we fail to increase our revenues from sales outside of the United States, this would have an adverse effect on our business, financial condition and results of operations.

Our customer base is dominated by a small number of large clinical testing laboratories (Quest Diagnostics, Inc., Specialty Laboratories, Inc., Mayo Medical Laboratories, Kaiser Permanente, and Berkeley Heart Laboratories) and research customers (University of Tokyo/RIKEN and Pioneer Hi-Bred International, Inc.). We regularly experience pricing and other competitive pressures in these accounts. Many of our contracts with key customers are short-term contracts and/or subject to early termination. Our customers are not obligated to renew contracts after they expire. If, for any reason, we are unable to maintain or renew our contracts, particularly our contracts with key customers, or if, for any reason, we are unable to maintain current pricing levels and/or volumes with our customers, our revenues and business may suffer materially.

***THE EARLY TERMINATION OF ANY OF OUR STRATEGIC COLLABORATION OR CUSTOMER SUPPLY AGREEMENTS COULD SERIOUSLY HARM OUR BUSINESS AND FINANCIAL CONDITION.***

Certain of our strategic, research collaboration, and customer supply agreements may be terminated with little or no notice. In particular, the supply of products to Japanese customers may be terminated upon specified notice at any time. These customers will likely account for a material portion of our revenues for 2006. Accordingly, early termination of these relationships and supply agreements would seriously harm our revenues, and in turn, our business, and financial condition.

***WE MAY REQUIRE ADDITIONAL FINANCING FOR OUR FUTURE OPERATING PLANS. FINANCING MAY NOT BE AVAILABLE ON ACCEPTABLE TERMS, IF AT ALL.***

We may need to raise additional capital in the future. We have expended significant resources and expect to continue to expend significant resources in our research and product development and commercialization activities and to improve production processes, litigate intellectual property disputes, and seek FDA clearance or approvals. The amount of additional capital we will need to raise will depend on many factors, including:

- our progress with our research and development programs;
- the needs we may have to pursue FDA clearances or approvals of our products;
- our level of success in selling our products and technologies;
- our ability to establish and maintain successful collaborations;
- the costs we incur in securing intellectual property rights, whether through patents, licenses or otherwise;
- the costs we incur in enforcing and defending our patent claims and other intellectual property rights;
- the timing of purchases of additional capital;
- the need to respond to competitive pressures; and
- the possible acquisition of complementary products, businesses or technologies.

If we raise additional funds through the sale of equity, convertible debt or other equity-linked securities, our shareholders' percentage ownership in the Company will be reduced. In addition, these transactions may dilute the value of our outstanding stock. We may issue securities that have rights, preferences and privileges senior to our common stock. If we raise additional funds through collaborations or licensing arrangements, we may relinquish rights to certain of our technologies or products, or grant licenses to third parties on terms that are unfavorable to us. If future financing is not available to us or is not available on terms acceptable to us, we may not be able to fund our future needs that would have an adverse effect on our business, financial condition and results of operations.

***FAILURE TO MAINTAIN EFFECTIVE INTERNAL CONTROLS IN ACCORDANCE WITH SECTION 404 OF THE SARBANES-OXLEY ACT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS AND STOCK PRICE.***

If we fail to maintain adequacy of our internal controls in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain an effective internal control environment could have a material adverse effect on our stock price.

***COMMERCIALIZATION OF OUR TECHNOLOGIES MAY DEPEND ON STRATEGIC PARTNERSHIPS AND COLLABORATIONS WITH OTHER COMPANIES, AND IF OUR CURRENT OR FUTURE PARTNERSHIPS AND COLLABORATIONS ARE NOT SUCCESSFUL, WE MAY EXPERIENCE DIFFICULTY COMMERCIALIZING OUR TECHNOLOGIES AND PRODUCTS.***

In order to augment our internal sales and marketing efforts and to reach additional product and geographic markets, we have entered into or may enter into strategic partnerships and collaborations for the development, marketing, sales or distribution of our products. These agreements provide us, in some instances, with distribution of our products, access to products and technologies that are complementary to ours and funding for development of our products. We may also be dependent on collaborators for regulatory approvals and clearances, and manufacturing in particular geographic and product markets. If our strategic partnerships and collaborations are not successful, we may not be able to develop or successfully commercialize the products that are the subject of the collaborations on a timely basis, if at all, or effectively distribute our products. In addition, if we do not enter into additional partnership agreements, or if these agreements are not successful, our ability to develop, commercialize and distribute products will be negatively affected which will harm our future operating results.

We have no control over the resources that any partner or collaborator may devote to our products. Any of our present or future partners or collaborators may not perform their obligations as expected. These partners or collaborators may breach or terminate their agreements with us or otherwise fail to meet their obligations or perform their collaborative activities successfully and in a timely manner. Further, any of our partners or collaborators may elect not to develop products arising out of our partnerships or collaborations or devote sufficient resources to the development, manufacture, commercialization or distribution of these products. If any of these events occur, we may not be able to develop our products and technologies and our ability to generate revenues will decrease.

***WE ARE IN A HIGHLY COMPETITIVE INDUSTRY AND MARKETPLACE. COMPETITIVE DEVELOPMENTS, INCLUDING NEW TECHNOLOGIES THAT RENDER OURS LESS COMPETITIVE OR OBSOLETE, COULD SERIOUSLY HARM OUR BUSINESS.***

The biotechnology and life sciences industries generally and the genetic analysis and molecular diagnostics markets specifically are highly competitive, and we expect the intensity of competition to increase. We compete with organizations in the United States and abroad that develop and manufacture products and provide services for the analysis of genetic information for research and/or clinical applications. These organizations include:

- diagnostic, biotechnology, pharmaceutical, healthcare, chemical and other companies;
- academic and scientific institutions;
- governmental agencies;
- public and private research organizations; and
- clinical labs.

Many of our competitors have greater financial, technical, research, marketing, sales, distribution, service and other resources than we do. Moreover, our competitors may offer broader product lines and have greater name recognition than we do, and may offer discounts as a competitive tactic. In addition, several development stage companies are currently making or developing technologies, products or services that compete with or are being designed to compete with our technologies and products. Our competitors may develop or market technologies, products or services that are more effective or commercially attractive than our current or future products, or that may render our technologies or products less competitive or obsolete. Competitors may make rapid technological developments which may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue or market acceptance. Competitors may also obtain regulatory advances or approvals of their diagnostic products more rapidly than we do. Accordingly, if competitors introduce superior technologies or products or obtain regulatory approvals or clearances quicker than we do, and we cannot make enhancements to our technologies and products necessary for them to remain competitive, our competitive position, and in turn our business, revenues and financial condition, will be seriously harmed. This, in turn, would likely cause our stock price to decline.

Our existing and potential competitors may be in the process of seeking FDA or foreign regulatory approval for their respective products or may also enjoy substantial advantages over us in terms of research and development expertise, clinical trial expertise, experience in submission of products to regulatory authorities and the marketing or commercialization of FDA approved or cleared products. In addition, many of our competitors may have or will establish third-party reimbursement for their products. We may not be able to compete effectively against competitors that hold such an advantage which may have a material adverse effect on our business, financial condition and results of operations.

***WE MAY BE UNABLE TO PROTECT OUR PROPRIETARY METHODS AND TECHNOLOGIES AND MAY BE SUBJECT TO CLAIMS OF INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS.***

Our commercial success will depend, to a significant degree, on our ability to obtain patent protection on many aspects of our business, including the products, methods and services we develop. Patents issued to us may not

provide us with substantial protection or be commercially beneficial to us. The issuance of a patent is not conclusive as to its validity or its enforceability. In addition, our patent applications or those we have licensed, may not result in issued patents. If our patent applications do not result in issued patents, our competitors may obtain rights to commercialize our discoveries which would harm our competitive position.

We also may apply for patent protection on novel genetic variations in known genes and their uses, as well as novel uses for previously identified genetic variations discovered by third parties. In the latter cases or in the area of new product development, we may need licenses from the holders of patents with respect to such genetic variations in order to make, use or sell any related products. We may not be able to acquire such licenses on terms acceptable to us, if at all.

Certain parties are attempting to rapidly identify and characterize genes and genetic variations through the use of sequencing and other technologies. To the extent any patents are issued to other parties on such partial or full-length genes or genetic variations or uses for such genes or genetic variations, the risk increases that the sale of products developed by us or our collaborators may give rise to claims of patent infringement against us. Others may have filed and, in the future, are likely to file patent applications covering many genetic variations and their uses. Others may file and, in the future, may file, patent applications covering improvements to our technologies. Any such patent application may have priority over our patent applications and could further restrict our ability to market our products. We cannot assure you that any license that we may require under any such patent will be made available to us on commercially acceptable terms, if at all.

While we believe our technology does not infringe any third party rights, we have in the past been party to and are currently party to litigation involving patents and intellectual property rights. See Part I, Item 3 — Legal Proceedings. We may in the future become party to other litigation involving claims of infringement of intellectual property rights. We could also become involved in disputes regarding the ownership of intellectual property rights that relate to our technologies. These disputes could arise out of collaboration relationships, strategic partnerships or other relationships. Any such litigation could be expensive, take significant time, and could divert management's attention from other business concerns. If we do not prevail in any pending or future legal proceeding, we may be required to pay significant monetary damages. In addition, we could also be enjoined from use of certain processes or prevented from selling certain configurations of our products that were found to be within the scope of the patent claims. In the event we did not prevail in any pending or future proceeding, we would either have to obtain licenses from the other party, avoid certain product configurations or modify some of our products and processes to design around the patents. Licenses could be costly or unavailable on commercially reasonable terms. Designing around patents or focusing efforts on different configurations could be time consuming, and we could be forced to remove some of our products from the market while we were completing redesigns. Accordingly, if we are unable to settle pending or future intellectual property disputes through licensing or similar arrangements, or if any such pending or future disputes are determined adversely to us, our ability to market and sell our products could be seriously harmed. This would in turn harm our business, financial condition and results of operations.

In addition, in order to protect or enforce our patent rights or to protect our ability to operate our business, we may need to initiate other patent litigation against third parties. These lawsuits could be expensive, take significant time, and could divert management's attention from other business concerns. These lawsuits could result in the invalidation or limitation in the scope of our patents or forfeiture of the rights associated with our patents. We cannot assure you that we would prevail in any such proceedings or that a court will not find damages or award other remedies in favor of our opposing party in any of these suits. During the course of any future proceedings, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. Securities analysts or investors may perceive these announcements to be negative, which could cause the market price of our stock to decline.

***OTHER RIGHTS AND MEASURES THAT WE RELY UPON TO PROTECT OUR INTELLECTUAL PROPERTY MAY NOT BE ADEQUATE TO PROTECT OUR PRODUCTS AND COULD REDUCE OUR ABILITY TO COMPETE IN THE MARKET.***

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, nondisclosure agreements and other contractual provisions and technical measures to protect our intellectual property rights.

While we require employees, collaborators, consultants and other third parties to enter into confidentiality and/or non-disclosure agreements where appropriate, any of the following could still occur:

- the agreements may be breached;
- we may have inadequate remedies for any breach;
- the employees, collaborators, consultants and other third parties may apply for patents on improvements to our technologies without assigning ownership rights to us;
- proprietary information could be disclosed to our competitors; or
- others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

If for any of the above reasons our intellectual property is disclosed, invalidated or misappropriated, it would harm our ability to protect our rights and our competitive position.

***IF WE FAIL TO RETAIN OUR KEY PERSONNEL AND HIRE, TRAIN AND RETAIN QUALIFIED EMPLOYEES, WE MAY NOT BE ABLE TO COMPETE EFFECTIVELY, WHICH COULD RESULT IN REDUCED REVENUES.***

Our future success will depend on the continued services and on the performance of our senior management, scientific staff, and key employees.

If a competitor hired members of our senior management staff, scientific staff, or key employees, or if for any reason these employees would not continue to work for us, we would have difficulty hiring employees with equivalent skills.

In addition, our researchers, scientists and technicians have significant experience in research and development related to the analysis of genetic variations. If we were to lose these employees to our competitors, we could spend a significant amount of time and resources to replace them, which could impair our research and development efforts. Further, in order to scale up our commercialization activity and to further our research and development efforts, we will need to hire, train and retain additional sales, marketing, research, scientific, and technical personnel. If we are unable to hire, train and retain the personnel we need, we may experience delays in the research, development and commercialization of our technologies and products. This would result in reduced revenues and would harm our results of operations.

***WE PLAN TO CONTINUE TO INTRODUCE PRODUCTS FOR THE CLINICAL MARKET, AND WE MAY NEED TO OBTAIN FDA CLEARANCES AND APPROVALS AND COMPLY WITH FDA QUALITY SYSTEM REGULATIONS AND OTHER REGULATIONS RELATING TO THE MANUFACTURING, MARKETING AND SALE OF CLINICAL PRODUCTS.***

We anticipate that the manufacturing, labeling, distribution and marketing of a number of our clinical diagnostic products will be subject to extensive regulation in the United States and in certain other countries.

The Food, Drug and Cosmetic Act requires that medical devices introduced to the U.S. market, unless otherwise exempted, be subject of either a premarket notification clearance, known as a 510(k), or a premarket approval, known as a PMA. In the United States, the FDA regulates, as medical devices, most diagnostic tests and in vitro diagnostic (IVD) reagents that are marketed as finished test kits. Some clinical laboratories, however, purchase products that are marketed under FDA regulations as analyte specific reagents (ASRs), and develop and prepare their own finished diagnostic tests. FDA also considers ASRs to be medical devices, however, most ASRs are exempt from 510(k) clearance or PMA approval requirements. The FDA restricts the sale of these products to clinical laboratories certified under CLIA to perform high complexity testing and also restricts the types of products that can be sold as ASRs. We currently market the majority of our diagnostic products as IVDs, ASRs, and General Purpose Reagents (GPRs). Consequently, these clinical products are regulated as medical devices. Should the FDA modify the ASR rules or its interpretation and enforcement of them in a fashion that makes it difficult or impossible for us to market some or all of our products, we may be required to terminate those ASR product sales, conduct

clinical studies and make submissions of our products to the FDA for clearance or approval. The FDA is currently in the process of considering the issuance of new guidance that may restrict the products that the FDA believes can be marketed as ASRs. In that event, we could experience significant revenue loss, additional expenses and loss of our clinical customer base which would cause the market price of our stock to decline.

Unless otherwise exempt, medical devices require FDA approval or clearance prior to marketing in the United States. Although we believe the majority of our currently marketed products, as well as those ASRs we intend to market in the future, are exempt from 510(k) premarket notification and premarket approval requirements, the process of obtaining approvals and clearances necessary to market our proposed clinical products can be time-consuming, expensive and uncertain. To date, we have applied for one FDA clearance with respect to our clinical diagnostic products. This clearance was for our Invader® UGT1A1 Molecular Assay and was obtained in August 2005. We plan to seek additional FDA approvals or clearances for certain products in 2006, however, we cannot predict the likelihood of obtaining those approvals or clearances. Also, clinical products that we may seek to introduce in the future may require FDA approvals or clearances prior to commercial sale in the United States. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of new clinical products. In addition, we cannot assure that regulatory approval or clearance of any clinical products for which we seek such approvals will be granted by the FDA or foreign regulatory authorities on a timely basis, if at all. Furthermore, in the event that the ASR regulatory landscape is modified by the FDA to reduce the number of products qualifying as ASRs, we could experience significant revenue loss, additional expenses and loss of our clinical customer base which would cause the market price of our stock to decline.

If approval or clearance is obtained we will be subject to continuing FDA obligations. When manufacturing medical devices, including ASRs, we will be required to adhere to Quality System Regulations, which will require us to manufacture our products and maintain records in a prescribed manner. We have never been subject to an FDA Quality System inspection, and we cannot assure that we would pass an FDA audit or maintain compliance in the future. Further, the FDA may place substantial restrictions on the indications for which our products may be marketed or to whom they may be marketed. Additionally, there can be no assurance that FDA will not require us to conduct clinical studies as a condition of approval or clearance. Failure to comply with applicable FDA requirements can result in, among other things:

- administrative or judicially imposed sanctions;
- injunctions, civil penalties, recall or seizure of our products;
- total or partial suspension of production;
- failure of the government to grant premarket clearance or premarket approval for our products;
- withdrawal of marketing clearances or approvals; and
- criminal prosecution.

Any of our customers using our products for clinical use in the United States may be regulated under CLIA. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualification, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA establish three levels of clinical tests and the standards applicable to a clinical laboratory depend on the level of the tests it performs. CLIA requirements may prevent some clinical laboratories, including those laboratories that do not comply with those requirements, from using some or all of our products. In addition, CLIA regulations and future administrative interpretations of CLIA could harm our business by limiting the potential market for some or all of our products.

***OUR INTERNATIONAL SALES ARE SUBJECT TO CURRENCY, MARKET AND REGULATORY RISKS THAT ARE BEYOND OUR CONTROL.***

In 2005 we derived approximately 27% of our product revenues from sales to international end-users and we expect that international sales will continue to account for a portion of our sales. Changes in the rate of exchange of foreign currencies into United States dollars have and will continue to impact our revenues and results of operations.

The extent and complexity of medical products regulation are increasing worldwide, with regulation in some countries nearly as extensive as in the United States. Further, we must comply with import and export regulations when distributing our products to foreign nations. Each foreign country's regulatory requirements for product approval and distribution are unique and may require the expenditure of substantial time, money and effort. As a result, we may not be able to successfully commercialize our products in foreign markets at or beyond the level of commercialization we have already achieved.

***OUR FAILURE TO COMPLY WITH ANY APPLICABLE ENVIRONMENTAL, HEALTH, SAFETY AND RELATED GOVERNMENT REGULATIONS MAY AFFECT OUR ABILITY TO DEVELOP, PRODUCE OR MARKET OUR POTENTIAL PRODUCTS AND MAY ADVERSELY AFFECT OUR RESULTS OF OPERATIONS.***

Our research, development and manufacturing activities involve the use, transportation, storage and disposal of hazardous materials and are subject to related environmental and health and safety statutes and regulations. As we expand our operations, our increased use of hazardous substances will lead to additional and more stringent requirements. This may cause us to incur substantial costs to maintain compliance with applicable statutes and regulations. In addition, we are obligated to file a report to the U.S. Environmental Protection Agency, or EPA, regarding specified types of microorganisms we use in our operations. The EPA could, upon review of our use of these microorganisms, require us to discontinue its use. If this were to occur, we would have to substitute a different microorganism from the EPA's approved list. We could experience delays or disruptions in production while we convert to the new microorganism. In addition, any failure to comply with laws and regulations and any costs associated with unexpected and unintended releases of hazardous substances by us into the environment, or at disposal sites used by us, could expose us to substantial liability in the form of fines, penalties, remediation costs or other damages and could require us to shut down our operations. Any of these events would seriously harm our business and operating results.

***WE MAY BE HELD LIABLE FOR ANY INACCURACIES ASSOCIATED WITH NUCLEIC ACID TESTS PERFORMED USING OUR PRODUCTS, WHICH MAY REQUIRE US TO DEFEND OURSELVES IN COSTLY LITIGATION.***

We may be subject to claims resulting from incorrect results of analysis of nucleic acid tests performed using our products. Litigating any such claims could be costly. We could expend significant funds during any litigation proceeding brought against us. Further, if a court were to require us to pay damages to a plaintiff, the amount of such damages could significantly harm our business, financial condition and results of operations.

***IF OUR VENDORS FAIL TO SUPPLY US WITH COMPONENTS FOR WHICH AVAILABILITY IS LIMITED, WE MAY EXPERIENCE DELAYS IN OUR PRODUCT DEVELOPMENT AND COMMERCIALIZATION.***

Certain key components of our manufacturing equipment and products are currently available only from a single source or a limited number of sources. We currently rely on outside vendors to manufacture certain components of our products and certain reagents we provide in our products. Some or all of these key components may not continue to be available in commercial quantities at acceptable costs. It could be time consuming and expensive for us to seek alternative sources of supply. Consequently, if any events cause delays or interruptions in the supply of our components, we may not be able to supply our customers with our products on a timely basis which would adversely affect our results of operations.

***RELIANCE ON COMPUTER HARDWARE, SOFTWARE AND APPLICATIONS FOR OPERATIONS***

We depend on the continuous, effective, reliable and secure operation of our computer hardware, software, networks, servers, related infrastructure and applications for the successful operations of our business. Should we encounter difficulties with such systems, our business, financial condition and results of operations could be negatively impacted.

***FUTURE ISSUANCE OF OUR PREFERRED STOCK MAY DILUTE THE RIGHTS OF OUR COMMON STOCKHOLDERS.***

Our Board of Directors has the authority to issue up to 10,000,000 shares of preferred stock and to determine the price, privileges and other terms of these shares without any further approval of our stockholders. The rights of the holders of common stock may be adversely affected by the rights of our holders of our preferred stock that may be issued in the future.

***WE HAVE VARIOUS MECHANISMS IN PLACE THAT A STOCKHOLDER MAY NOT CONSIDER FAVORABLE AND WHICH MAY DISCOURAGE UNSOLICITED TAKEOVER ATTEMPTS.***

Certain provisions of our certificate of incorporation and bylaws, Section 203 of the Delaware General Corporation Law, and certain provisions in our executive compensation plans, long-term incentive plans and employment and similar agreements may discourage, delay or prevent changes in our board of directors, executive officers or other senior management. These provisions may also be used by incumbent management to delay a change of control or acquisition of our Company. These provisions include:

- authorizing our Board of Directors to issue preferred stock and to determine the price, privileges and other terms of these shares without any further approval of our stockholders, which could increase the number of outstanding shares or thwart an unsolicited takeover attempt;
- establishing a classified Board of Directors with staggered, three-year terms, which may lengthen the time required to gain control of our Board of Directors;
- prohibiting cumulative voting in the election of directors, which would allow a majority of stockholders to control the election of all directors;
- requiring super-majority voting to effect certain amendments to our certificate of incorporation and bylaws;
- limiting who may call special meetings of stockholders;
- prohibiting stockholder action by written consent, which requires all actions to be taken at a meeting of stockholders;
- establishing advance notice requirements for nominations of candidates for election to the Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings; and
- payments due to executive officers and other employees under executive compensation plans, long-term incentive plans and employment and similar agreements that could be triggered certain change of control events.

A change of control could be beneficial to stockholders in a situation in which the acquisition price being paid by the party seeking to acquire us represented a substantial premium over the prevailing market price of our common stock. If our board of directors were not in favor of such a transaction, the provisions of our certificate of incorporation and bylaws described above could be used by our board of directors to delay or reduce the likelihood of completion of the acquisition.

***OUR DIRECTORS, EXECUTIVE OFFICERS AND PRINCIPAL STOCKHOLDERS WILL HAVE SUBSTANTIAL CONTROL OVER OUR AFFAIRS.***

As of February 14, 2006, our directors and executive officers beneficially owned approximately 9% of our common stock. Stockholders that own 5% or more of our outstanding shares own, in the aggregate, approximately 32% of our common stock. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders. These matters include the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, they may dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control, or impeding a merger or consolidation, takeover or other business combination of which you might otherwise approve.

## **RISKS RELATED TO THE BIOTECHNOLOGY INDUSTRY**

### ***PUBLIC OPINION REGARDING ETHICAL ISSUES SURROUNDING THE USE OF GENETIC INFORMATION MAY ADVERSELY AFFECT DEMAND FOR OUR PRODUCTS.***

Public opinion regarding ethical issues related to the confidentiality and appropriate use of genetic testing results may influence governmental authorities to call for limits on, or regulation of the use of, genetic testing. In addition, such authorities could prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Furthermore, adverse publicity or public opinion relating to genetic research and testing, even in the absence of any governmental regulation, could harm our business. Any of these scenarios could reduce the potential markets for our products, which could materially and adversely affect our revenues.

### ***GOVERNMENT REGULATION OF GENETIC RESEARCH OR TESTING MAY ADVERSELY AFFECT THE DEMAND FOR OUR PRODUCTS AND IMPAIR OUR BUSINESS AND OPERATIONS.***

Federal, state, local and foreign governments may adopt further regulations relating to the conduct of genetic research and genetic testing. These new regulations could limit or restrict genetic research activities as well as genetic testing for research or clinical purposes. In addition, if state and local regulations are adopted, these regulations may be inconsistent with, or in conflict with, regulations adopted by other state or local governments. Foreign regulations may be inconsistent with, or in conflict with United States regulations. Regulations relating to genetic research activities could adversely affect our ability to conduct our research and development activities. Regulations restricting genetic testing could adversely affect our ability to market and sell our products. Accordingly, any regulations of this nature could harm our business.

### ***HEALTH CARE COST CONTAINMENT INITIATIVES COULD LIMIT THE ADOPTION OF GENETIC TESTING AS A CLINICAL TOOL, WHICH WOULD HARM OUR REVENUES AND PROSPECTS.***

In recent years, health care payors as well as federal and state governments have focused on containing or reducing health care costs. We cannot predict the effect that any of these initiatives may have on our business, and it is possible that they will adversely affect our business. Health care cost containment initiatives focused on genetic testing could cause the growth in the clinical market for genetic testing to be curtailed or slowed. In addition, health care cost containment initiatives could also cause pharmaceutical companies to reduce research and development spending. In either case, our business and our operating results would be harmed. In addition, genetic testing in clinical settings is often billed to third-party payors, including private insurers and governmental organizations. If our current and future clinical products are not considered cost-effective by these payors, reimbursement may not be available to users of our products. In this event, potential customers would be much less likely to use our products, and our business and operating results would be seriously harmed.

### ***REIMBURSEMENT FOR USE OF OUR PRODUCTS***

Sales of our products will depend, in large part, on the availability of adequate reimbursement to users of those products from government insurance plans, managed care organizations and private insurance plans. Physicians' recommendations to use our products are likely to be influenced by the availability of reimbursement by insurance companies and other third-party payors. There can be no assurance that insurance companies or third-party payors will provide or continue to provide coverage for our products or that reimbursement levels will be adequate for the reimbursement of the providers of our products. In addition, outside the United States, reimbursement systems vary from country to country and there can be no assurances that third-party reimbursement will be made available at an adequate level, if at all, for our products under any other reimbursement system. Lack of or inadequate reimbursement by government or other third-party payors for our products would have a material adverse effect on our business, financial condition and results of operations.

### **ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES**

Our facility consists of space for research and development, manufacturing, product support operations, marketing and corporate headquarters and administration. Our facility is located in Madison, Wisconsin. Our facility is leased and described by the following:

<u>Type of Facility</u>	<u>Approx. Square Footage</u>	<u>Lease Expiration</u>
Headquarters, research and development, manufacturing, selling, marketing, and administration . . . . .	95,000	September 2011, with an option to extend for three 5-year periods.

Under the terms of the existing lease, we pay rent of approximately \$177,000 per month. We believe that our current facility will be adequate to meet our near-term space requirements. We also believe that suitable additional space will be available to us, if needed, on commercially reasonable terms.

**ITEM 3. LEGAL PROCEEDINGS**

In September 2004, we filed a suit against Stratagene Corporation in the United States District Court for the Western District of Wisconsin. The complaint alleged patent infringement of two of our patents concerning our proprietary Invader technology by Stratagene’s sale of its QPCR and QRT-PCR Full Velocity products. The case was tried before a jury in August 2005, and the jury found that Stratagene willfully infringed our patents and that our patents were valid. The jury awarded us \$5.29 million in damages. The Court subsequently entered a permanent injunction barring Stratagene from making, selling or offering to sell its Full Velocity QPCR and QRT-PCR products and any other products that practice our patented Invader methods. In December 2005, the Court tripled the damages award to \$15.9 million and ruled that Stratagene must pay attorney fees of \$4.2 million. Stratagene has appealed the verdict to the Court of Appeals for the Federal Circuit in Washington, D.C. In January 2006, the Court awarded additional interest on the damages award in the amount of \$485,716, increasing the total damages amount to \$16.4 million. Also in January 2006, Stratagene posted a \$21 million civil bond to stay payment of the judgment while it conducts its appeal.

In May 2005, Stratagene Corporation filed suit against us in the United States District Court for the District of Delaware. The complaint alleges patent infringement of claims of two Stratagene patents relating to our Invader Plus chemistry. The complaint was served on us in September 2005. Discovery is expected to begin in the near future. A trial date of November 5, 2007 was set by the Court.

In September 2005, Innogenetics filed suit against us in the United States District Court for the Western District of Wisconsin. The complaint alleged that our HCVg ASRs infringe a patent owned by Innogenetics relating to the detection of the hepatitis C virus. In February 2006, we reached an agreement with Innogenetics that resolved the litigation. In connection with the agreement, Third Wave acquired a non-exclusive license to Innogenetics’ patent for the United States. The agreement includes certain opt-out rights for Third Wave, as well as an option to extend both the term and global reach of the license.

In October 2005, we filed a declaratory judgment suit in the United States District Court for the Western District of Wisconsin against Digene Corporation seeking a ruling that our HPV ASRs do not infringe any valid claims of Digene’s human papillomavirus related patents. In January 2006, we reached an agreement with Digene to dismiss the suit without prejudice. We also agreed that neither party would file a suit against the other relating to the Digene human papillomavirus patents for one year.

Also in October 2005, we filed a declaratory judgment suit in the United States District Court for the Western District of Wisconsin against Chiron Corporation and Bayer Corporation seeking a ruling that our HCVg ASRs do not infringe any valid claims of Chiron’s hepatitis C related patents. In February 2006, we reached an agreement with Chiron and Bayer to dismiss the suit without prejudice. No licenses were granted or taken under the agreement and no payment of any monies was made to any of the companies.

While no assurance can be given regarding the outcome of the above matters, based on information currently available, the Company believes that the resolution of these matters will not have a material adverse effect on the financial position or results of future operations of the Company. However, because of the nature and inherent uncertainties of litigation, should the outcome of any of the actions be unfavorable, the Company's business, financial condition, results of operations and cash flows could be materially adversely affected.

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

None.

**PART II**

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

Our common stock is quoted on the NASDAQ National Market under the symbol "TWTT" and has been publicly traded since February 2001. The following table sets forth for each quarter in 2005 and 2004 the high and low sales prices per share, based on closing prices, for our common stock as reported on the NASDAQ National Market.

<u>Fiscal Year Ended December 31, 2005</u>	<u>High</u>	<u>Low</u>
First Quarter . . . . .	\$8.45	\$4.56
Second Quarter . . . . .	\$5.66	\$3.66
Third Quarter . . . . .	\$5.78	\$3.96
Fourth Quarter . . . . .	\$5.17	\$2.63
<u>Fiscal Year Ended December 31, 2004</u>	<u>High</u>	<u>Low</u>
First Quarter . . . . .	\$4.82	\$3.37
Second Quarter . . . . .	\$5.40	\$4.21
Third Quarter . . . . .	\$6.88	\$3.19
Fourth Quarter . . . . .	\$8.94	\$6.88

As of March 1, 2006, approximately 346 shareholders of record held our common stock.

We have never declared or paid any dividends on our capital stock. We currently expect to retain future earnings, if any, to support the development of our business and do not anticipate paying any cash dividends in the foreseeable future.

**Use of Proceeds.**

Pursuant to our Registration Statement on Form S-1, as amended, filed with the Securities and Exchange Commission and declared effective February 9, 2001, (Registration No. 333-42694), we commenced our initial public offering of 7,500,000 registered shares of common stock, \$0.001 par value, on February 9, 2001, at a price of \$11.00 per share (the "Offering"). The Offering was completed on February 14, 2001, and all of the 7,500,000 shares were sold, generating gross proceeds of approximately \$82,500,000. The managing underwriters for the Offering were Lehman Brothers Inc., CIBC World Markets, Dain Rauscher Incorporated, Robert W. Baird & Co. Incorporated, and Fidelity Capital Markets.

In connection with the Offering, we incurred approximately \$5.8 million in underwriting discounts and commissions, and approximately \$1.9 million in other related expenses. The net offering proceeds to us, after deducting the foregoing expenses, were approximately \$74.8 million.

From the time of receipt through December 31, 2005, we have invested the net proceeds from the Offering in investment-grade, interest-bearing securities. We used \$4.0 million of the proceeds to satisfy a cancellation fee for

the termination of a distribution agreement with Endogen Corporation. We used \$31.3 million for general corporate purposes, including working capital and research and development activities.

**ITEM 6. SELECTED FINANCIAL DATA**

The following table summarizes certain selected financial data that is derived from the Company's audited financial statements. All the information should be read in conjunction with the Company's audited financial statements and notes thereto and with Management's Discussion and Analysis of Financial Condition and Results of Operations, which are included elsewhere in this Form 10-K.

	For Year Ended December 31,				
	2005	2004	2003	2002	2001
	(In thousands, except for per share amounts)				
STATEMENT OF OPERATIONS DATA:					
Revenues . . . . .	\$ 23,906	\$46,493	\$36,320	\$ 32,355	\$ 34,092
Operating expenses:					
Cost of goods sold . . . . .	7,104	12,492	12,840	21,320	32,746
Research and development . . . . .	8,389	11,637	12,035	13,934	16,179
Selling and marketing . . . . .	12,772	10,803	8,859	9,578	9,200
General and administrative . . . . .	11,788	12,913	9,642	11,666	14,521
Litigation . . . . .	6,887	349	721	318	—
Restructuring and other charges . . . . .	—	(98)	—	11,087	—
Impairment of goodwill and other intangible assets . . . . .	—	—	—	4,810	—
Impairment of equipment . . . . .	203	795	—	—	—
Total operating expenses . . . . .	<u>47,143</u>	<u>48,891</u>	<u>44,097</u>	<u>72,713</u>	<u>72,646</u>
Loss from operations . . . . .	(23,237)	(2,398)	(7,777)	(40,358)	(38,554)
Other income (expense), net . . . . .	891	513	(339)	(506)	1,762
Loss before income taxes . . . . .	(22,346)	(1,885)	(8,116)	(40,864)	(36,792)
Provision for income taxes . . . . .	—	57	—	—	—
Net loss . . . . .	<u>\$(22,346)</u>	<u>\$(1,942)</u>	<u>\$(8,116)</u>	<u>\$(40,864)</u>	<u>\$(36,792)</u>
Basic and diluted net loss per share . . . . .	<u>\$ (0.54)</u>	<u>\$ (0.05)</u>	<u>\$ (0.20)</u>	<u>\$ (1.04)</u>	<u>\$ (1.03)</u>
Shares used in computing basic and diluted net loss per share . . . . .	41,125	40,463	39,749	39,457	35,714
Pro forma basic and diluted net loss per share (a) . . . . .					\$ (0.98)
Shares used in computing pro forma basic and diluted net loss per share . . . . .					37,483

	December 31,				
	2005	2004	2003	2002	2001
	(In thousands)				
<b>BALANCE SHEET DATA:</b>					
Cash, cash equivalents, and short term investments . . . . .	\$ 38,717	\$ 66,690	\$ 57,816	\$ 60,315	\$ 73,299
Working capital . . . . .	32,997	52,901	42,655	43,518	64,834
Total assets . . . . .	58,405	88,068	80,422	89,223	131,615
Long-term obligations, net of current portion . . . . .	831	487	13	13	6,694
Accumulated deficit . . . . .	(158,120)	(135,774)	(133,832)	(125,715)	(84,852)
Total shareholders' equity . . . . .	40,074	62,735	59,288	65,287	104,753

(a) Pro forma basic and diluted net loss per common share for 2001 gives effect to common stock equivalent shares arising, assuming that the preferred stock and convertible note payable were converted to common stock upon issuance using the “if converted” method. This pro forma disclosure has been included because the preferred stock and convertible note payable automatically converted to common stock upon closing of our initial public offering in February 2001.

**ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This Management’s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with “Selected Financial Data” and our financial statements, including the notes thereto, included elsewhere in this Form 10-K.

**OVERVIEW**

Third Wave Technologies, Inc. is a leading molecular diagnostics company. We believe our proprietary Invader® chemistry, a novel, molecular chemistry, is easier to use, cost-effective, and enables higher testing throughput. These and other advantages conferred by our chemistry are enabling us to provide clinicians and researchers with superior molecular solutions.

More than 130 clinical laboratory customers are using Third Wave’s molecular diagnostic reagents. Other customers include pharmaceutical and biotechnology companies, academic research centers and major health care providers.

Third Wave has received clearance from the U.S. Food and Drug Administration for its Invader UGT1A1 Molecular Assay. The Invader UGT1A1 Molecular Assay is cleared for use to identify patients who may be at increased risk of adverse reaction to the chemotherapy drug Camptosar® (irinotecan) by detecting and identifying specific mutations in the UGT1A1 gene that have been associated with that risk. Camptosar, marketed in the United States by Pfizer, Inc., is used to treat colorectal cancer and was relabeled recently to include dosing recommendations based on a patient’s genetic profile. The Company also markets a growing number of products, including analyte specific reagents (ASRs). These ASRs allow certified clinical reference laboratories to create assays to perform hepatitis C virus genotyping, inherited disorders testing (e.g., Factor V Leiden), and a host of other mutations associated with genetic predispositions and other diseases. The Company has developed or plans to develop a menu of molecular diagnostic products for clinical applications that include genetic testing, pharmacogenetics, and women’s health. The Company also has a number of other Invader products including those for research, agricultural and other applications.

Our financial results may vary significantly from quarter to quarter due to fluctuations in the demand for our products, timing of new product introductions and deliveries made during the quarter, the timing of research, development and grant revenues, and increases in spending, including expenses related to our product development submissions for FDA clearances or approvals and intellectual property litigation.

## **CRITICAL ACCOUNTING POLICIES**

Management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. We review the accounting policies we use in reporting our financial results on a regular basis. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to accounts receivable, inventories, equipment and leasehold improvements and intangible assets. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Results may differ from these estimates due to actual outcomes being different from those on which we based our assumptions. These estimates and judgments are reviewed by management on an ongoing basis, and by the Audit Committee at the end of each quarter prior to the public release of our financial results. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

## **REVENUE RECOGNITION**

Revenue from product sales is recognized upon delivery which is generally when the title passes to the customer, provided that the Company has completed all performance obligations and the customer has accepted the products. Customers have no contractual rights of return or refunds associated with product sales. Consideration received in multiple element arrangements is allocated to the separate units based upon their relative fair values.

Grant and development revenues consist primarily of research grants from agencies of the federal government and revenue from companies with which the Company has established strategic alliances, the revenue from which is recognized as research is performed. Payments received which are related to future performance are deferred and recorded as revenue when earned. Grant payments designated to purchase specific assets to be used in the performance of a contract are recognized as revenue over the shorter of the useful life of the asset acquired or the contract.

License and royalty revenue includes amounts earned from third parties for licenses of the Company's intellectual property and are recognized when earned under the terms of the related agreements. License revenues are generally recognized upon receipt unless the Company has continuing performance obligations, in which case the license revenue is recognized ratably over the period of expected performance.

## **RESTRUCTURING AND OTHER CHARGES**

The restructuring and other charges resulting from the restructuring plan in the third quarter of 2002 was recorded in accordance with Emerging Issues Task Force ("EITF") Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)," Staff Accounting Bulletin No. 100, "Restructuring and Impairment Charges," and Financial Accounting Standards Board ("FASB") Statement No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." The restructuring charge was comprised primarily of costs to consolidate facilities, impairment charges for abandoned leasehold improvements and equipment to be sold or abandoned, prepayment penalties related mainly to capital lease obligations on equipment to be sold or abandoned, and other costs related to the restructuring. In calculating the cost to consolidate the facilities, we estimated the future lease and operating costs to be paid until the leases are terminated and the amount, if any, of sublease receipts for each location. This required us to estimate the timing and costs of each lease to be terminated, the amount of operating costs, and the timing and rate at which we might be able to sublease the site. To form our estimates for these costs, we performed an assessment of the affected facilities and considered the current market conditions for each site. Estimates were also used in our calculation of the estimated realizable value on equipment that was held for sale. These estimates were formed based on recent history of sales of similar equipment and market conditions. Our assumptions on the lease termination payments, operating costs until terminated, and the offsetting sublease receipts may turn out to be incorrect and our actual cost may be materially different from our estimates.

## **LONG-LIVED ASSETS — IMPAIRMENT**

Equipment, leasehold improvements and amortizable identifiable intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. For assets held and used, if the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and carrying value of the asset or group of assets. For assets removed from service and held for sale, we estimate the fair market value of such assets and record an adjustment if fair value less costs to sell is lower than carrying value.

Goodwill and intangible assets deemed to have indefinite lives are not amortized, but are subject to annual impairment tests under Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets." The annual impairment test was completed in the quarters ended September 30, 2005, 2004, and 2003.

## **DERIVATIVE INSTRUMENTS**

We sell products in a number of countries throughout the world. During 2005, 2004 and 2003, we sold certain products with the resulting accounts receivable denominated in Japanese Yen. Prior to 2005, we purchased foreign currency forward contracts to manage the risk associated with collections of receivables denominated in foreign currencies in the normal course of business. These derivative instruments had maturities of less than one year and were intended to offset the effect of transaction gains and losses. There were no contracts outstanding at December 31, 2005 or December 31, 2004. Contracts outstanding at December 31, 2003 represented a combined U.S. dollar equivalent commitment of approximately \$9.5 million. The changes in the fair value of the derivatives and the loss or gain on the hedged asset relating to the risk being hedged are recorded currently in earnings.

## **INVENTORIES — SLOW MOVING AND OBSOLESCENCE**

Significant management judgment is required to determine the reserve for obsolete or excess inventory. Inventory on hand may exceed future demand either because of process improvements or technology advancements, the amount on hand is more than can be used to meet future need, or estimates of shelf lives may change. We currently consider all inventory that we expect will have no activity within one year as well as any additional specifically identified inventory to be subject to a provision for excess inventory. We also provide for the total value of inventories that we determine to be obsolete based on criteria such as changing manufacturing processes and technologies. At December 31, 2005, our inventory reserves were \$675,000, or 23% of our \$2.9 million total gross inventories.

## **STOCK-BASED COMPENSATION EXPENSE**

We currently account for share-based payments to employees using APB Opinion No. 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options when granted. On January 1, 2006 we adopted SFAS No. 123(R) as a result of which in future periods we will recognize expense for all share-based payments to employees, including grants of employee stock options, based on their fair values. Accordingly, the adoption of SFAS No. 123(R)'s fair value method will have a significant impact on the Company's results of operations, although it will have no impact on the Company's overall cash position. The impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future.

## **RESULTS OF OPERATIONS**

### ***Years Ended December 31, 2005 and 2004***

*Revenues.* Revenues for the year ended December 31, 2005 of \$23.9 million represented a decrease of \$22.6 million as compared to revenues of \$46.5 million for the year ended December 31, 2004. Following is a discussion of changes in revenues:

Total clinical molecular diagnostic product revenue increased to \$15.7 million in 2005 from \$15.0 million in 2004. U.S. clinical molecular diagnostic revenue increased to \$14.5 million in 2005 from \$12.3 million in 2004. We expect our clinical molecular diagnostic revenue to continue to increase in 2006.

Research product revenues decreased significantly to \$7.5 million in the year ended December 31, 2005 from \$31.1 million in the year ended December 31, 2004. The decrease in research product sales during 2005 resulted from a significant decrease in genomic research product sales to a Japanese research institute for use by several end users compared to prior year. We do not expect our 2006 genomic research product sales to recover to pre-2005 levels due to the completion of the HapMap projects.

License and royalty revenue was \$0.4 million in the year ended December 31, 2005 compared to \$0.2 million in 2004. In the years ended December 31, 2005 and 2004, we received royalty revenue of \$250,000 and \$150,000 respectively, from Monogram Biosciences (formerly Aclara), per the license and supply agreement.

*Significant Customer.* We generated \$3.9 million, or 16% of our revenues, from sales to a major Japanese research institute for use by several end-users during the year ended December 31, 2005, compared to \$27.6 million or 59% of our revenue in 2004. As of December 31, 2005, \$0.2 million of our accounts receivable were attributable to this customer. This customer will continue to purchase our products in 2006; however, the timing and total of such purchases will be influenced by the funding process and amounts which are unpredictable and unknown to us.

*Cost of Goods Sold.* Cost of goods sold consists of materials used in the manufacture of product, depreciation on manufacturing capital equipment, salaries and related expenses for management and personnel associated with our manufacturing and quality control departments and amortization of licenses and settlement fees. For the year ended December 31, 2005, cost of goods sold decreased to \$7.1 million, compared to \$12.5 million for the year ended December 31, 2004. The decrease was due to decreased sales volume related to Japan research products.

*Research and Development Expenses.* Our research activities are focused on moving our technology into broader markets. Our development activities are focused on new products to expand our molecular diagnostics menu. Research and development expenses consist primarily of salaries and related personnel costs, material costs for assays and product development, fees paid to consultants, depreciation and facilities costs and other expenses related to the design, development, testing, including clinical trials to validate the performance of our products, and enhancement of our products and acquisition of technologies used or to be used in our products. Research and development costs are expensed as they are incurred. Research and development expenses for the year ended December 31, 2005 were \$8.4 million, compared to \$11.6 million for the year ended December 31, 2004. The decrease in research and development expenses was primarily attributable to decrease in headcount related expenses. We will continue to invest in research and development, and expenditures in this area may increase as we expand our product development efforts. In addition, as the Company moves towards consideration of FDA cleared or approved products, there will be increased expenses attributed to these activities.

*Selling and Marketing Expenses.* Selling and marketing expenses consist primarily of salaries and related personnel costs for our sales and marketing management and field sales force, commissions, office support and related costs, and travel and entertainment. Selling and marketing expenses for the year ended December 31, 2005 were \$12.8 million, an increase of \$2.0 million, as compared to \$10.8 million for the year ended December 31, 2004. The increase was attributable to an increase in personnel related expenses.

*General and Administrative Expenses.* General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, legal and professional fees, office support and depreciation. General and administrative expenses decreased to \$11.8 million for the year ended December 31, 2005, from \$12.9 million for the year ended December 31, 2004. The decrease in general and administrative expenses was primarily due to a decrease in stock based compensation expense.

*Litigation Expense.* Litigation expense consists of legal fees and other costs associated with patent infringement and other lawsuits. Litigation expense increased to \$6.9 million in the year ended December 31, 2005 from \$0.3 million in 2004. The increase was due to the successful patent infringement lawsuit against Stratagene to defend our core technology. See Item I, Part 3-Legal Proceedings.

*Impairment Loss.* In the year ended December 31, 2005 an impairment charge of \$0.2 million was recorded for the loss on equipment that was sold, compared to \$0.8 million for the year ended December 31, 2004 for equipment written down to fair value.

*Interest Income.* Interest income for the year ended December 31, 2005 was \$1.7 million, compared to \$0.8 million for the year ended December 31, 2004. This increase was primarily due to higher interest rates in 2005 compared to 2004.

*Interest Expense.* Interest expense for the years ended December 31, 2005 was \$0.5 million compared to \$0.3 million in 2004.

*Provision for Income Taxes.* Income tax expense for the year ended December 31, 2004 of \$57,000 was due to alternative minimum tax. The Company was not subject to alternative minimum tax for the year ended December 31, 2005.

#### **Years Ended December 31, 2004 and 2003**

*Revenues.* Revenues for the year ended December 31, 2004 of \$46.5 million represented an increase of \$10.2 million as compared to revenues of \$36.3 million for the year ended December 31, 2003.

Total clinical molecular diagnostic product revenue increased to \$15.0 million in 2004, compared to \$8.5 million in 2003. U.S. clinical molecular diagnostic revenue increased to \$12.3 million in 2004 from \$6.8 million in 2003.

Research product revenues increased to \$31.1 million in the year ended December 31, 2004 from \$26.6 million in the year ended December 31, 2003. The increase in research product sales during 2004 resulted from an increase product sales to a Japanese research institute for use by several end users compared to prior year.

There were no development revenues in the year ended December 31, 2004, compared to \$0.9 million for the year ended December 31, 2003. The decrease was due to the transition from development revenue to product revenue in our development and commercialization agreement with BML, Inc. (BML).

License and royalty revenue was \$0.2 million in the years ended December 31, 2004 and 2003. In the years ended December 31, 2004 and 2003, we received royalty revenue of \$150,000 and \$100,000 respectively, from Monogram (formerly Aclara), per the license and supply agreement.

*Significant Customer.* We generated \$27.6 million, or 59% of our revenues, from sales to a major Japanese research institute for use by several end-users during the year ended December 31, 2004. As of December 31, 2004, \$2.1 million of our accounts receivable were attributable to this customer.

*Cost of Goods Sold.* Cost of goods sold consists of materials used in the manufacture of product, depreciation on manufacturing capital equipment, salaries and related expenses for management and personnel associated with our manufacturing and quality control departments and amortization of licenses and settlement fees. For the year ended December 31, 2004, cost of goods sold decreased to \$12.5 million, compared to \$12.8 million for the year ended December 31, 2003. The decrease was due to improved efficiencies.

*Research and Development Expenses.* Research and development expenses for the year ended December 31, 2004 were \$11.6 million, compared to \$12.0 million for the year ended December 31, 2003. The decrease in research and development expenses was primarily attributable to decreased material costs for assay and product development and a decrease in personnel related expenses.

*Selling and Marketing Expenses.* Selling and marketing expenses for the year ended December 31, 2004 were \$10.8 million, an increase of \$1.9 million, as compared to \$8.9 million for the year ended December 31, 2003. The increase was attributable to an increase in personnel related expenses.

*General and Administrative Expenses.* General and administrative expenses increased to \$12.9 million for the year ended December 31, 2004, from \$9.6 million for the year ended December 31, 2003. The increase was due to an increase in personnel related expenses and professional and consulting fees in 2004 compared to 2003.

*Litigation Expense.* Litigation expense decreased to \$0.3 million in the year ended December 31, 2004 from \$0.7 million in the year ended December 31, 2003. The decrease was due to the settlement of lawsuits.

*Impairment Loss.* In the year ended December 31, 2004, an impairment charge of \$0.8 million was recorded for equipment written down to fair value.

*Restructuring.* In the year ended December 31, 2004, a \$98,000 reduction to the restructuring reserve was recorded due to a change in assumptions. The estimate of the amount of sublease income expected was reduced. In addition, the estimated lease and operating expenses were also reduced, based on a portion of the office space being utilized.

*Interest Income.* Interest income for the year ended December 31, 2004 was \$0.8 million, compared to \$0.6 million for the year ended December 31, 2003. This increase was primarily due to higher interest rates and higher average cash balances in 2004 compared to 2003.

*Interest Expense.* Interest expense for the years ended December 31, 2004 and 2003 was approximately \$0.3 million.

*Provision for Income Taxes.* Income tax expense for the year ended December 31, 2004 of \$57,000 was due to alternative minimum tax.

## **LIQUIDITY AND CAPITAL RESOURCES**

Since our inception, we have financed our operations primarily through private placements of equity securities, research grants from federal and state government agencies, payments from strategic collaborators, equipment loans, capital leases, sale of products, a convertible note and our initial public offering. As of December 31, 2005, we had cash, cash equivalents and short-term investments of \$38.7 million.

Net cash used in operations for the year ended December 31, 2005 was \$17.8 million, compared with net cash provided of \$6.6 million in 2004 and net cash used of \$3.2 million in 2003. The change was primarily due to the decline in revenue from Japan and increased legal expenses related to litigation.

Net cash used in investing activities for the year ended December 31, 2005 was \$1.2 million, compared to \$0.8 million in 2004 and cash provided of \$0.2 million in 2003. Capital expenditures were \$0.4 million in the year ended December 31, 2005, compared to \$0.6 million in 2004 and \$0.2 million in 2003. Investing activities included proceeds from the sale of equipment of \$0.2 million in the year ended December 31, 2005, less than \$0.1 million in year ended December 31, 2004 and \$0.3 million in 2003. In the year ended December 31, 2005, the net cash provided from the purchases and maturities of short-term investments was \$35,000, compared to net cash used of \$0.3 million in 2004 and cash provided of \$0.2 million in 2003. In 2005, 2004 and 2003, we purchased certificates of deposit to collateralize our term loan with the bank. Additionally, in 2005, \$0.8 million was transferred to a bank account to collateralize our note with the bank.

Net cash used in financing activities was \$9.0 million in the year ended December 31, 2005, compared to net cash provided by financing activities of \$2.8 million in the year ended December 31, 2004 and \$0.7 million in 2003. Cash used in financing activities in the year ended December 31, 2005 consisted of \$9.7 million to repay debt, compared to \$34,000 in 2004 and \$15,000 in 2003. Additionally, in 2005 and 2004, \$0.1 million and \$12,000 was used for capital lease obligation payments, respectively. In 2005 and 2004, cash provided by financing activities included proceeds from long-term debt of \$0.8 million and \$0.5 million, respectively. During 2002, we entered into a term loan agreement due on July 31, 2003 to pay off the then existing debt and capital lease obligations. Upon expiration in 2003, 2004 and 2005 we renewed the term loan for an additional year. The Company paid the term loan in full in December 2005. Proceeds from the issuance of common stock through stock option exercises and employee stock purchase plan were \$0.9 million in 2005, compared to \$2.4 million in 2004 and \$0.7 million in 2003. Additionally, in 2005, \$0.9 million was used to repurchase 218,000 shares of common stock.

In 2005, we won a \$5.29 million judgment against Stratagene Corporation in connection with a patent infringement suit. The Court subsequently tripled that judgment and awarded us interest and attorneys fees. The total judgment is currently \$16.4 million plus \$4.2 million in attorneys fees. Stratagene has filed an appeal, and posted a \$21 million civil bond to stay payment of the judgment while it conducts its appeal. We expect the appeal process to last approximately eighteen months. If we prevail on appeal, payment by Stratagene of all or part of the judgment would result in a significant capital infusion for us. See Part I, Item 3 — Legal Proceedings.

As of December 31, 2005 and 2004, a valuation allowance equal to 100% of our net deferred tax assets had been recognized since future realization is not assured. At December 31, 2005, we had federal and state net operating loss carryforwards of approximately \$134 million. The net operating loss carryforwards will expire at various dates beginning in 2008, if not utilized. Utilization of the net operating losses to offset future taxable income

may be subject to an annual limitation due to the change of ownership provisions of federal tax laws and similar state provisions as a result of our initial public offering in February 2001.

We cannot assure you that our business or operations will not change in a manner that would consume available resources more rapidly than anticipated. We also cannot assure you that we will not require substantial additional funding before we can achieve profitable operations. Our capital requirements depend on numerous factors, including the following:

- our progress with our research and development programs;
- the needs we may have to pursue FDA clearances or approvals of our products;
- our level of success in selling our products and technologies;
- our ability to establish and maintain successful collaborative relationships;
- the costs we incur in securing intellectual property rights, whether through patents, licenses or otherwise;
- the costs we incur in enforcing and defending our patent claims and other intellectual property rights;
- the need to respond to competitive pressures;
- the possible acquisition of complementary products, businesses or technologies; and
- the timing of capital expenditures.

## CONTRACTUAL OBLIGATIONS

The following summarizes our contractual obligations at December 31, 2005 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	<u>Total</u>	<u>Less Than 1 Year</u>	<u>Years 2 – 3</u>	<u>Years 4 – 5</u>	<u>Over 5 Years</u>
CONTRACTUAL OBLIGATIONS					
Non-cancelable operating lease obligation . . . .	\$11,890	\$1,879	\$3,986	\$4,311	\$1,714
Capital lease obligations . . . . .	307	115	147	45	—
License arrangements . . . . .	1,772	341	786	645	—
Long-term debt . . . . .	<u>1,018</u>	<u>378</u>	<u>590</u>	<u>50</u>	<u>—</u>
Total obligations . . . . .	<u>\$14,987</u>	<u>\$2,713</u>	<u>\$5,509</u>	<u>\$5,051</u>	<u>\$1,714</u>

We also have an available and unused \$1.3 million letter of credit.

## OFF-BALANCE SHEET ARRANGEMENTS

There were no off-balance sheet arrangements as of December 31, 2005.

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

Our exposure to market risk is currently confined to changes in foreign exchange and interest rates. The securities in our investment portfolio are not leveraged and, due to their short-term nature, are subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Due to the short-term maturities of our investments, we do not believe that an increase in market rates would have any negative impact on the realized value of our investment portfolio.

To reduce foreign exchange risk, we selectively use financial instruments. Our earnings are affected by fluctuations in the value of the U.S. Dollar against foreign currencies as a result of the sales of our products in foreign markets. From time to time we may purchase forward foreign exchange contracts to hedge against the effects of such fluctuations. At December 31, 2005, we did not hold any forward foreign exchange contracts. Our policy prohibits the trading of financial instruments for profit. A discussion of our accounting policies for derivative financial instruments is included in the notes to the financial statements.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**CONSOLIDATED FINANCIAL STATEMENTS**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders  
of Third Wave Technologies, Inc.

We have audited the accompanying consolidated balance sheet of Third Wave Technologies, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2005, and the related consolidated statements of operations, shareholders' equity and cash flows for the year ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Third Wave Technologies, Inc. and subsidiaries as of December 31, 2005, and the results of their operations and their cash flows for the year ended December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

Our audit was conducted for the purpose of forming an opinion on the basic consolidated financial statements taken as a whole. Schedule II is presented for purposes of additional analysis and is not a required part of the basic consolidated financial statements. This schedule has been subjected to the auditing procedures applied in the audit of the basic consolidated financial statements and, in our opinion, is fairly stated in all material respects in relation to the basic consolidated financial statements taken as a whole.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 20, 2006 expressed an unqualified opinion.

GRANT THORNTON LLP

Madison, Wisconsin  
February 20, 2006

## **Report of Independent Registered Public Accounting Firm**

To the Board of Directors  
Third Wave Technologies, Inc.

We have audited the accompanying consolidated balance sheet of Third Wave Technologies, Inc. (the Company) as of December 31, 2004, and the related consolidated statements of operations, shareholders' equity and cash flows for the years ended December 31, 2004 and 2003. Our audits also included the financial statement schedule listed in the index at Item 15(a) for the years ended December 31, 2004 and 2003. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits 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. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Third Wave Technologies, Inc. at December 31, 2004, and the consolidated results of its operations and its cash flows for the years ended December 31, 2004 and 2003, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule for the years ended December 31, 2004 and 2003, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

Ernst & Young LLP

Milwaukee, Wisconsin  
March 4, 2005

**THIRD WAVE TECHNOLOGIES, INC.**

**Consolidated Balance Sheets**

	<u>December 31, 2005</u>	<u>December 31, 2004</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 27,681,704	\$ 55,619,981
Short-term investments . . . . .	11,035,000	11,070,000
Accounts receivables, net of allowance for doubtful accounts of \$200,000 and \$300,000 at December 31, 2005 and December 31, 2004, respectively . . . . .	3,764,519	5,784,679
Inventories . . . . .	2,248,183	1,236,392
Prepaid expenses and other . . . . .	<u>235,794</u>	<u>260,316</u>
Total current assets . . . . .	44,965,200	73,971,368
Equipment and leasehold improvements:		
Machinery and equipment . . . . .	15,563,119	15,832,489
Leasehold improvements . . . . .	<u>2,346,938</u>	<u>2,277,604</u>
	17,910,057	18,110,093
Less accumulated depreciation . . . . .	<u>13,192,617</u>	<u>12,139,423</u>
	<u>4,717,440</u>	<u>5,970,670</u>
Assets held for sale . . . . .	—	269,000
Restricted Cash . . . . .	805,184	—
Intangible assets, net of accumulated amortization . . . . .	2,641,620	4,146,372
Indefinite-lived intangible assets . . . . .	1,007,411	1,007,411
Goodwill . . . . .	489,873	489,873
Other assets . . . . .	<u>3,778,000</u>	<u>2,212,935</u>
Total assets . . . . .	<u>\$ 58,404,728</u>	<u>\$ 88,067,629</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 6,850,207	\$ 6,519,005
Accrued payroll and related liabilities . . . . .	2,158,870	2,873,506
Other accrued liabilities . . . . .	2,344,835	1,867,361
Deferred revenue . . . . .	121,497	129,530
Capital lease obligations due within one year . . . . .	114,693	66,867
Long-term debt due within one year . . . . .	<u>378,551</u>	<u>9,614,127</u>
Total current liabilities . . . . .	11,968,653	21,070,396
Long-term debt . . . . .	639,564	335,069
Deferred revenue — long-term . . . . .	145,382	254,434
Capital lease obligations — long-term . . . . .	191,924	151,885
Other liabilities . . . . .	5,384,904	3,520,948
Shareholders' equity:		
Participating preferred stock, Series A, \$.001 par value, 10,000,000 shares authorized, 0 shares issued and outstanding . . . . .	—	—
Common stock, \$.001 par value, 100,000,000 shares authorized, 41,461,377 shares issued, 41,243,377 shares outstanding at December 31, 2005 and 41,102,764 shares issued and outstanding at December 31, 2004 . . . . .	41,461	41,103
Additional paid-in capital . . . . .	199,097,187	198,990,162
Unearned stock compensation . . . . .	(114,892)	(554,293)
Treasury stock — 218,000 shares acquired at an average price of \$4.02 per share . . . . .	(877,159)	—
Foreign currency translation adjustment . . . . .	47,442	31,949
Accumulated deficit . . . . .	<u>(158,119,738)</u>	<u>(135,774,024)</u>
Total shareholders' equity . . . . .	40,074,301	62,734,897
Total liabilities and shareholders' equity . . . . .	<u>\$ 58,404,728</u>	<u>\$ 88,067,629</u>

See accompanying notes to the consolidated financial statements

**THIRD WAVE TECHNOLOGIES, INC.**

**Consolidated Statements of Operations**

	Year Ended December 31,		
	2005	2004	2003
Revenues:			
Clinical product sales . . . . .	\$ 15,665,519	\$14,950,815	\$ 8,530,809
Research product sales . . . . .	7,505,286	31,065,312	26,617,488
Development revenue . . . . .	—	—	916,664
License and royalty revenue . . . . .	362,372	234,841	193,792
Grant revenue . . . . .	372,483	242,032	61,098
Total revenues . . . . .	<u>23,905,660</u>	<u>46,493,000</u>	<u>36,319,851</u>
Operating expenses:			
Cost of goods sold (including amortization of capitalized legal settlement costs of \$1,504,752 in 2005, 2004, and 2003) . . . . .	7,103,834	12,491,783	12,839,502
Research and development . . . . .	8,389,316	11,636,620	12,035,375
Selling and marketing . . . . .	12,772,439	10,803,381	8,858,678
General and administrative . . . . .	11,787,976	12,913,848	9,642,434
Litigation . . . . .	6,886,928	348,525	720,705
Impairment of equipment . . . . .	202,707	794,716	—
Restructuring and other charges . . . . .	—	(98,000)	—
Total operating expense . . . . .	<u>47,143,200</u>	<u>48,890,873</u>	<u>44,096,694</u>
Loss from operations . . . . .	(23,237,540)	(2,397,873)	(7,776,843)
Other income (expense):			
Interest income . . . . .	1,714,346	776,295	571,282
Interest expense . . . . .	(457,004)	(283,240)	(298,182)
Other . . . . .	(365,516)	19,753	(612,493)
Total other income (expense) . . . . .	891,826	512,808	(339,393)
Loss before income taxes . . . . .	(22,345,714)	(1,885,065)	(8,116,236)
Provision for income taxes . . . . .	—	57,341	—
Net loss . . . . .	<u>\$(22,345,714)</u>	<u>\$(1,942,406)</u>	<u>\$(8,116,236)</u>
Net loss per share — basic and diluted . . . . .	\$ (0.54)	\$ (0.05)	\$ (0.20)

See accompanying notes to the consolidated financial statements

**Third Wave Technologies, Inc**  
**Consolidated Statement of Shareholders' Equity**

	Common Stock		Unearned Stock Compensation	Treasury Stock	Foreign Currency Translation	Accumulated Deficit	Total
	Par	Additional Paid in Capital					
Balance at December 31, 2002 . . . .	\$39,560	\$191,581,136	\$ (618,246)	\$ —	\$ —	\$(125,715,382)	\$ 65,287,068
Common stock issued for stock options and stock purchase plan — 461,670 shares . . . . .	461	721,568	—	—	—	—	722,029
Unearned stock compensation . . .	—	1,162,477	(1,162,477)	—	—	—	—
Amortization of unearned stock compensation . . . . .	—	—	1,374,377	—	—	—	1,374,377
Reversal of unearned stock compensation related to terminated employees . . . . .	—	(109,060)	96,350	—	—	—	(12,710)
Net loss . . . . .	—	—	—	—	—	(8,116,236)	(8,116,236)
Foreign currency translation adjustment . . . . .	—	—	—	—	33,307	—	33,307
Comprehensive loss . . . . .	—	—	—	—	—	—	(8,082,929)
Balance at December 31, 2003 . . . .	40,021	193,356,121	(309,996)	—	33,307	(133,831,618)	59,287,835
Common stock issued for stock options and stock purchase plan — 1,081,520 shares . . . . .	1,082	2,363,289	—	—	—	—	2,364,371
Unearned stock compensation . . .	—	3,270,752	(3,270,752)	—	—	—	—
Amortization of unearned stock compensation . . . . .	—	—	3,026,455	—	—	—	3,026,455
Net loss . . . . .	—	—	—	—	—	(1,942,406)	(1,942,406)
Foreign currency translation adjustment . . . . .	—	—	—	—	(1,358)	—	(1,358)
Comprehensive loss . . . . .	—	—	—	—	—	—	(1,943,764)
Balance at December 31, 2004 . . . .	41,103	198,990,162	(554,293)	—	31,949	(135,774,024)	62,734,897
Common stock issued for stock options and stock purchase plan — 358,613 shares . . . . .	358	915,403	—	—	—	—	915,761
Unearned stock compensation . . .	—	(808,378)	808,378	—	—	—	—
Amortization of unearned stock compensation . . . . .	—	—	(368,977)	—	—	—	(368,977)
Common stock repurchased for treasury — 218,000 shares . . . .	—	—	—	(877,159)	—	—	(877,159)
Net loss . . . . .	—	—	—	—	—	(22,345,714)	(22,345,714)
Foreign currency translation adjustment . . . . .	—	—	—	—	15,493	—	15,493
Comprehensive loss . . . . .	—	—	—	—	—	—	(22,330,221)
Balance at December 31, 2005 . . . .	<u>\$41,461</u>	<u>\$199,097,187</u>	<u>\$ (114,892)</u>	<u>\$(877,159)</u>	<u>\$47,442</u>	<u>\$(158,119,738)</u>	<u>\$ 40,074,301</u>

See accompanying notes to the consolidated financial statements

**THIRD WAVE TECHNOLOGIES, INC.**

**Consolidated Statements of Cash Flows**

	Year Ended December 31,		
	2005	2004	2003
<b>OPERATING ACTIVITIES:</b>			
Net loss . . . . .	\$(22,345,714)	\$ (1,942,406)	\$ (8,116,236)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization . . . . .	1,705,252	2,107,466	2,607,096
Amortization of intangible assets . . . . .	1,504,752	1,504,752	1,504,752
Amortization of licensed technology . . . . .	398,132	623,956	480,633
Noncash stock compensation . . . . .	(368,977)	3,026,455	1,361,667
Impairment charge and (gain) loss on disposal of equipment . . . . .	208,681	888,817	(410)
Changes in operating assets and liabilities:			
Receivables . . . . .	1,937,853	(3,724,983)	697,109
Inventories . . . . .	(1,011,791)	157,654	266,298
Prepaid expenses and other assets . . . . .	131,298	390,645	809,031
Accounts payable . . . . .	(10,029)	1,563,571	(2,133,528)
Accrued expenses and other liabilities . . . . .	195,852	1,664,244	224,512
Deferred revenue . . . . .	(117,085)	316,204	(877,904)
Net cash provided by (used in) operating activities . . . . .	(17,771,776)	6,576,375	(3,176,980)
<b>INVESTING ACTIVITIES:</b>			
Purchases of equipment and leasehold improvements . . . . .	(404,934)	(578,472)	(249,916)
Proceeds on sale of equipment . . . . .	197,683	88,320	321,264
Purchases of licensed technology . . . . .	(200,000)	—	(100,000)
Change in restricted cash balance . . . . .	(805,184)	—	—
Purchases of short-term investments . . . . .	(11,835,000)	(11,070,000)	(10,800,000)
Maturities of short-term investments . . . . .	11,870,000	10,800,000	11,013,000
Net cash provided by (used in) investing activities . . . . .	(1,177,435)	(760,152)	184,348
<b>FINANCING ACTIVITIES:</b>			
Proceeds from long-term debt . . . . .	800,000	470,000	—
Payments on long-term debt . . . . .	(9,731,081)	(34,137)	(15,152)
Payments on capital lease obligations . . . . .	(96,587)	(12,222)	—
Proceeds from issuance of common stock, net . . . . .	915,761	2,364,371	722,029
Repurchase of common stock for treasury . . . . .	(877,159)	—	—
Net cash provided by (used in) financing activities . . . . .	(8,989,066)	2,788,012	706,877
Net increase (decrease) in cash and cash equivalents . . . . .	(27,938,277)	8,604,235	(2,285,755)
Cash and cash equivalents at beginning of period . . . . .	55,619,981	47,015,746	49,301,501
Cash and cash equivalents at end of period . . . . .	\$ 27,681,704	\$ 55,619,981	\$ 47,015,746
Supplemental disclosure of cash flows information — Cash paid for interest . . . . .	\$ 468,520	\$ 277,226	\$ 301,817
Supplemental disclosure of cash flows information — Income taxes paid . . . . .	\$ 52,754	\$ —	\$ —

Noncash investing and financing activities:

During the years ended December 31, 2005 and 2004, the Company entered into capital lease obligations of \$184,452 and \$230,974, respectively.

During the year ended December 31, 2005 the Company entered into a license agreement in which the Company will pay \$2,000,000 over time through 2010. The estimated present value of the license obtained was \$1,772,172.

See accompanying notes to the consolidated financial statements

**Third Wave Technologies, Inc.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2005**

**1. NATURE OF OPERATIONS AND PRINCIPLES OF CONSOLIDATION**

***PRINCIPLES OF CONSOLIDATION***

The accompanying consolidated financial statements include the accounts of Third Wave Technologies, Inc. (the Company) and its wholly-owned subsidiaries, Third Wave-Japan KK and Third Wave Agbio, Inc. (Agbio). All significant intercompany balances and transactions are eliminated in the consolidation.

***NATURE OF OPERATIONS***

The Company is a leading molecular diagnostics company. The Company believes its proprietary Invader® technology platform is easier to use, more accurate and cost-effective, and enables higher testing throughput than conventional methods. These and other advantages conferred by the Company's technology platform are enabling the Company to provide physicians and researchers with superior molecular solutions for the analysis and treatment of disease.

The Company currently markets products domestically and internationally to clinical and research markets using an internal sales force as well as collaborative relationships with pharmaceutical companies and research institutions. Revenues to a major Japanese research institute for use by several end users during 2005, 2004 and 2003 were 16%, 59% and 69% of total revenues, respectively. The Company performs periodic credit evaluations of its customers' financial condition and generally does not require collateral. The Company evaluates the collectibility of its accounts receivable based on a combination of factors. For accounts greater than 60 days past due, an allowance for doubtful accounts is recorded based on a customer's ability and likelihood to pay based on management's review of the facts. For all other accounts, the Company recognizes an allowance based on the length of time the receivable is past due and the anticipated future write offs based on historical experience.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

A summary of the significant accounting policies consistently applied in the preparation of the accompanying financial statements follows.

***CASH EQUIVALENTS, SHORT-TERM INVESTMENTS, AND RESTRICTED CASH***

The Company considers highly liquid money market investments and short-term investments with maturities of 90 days or less from the date of purchase to be cash equivalents.

Short-term investments consist of certificates of deposit with original maturities less than one year. The cost of these securities, which are considered "available-for-sale" for financial reporting purposes, approximates fair value at December 31, 2005 and 2004.

The Company has cash in a bank account that is used as collateral for notes payable. The amount used as collateral is classified as restricted cash.

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

***INVENTORIES***

Inventories are carried at the lower of cost or market using the first-in, first-out method for determining cost and consist of the following:

	<b>December 31</b>	
	<u>2005</u>	<u>2004</u>
Raw materials . . . . .	\$1,486,166	\$1,318,771
Finished goods and work in process . . . . .	1,437,017	567,621
Reserve for excess and obsolete inventory . . . . .	<u>(675,000)</u>	<u>(650,000)</u>
Total inventories . . . . .	<u>\$2,248,183</u>	<u>\$1,236,392</u>

***ADVERTISING COSTS***

Advertising costs are expensed as incurred. Advertising costs were \$75,814, \$85,069, and \$165,854 in 2005, 2004 and 2003, respectively.

***FOREIGN CURRENCY TRANSLATION***

The Company's Japanese subsidiary uses the local currency as its functional currency. Accordingly, assets and liabilities are translated into U.S. dollars at year-end exchange rates, and revenues and expenses are translated at weighted-average exchange rates. The resulting translation adjustment is recorded as a separate component of shareholders' equity and will be included in the determination of net income (loss) only upon sale or liquidation of the subsidiary.

***EQUIPMENT AND LEASEHOLD IMPROVEMENTS***

Equipment and leasehold improvements are recorded at cost less accumulated depreciation. Depreciation of purchased equipment is computed by the straight-line method over the estimated useful lives of the assets which are generally three to ten years. Depreciation of leasehold improvements and leased equipment is computed by the straight-line method over the shorter of the estimated useful lives of the assets or the remaining lease term.

***PATENTS***

Patent-related development costs are expensed in the period incurred and are included in general and administrative expenses in the statements of operations. These costs were \$1,000,990, \$844,110, and \$780,959 in 2005, 2004 and 2003, respectively.

***GOODWILL AND OTHER INTANGIBLE ASSETS***

Under Statement of Financial Accounting Standards (SFAS) No. 142, "Goodwill and Other Intangible Assets" goodwill and intangible assets deemed to have indefinite lives are not amortized, but are subject to annual impairment tests. Remaining intangible assets at December 31, 2005, 2004 and 2003 consist primarily of costs of settling patent litigation, which are amortized over their estimated useful life of seven years.

The Company completed its annual impairment tests in the third quarter of 2003, 2004 and 2005. In addition, an interim impairment test was performed in the second quarter of 2004 due to a change in the Company's forecast. For goodwill, this analysis is based on the comparison of the fair value of its reporting units to the carrying value of the net assets of the respective reporting units. The fair value of the reporting units was determined using a combination of discounted cash flows method and other common valuation methodologies. For intangible assets with indefinite lives, the fair values of these assets determined using the discounted cash flow approach were compared to their carrying values.

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

The Company concluded that no impairment existed at the time of the annual impairment test in 2003, 2004 and 2005 or at the time of the additional impairment test in the second quarter of 2004.

Identifiable intangible assets with indefinite lives consist of the following at December 31, 2005 and 2004:

Technology license . . . . .	\$ 915,828
Trademark . . . . .	<u>91,583</u>
	<u>\$1,007,411</u>

Amortizable intangible assets consist of the following:

	<u>December 31, 2005</u>		<u>December 31, 2004</u>	
	<u>Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Carrying Amount</u>	<u>Accumulated Amortization</u>
Costs of settling patent litigation . . . . .	\$10,533,248	\$ 7,891,628	\$10,533,248	\$6,386,876
Reacquired marketing and distribution rights . . . . .	2,211,111	2,211,111	2,211,111	2,211,111
Customer agreements . . . . .	<u>38,000</u>	<u>38,000</u>	<u>38,000</u>	<u>38,000</u>
	<u>\$12,782,359</u>	<u>\$10,140,739</u>	<u>\$12,782,359</u>	<u>\$8,635,987</u>

The estimated future amortization expense related to intangible assets for the years subsequent to December 31, 2005 is as follows:

2006 . . . . .	\$1,504,752
2007 . . . . .	\$1,136,868

***IMPAIRMENT OF LONG-LIVED ASSETS***

Equipment, leasehold improvements and amortizable identifiable intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and carrying value of the asset or group of assets. Such analyses involve significant judgment. The Company recorded an impairment loss of \$203,000 and \$795,000 in 2005 and 2004, respectively, related to a write-down of certain equipment to its fair value.

***PREPAID LICENSE FEES***

Other assets at December 31, 2005 and 2004 include \$2,797,046 and \$1,223,005, respectively, of prepaid license fees (which is net of \$2,470,164 and \$2,072,033, respectively, of accumulated amortization) paid to third parties for the use of patented technology. The assets are being amortized to expense over the shorter of the term of the license or the estimated useful lives of the assets (generally three to ten years).

***DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES***

The Company sells its products in a number of countries throughout the world. During 2005, 2004 and 2003, the Company sold certain products with the resulting accounts receivable denominated in Japanese Yen. The Company may from time to time purchase foreign currency forward contracts to manage the risk associated with collections of receivables denominated in foreign currencies in the normal course of business. These derivative instruments have maturities of less than one year and are intended to offset the effect of currency gains and losses on the underlying Yen receivables. There were no contracts outstanding at December 31, 2005 and 2004. Forward contracts outstanding at December 31, 2003, represented a U.S. dollar equivalent commitment of approximately \$9,500,000. The changes in the fair value of the Company's derivatives and the loss or gain on the hedged asset

## **Third Wave Technologies, Inc.**

### **Notes to Consolidated Financial Statements — (Continued)**

relating to the risk being hedged both are recorded currently in operations. Aggregate losses (gains) from foreign currency transactions are included in other income (expense) and were approximately \$451,000, (\$71,000), and \$708,000 in 2005, 2004 and 2003, respectively.

#### ***REVENUE RECOGNITION***

Revenue from product sales is recognized upon delivery which is generally when the title passes to the customer, provided that the Company has completed all performance obligations and the customer has accepted the products. Customers have no contractual rights of return or refunds associated with product sales. Consideration received in multiple element arrangements is allocated to the separate units based upon their relative fair values determined at the time the contract is initiated.

Grant and development revenues consist primarily of research grants from agencies of the federal government and revenue from companies with which the Company has established strategic alliances, the revenue from which is recognized as research is performed. Payments received which are related to future performance are deferred and recorded as revenue when earned. Grant payments designated to purchase specific assets to be used in the performance of a contract are recognized as revenue over the shorter of the useful life of the asset acquired or the contract.

License and royalty revenue includes amounts earned from third parties for licenses of the Company's intellectual property and are recognized when earned under the terms of the related agreements. License revenues are generally recognized upon receipt unless the Company has continuing performance obligations, in which case the license revenue is recognized ratably over the period of expected performance. Royalty revenues are recognized under the terms of the related agreements, generally upon manufacture or shipment of a product by a licensee.

#### ***RESEARCH AND DEVELOPMENT***

All costs for research and development activities are expensed in the period incurred.

#### ***SHIPPING AND HANDLING COSTS***

Shipping and handling costs incurred are classified as cost of goods sold in the accompanying statements of operations.

#### ***INCOME TAXES***

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the current tax payable for the period plus or minus the change during the period in deferred tax assets and liabilities. Prior to 2004, no current or deferred income taxes have been provided because of the net operating losses incurred by the Company since its inception (see Note 6).

#### ***STOCK-BASED COMPENSATION***

The Company has stock-based employee compensation plans (see Note 5). For 2005 and prior years, SFAS No. 123, "Accounting for Stock-Based Compensation," encouraged, but did not require companies to record compensation cost for stock-based employee compensation plans at fair value. The Company has chosen to continue using the intrinsic value method prescribed in Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations, in accounting for its stock option plans through December 31, 2005.

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

Had compensation cost been determined based upon the fair value method prescribed by SFAS No. 123 at the grant date for awards under the plans, the Company's SFAS No. 123 pro forma net loss and net loss per share would have been as follows:

	Year Ended December 31,		
	2005	2004	2003
Net loss:			
As reported . . . . .	\$(22,345,714)	\$(1,942,406)	\$ (8,116,236)
Add: Stock-based compensation, as recognized . . .	(368,977)	3,026,455	1,361,667
Add: Stock-based compensation expense related to stock options determined under SFAS No. 123 . .	(10,050,950)	(4,347,817)	(4,216,913)
Add: Stock-based compensation related to the employee stock purchase plan under SFAS No. 123 . . . . .	(207,989)	(283,898)	(172,571)
SFAS No. 123 Pro forma . . . . .	\$(32,973,630)	\$(3,547,666)	\$(11,144,053)
Net loss per share:			
As reported, basic and diluted . . . . .	\$ (0.54)	\$ (0.05)	\$ (0.20)
SFAS No. 123 pro forma, basic and diluted . . . . .	\$ (0.80)	\$ (0.09)	\$ (0.28)

Stock compensation expense for options granted to nonemployees has been determined in accordance with SFAS No. 123 and Emerging Issues Task Force (EITF) Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," and represents the fair value of the consideration received or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to nonemployees is periodically remeasured as the underlying options vest.

***FAIR VALUE OF FINANCIAL INSTRUMENTS***

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, short-term investments, accounts receivable, accounts payable and long-term debt are considered to approximate their respective fair values.

***USE OF ESTIMATES***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

***NET LOSS PER SHARE***

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the respective periods. The effect of stock options is antidilutive for all periods presented due to the existence of net losses.

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

The following table presents the calculation of basic and diluted net loss per share.

	Year Ended December 31		
	2005	2004	2003
Net loss . . . . .	\$(22,345,714)	\$ (1,942,406)	\$ (8,116,236)
Weighted-average shares of common stock outstanding — basic and diluted . . . . .	41,125,000	40,463,000	39,749,000
Basic and diluted net loss per share . . . . .	\$ (0.54)	\$ (0.05)	\$ (0.20)
Weighted-average shares from options that could potentially dilute basic earnings per share in the future that are not included in the computation of diluted loss per share as their impact is antidilutive (computed under the treasury stock method) . . . . .	1,591,000	2,091,000	1,213,000

***NEW ACCOUNTING PRONOUNCEMENTS***

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), “Share-Based Payment,” which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB Opinion No. 25 and amends SFAS No. 95, “Statement of Cash Flows.” Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

SFAS No. 123(R) must be adopted no later than January 1, 2006. The Company will adopt SFAS No. 123(R) on January 1, 2006. SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods: (1) a “modified prospective” method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123(R) for all-share based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123(R) that remain unvested on the effective date; or (2) 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 No. 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. The Company has determined that it will adopt the modified prospective approach.

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB Opinion No. 25’s intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options when granted as the number of shares is fixed and the exercise price of the stock options equals the market price of the underlying stock on the date of grant. Accordingly, the adoption of SFAS No. 123(R)’s fair value method will have a significant impact on the Company’s results of operations, although it will have no impact on the Company’s overall cash position. The impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current pronouncement.

***RECLASSIFICATION***

Certain reclassifications have been made to the 2004 and 2003 financial statements to conform to the 2005 presentation.

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

**3. CHANGE IN ACCOUNTING ESTIMATE**

The Company has Long-Term Incentive Plans in place which compensate certain employees if performance targets are met over the three-year performance period. The amount of compensation is determined by the level of achievement against the performance targets.

During the fourth quarter of 2005, the Company revised its estimate for the liability related to its Long-term Incentive Plans. Based on revised forecasts and other available information, the Company determined that the likelihood of achieving the performance target levels previously used to calculate the accrual was diminished. As a result of this change, the Company recognized a \$921,000 decrease to the Long-term Incentive Plans during the fourth quarter of 2005.

**4. LONG-TERM DEBT**

Long-term debt is as follows:

	December 31	
	2005	2004
Notes payable . . . . .	\$1,018,115	\$9,935,863
Other . . . . .	—	13,333
	1,018,115	9,949,196
Less current portion . . . . .	378,551	9,614,127
	<u>\$ 639,564</u>	<u>\$ 335,069</u>

Future long-term debt payments, as of December 31, 2005, by year are as follows:

2006 . . . . .	\$378,551
2007 . . . . .	368,298
2008 . . . . .	221,490
2009 . . . . .	49,776

The Company had a \$9,500,000 note payable with a bank due on August 14, 2005, bearing annual interest at 3.36%. The Company renewed the note payable upon expiration in 2005 for an additional one year term, bearing annual interest at 5.17%, and subsequently paid the note in full in December 2005. The Company has three additional notes payable in the original amounts of \$200,000, \$270,000, and \$800,000. These additional notes have respective final maturity dates of July 1, 2007, October 1, 2009, and July 1, 2008, bear annual interest at 4.25%, 4.93%, and 5.2%, respectively, and require monthly principal and interest payments. The Company has an available and unused \$1,300,000 letter of credit with the same bank that expires on September 1, 2006 (see Note 7). The letter of credit and borrowings under the notes payable are secured by short-term investments consisting of certificates of deposit in the aggregate amount of \$1,535,000 and balances in a specified bank account.

**5. SHAREHOLDERS' EQUITY**

The Board of Directors has authorized a program for the repurchase by the Company of up to 5% of its outstanding common stock. As of December 31, 2005, 218,000 shares of common stock have been repurchased at an average price of \$4.02 per share. The program expired on December 31, 2005.

***STOCK PURCHASE PLAN***

The Company has an Employee Stock Purchase Plan (Purchase Plan) under which an aggregate of 1,256,800 common shares may be issued. The Purchase Plan also provides for annual increases in the number of shares available for issuance, beginning in 2001, equal to the lesser of 1% of the outstanding shares of common stock on

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

the first day of the fiscal year, 428,400 shares or an amount determined by the Board of Directors. In 2005, there were no additional shares authorized for issuance under the plan. During 2004, 400,000 additional shares were authorized for issuance under the plan. During 2005, 2004 and 2003, 114,562, 306,211, and 254,421 shares, respectively, were issued. Employees are eligible to participate in the Purchase Plan if they work at least 20 hours per week and more than five months in any calendar year. Eligible employees may make contributions through payroll deductions of up to 10% of their compensation. The price of common stock purchased under the Purchase Plan is 85% of the lower of the fair market value of the common stock at the beginning or end of the offering period. The Plan is considered noncompensatory under APB Opinion No. 25 and, therefore, no expense is recorded for the 15% discount.

***STOCK OPTION PLANS***

The Company has Incentive Stock Option Plans for its employees and Nonqualified Stock Option Plans (the Plans) for employees and non-employees under which an aggregate of 13,213,183 options may be granted. Annual increases in the number of shares available for issuance are allowed beginning in 2001, limited to the lesser of 4.5% of the outstanding shares of common stock on the first day of the fiscal year, 2,571,600 shares or an amount determined by the Board of Directors. During 2005 and 2004, 1,800,000 and 1,500,000 additional shares, respectively, were authorized for grant. There were no additional shares authorized for grant in 2003. Options under the Plans have a maximum life of ten years. Options vest at various intervals, as determined by the Board of Directors at the date of grant.

The rollforward of shares available for grant through December 31, 2005, is as follows:

Shares available for grant at December 31, 2002 . . . . .	3,198,587
Options granted . . . . .	(2,813,300)
Options forfeited . . . . .	<u>1,093,405</u>
Shares available for grant at December 31, 2003 . . . . .	1,478,692
Options granted . . . . .	(2,127,255)
Options forfeited . . . . .	1,161,928
Increase in options available for grant . . . . .	<u>1,500,000</u>
Shares available for grant at December 31, 2004 . . . . .	2,013,365
Options granted . . . . .	(2,521,790)
Options forfeited . . . . .	622,964
Increase in options available for grant . . . . .	<u>1,800,000</u>
Shares available for grant at December 31, 2005 . . . . .	<u><u>1,914,539</u></u>

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

The Company's option activity is as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
Outstanding at December 31, 2002 .....	5,743,859	\$5.29
Granted .....	2,813,300	3.42
Exercised .....	(207,249)	1.75
Forfeited .....	<u>(1,093,405)</u>	<u>7.32</u>
Outstanding at December 31, 2003 .....	7,256,505	4.37
Granted .....	2,127,255	4.97
Exercised .....	(775,309)	2.42
Forfeited .....	<u>(1,161,928)</u>	<u>5.57</u>
Outstanding at December 31, 2004 .....	7,446,523	4.55
Granted .....	2,521,790	4.20
Exercised .....	(244,051)	2.22
Forfeited .....	<u>(622,964)</u>	<u>7.20</u>
Outstanding at December 31, 2005 .....	9,101,298	\$4.34
Options Exercisable at December 31, 2005 .....	5,429,131	\$4.81

	<u>Shares Outstanding at December 31, 2005</u>	<u>Wtd Average Exercise Price</u>	<u>Remaining Contractual Life</u>	<u>Number of Shares Exercisable at December 31, 2005</u>	<u>Wtd Average Exercise Price</u>
Options granted between \$0.27 and \$1.11 .....	108,200	\$ 1.00	0.2	108,200	\$ 1.00
Options granted between \$1.11 and \$2.21 .....	891,450	\$ 1.90	6.1	704,337	\$ 1.90
Options granted between \$2.21 and \$3.32 .....	1,962,762	\$ 2.77	7.0	991,137	\$ 2.73
Options granted between \$3.32 and \$4.42 .....	3,494,447	\$ 3.92	7.6	1,430,011	\$ 3.87
Options granted between \$4.42 and \$5.53 .....	579,750	\$ 4.69	8.3	130,870	\$ 4.80
Options granted between \$5.53 and \$6.64 .....	580,714	\$ 6.35	5.8	580,601	\$ 6.35
Options granted between \$6.64 and \$7.74 .....	549,125	\$ 6.89	8.3	549,125	\$ 6.89
Options granted between \$7.74 and \$8.85 .....	837,850	\$ 8.70	4.6	837,850	\$ 8.70
Options granted between \$8.85 and \$9.96 .....	10,800	\$ 9.69	3.0	10,800	\$ 9.69
Options granted between \$9.96 and \$11.06 .....	<u>86,200</u>	<u>\$10.91</u>	<u>2.0</u>	<u>86,200</u>	<u>\$10.91</u>
	<u>9,101,298</u>	<u>\$ 4.34</u>	<u>6.9</u>	<u>5,429,131</u>	<u>\$ 4.81</u>

Prior to February 9, 2001, the Company granted certain options to employees having exercise prices below what was considered the fair value of the underlying stock. The Company amortized to expense \$80,791 in 2004 and

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

\$387,709 in 2003 using an accelerated vesting method whereby each of the years' vesting components is amortized over its own vesting period. During 2005, 2004 and 2003, in connection with employee terminations, the Company extended the exercise period and accelerated vesting for certain option grants. Accordingly, the options had a new measurement date and were expensed based upon their new intrinsic value. In December 2005, the Company accelerated vesting for all outstanding options with an exercise price per share of \$5.00 or above. The options also had a new measurement date and were expensed based upon their new intrinsic value. Also, options granted to non-employee consultants are accounted for in accordance with SFAS No. 123 and EITF No. 96-18, and therefore are measured based upon their fair value as calculated using the Black-Scholes option pricing model. The fair value of options granted to non-employees is periodically remeasured as the underlying options vest. Option expense related to such terminations, modifications and consulting arrangements in 2005, 2004 and 2003 was \$(368,977), \$2,945,664, and \$973,958, respectively.

Included in operating expenses are the following stock compensation charges, net of reversals related to terminated employees:

	Year Ended December 31		
	2005	2004	2003
Cost of goods sold . . . . .	\$ 24,251	\$ 155,275	\$ 86,793
Research and development . . . . .	(501,754)	1,133,617	504,477
Selling and marketing . . . . .	(5,256)	144,519	215,935
General and administrative . . . . .	113,782	1,593,044	554,462
	\$(368,977)	\$3,026,455	\$1,361,667

The weighted-average fair value of options granted in 2005, 2004, and 2003 was \$2.82, \$3.49, and \$2.50, respectively, using the Black-Scholes option-pricing model. The calculations were made assuming a dividend yield of 0%, a weighted-average expected option life of five years and a weighted-average risk-free interest rate of 4.3%, 4.1%, and 4.0% in 2005, 2004 and 2003, respectively. The volatility factor used in the Black-Scholes method for 2005, 2004 and 2003 was 81%, 84%, and 89%, respectively.

**6. INCOME TAXES**

At December 31, 2005, the Company had net operating loss carryforwards of approximately \$134 million for U.S. federal and state income tax purposes, which expire beginning in 2008. In the event of a change in ownership greater than 50% in a three-year period, utilization of the net operating losses may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions.

There was no provision for income taxes in 2005 due to the net operating loss. The 2004 provision represents the amount computed under the alternative minimum tax (AMT) requirements.

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

The types of temporary differences between tax bases of assets and liabilities and their financial reporting amounts that give rise to the deferred tax asset (liability) and their approximate tax effects are as follows:

	<u>December 31</u>	
	<u>2005</u>	<u>2004</u>
Deferred tax assets:		
Patent expense . . . . .	\$ 1,930,000	\$ 1,563,000
Stock compensation expense . . . . .	203,000	609,000
Deferred revenue . . . . .	104,000	154,000
Inventory obsolescence . . . . .	270,000	260,000
Accrued liabilities . . . . .	1,891,000	1,945,000
Other . . . . .	227,000	168,000
AMT credit carryforward . . . . .	39,000	57,000
Net operating loss carryforwards . . . . .	<u>53,440,000</u>	<u>45,321,000</u>
Total deferred tax assets . . . . .	58,104,000	50,077,000
Valuation allowance . . . . .	<u>(56,934,000)</u>	<u>(48,369,000)</u>
Net deferred tax assets . . . . .	<u>1,170,000</u>	<u>1,708,000</u>
Deferred tax liabilities:		
Equipment and leasehold improvements . . . . .	(113,000)	(49,000)
Intangibles . . . . .	<u>(1,057,000)</u>	<u>(1,659,000)</u>
Deferred tax liabilities . . . . .	<u>(1,170,000)</u>	<u>(1,708,000)</u>
Net deferred tax assets / (liabilities) . . . . .	<u>\$ —</u>	<u>\$ —</u>

The Company's provision for income taxes differs from the expected tax benefit amount computed by applying the federal income tax rate to loss before taxes as a result of the following:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Federal statutory rate . . . . .	(34.0)%	(34.0)%	(34.0)%
State taxes . . . . .	(5.9)%	(5.1)%	(5.7)%
Foreign taxes . . . . .	0.0%	2.1%	0.0%
Meals and entertainment . . . . .	0.2%	1.7%	0.4%
Other permanent differences . . . . .	0.0%	1.0%	1.1%
Valuation allowance . . . . .	<u>39.7%</u>	<u>37.3%</u>	<u>38.2%</u>
	<u>0.0%</u>	<u>3.0%</u>	<u>0.0%</u>

At December 31, 2005, the Company had \$39,000 of AMT credits which do not expire. The valuation allowance at December 31, 2005 and 2004 was provided because of the Company's history of net losses and uncertainty as to the realization of the deferred tax assets. As a result, the Company believes it is more likely than not that the deferred tax assets will not be realized. Through December 31, 2005, the Company's foreign subsidiary has operated at a loss, and accordingly, no provision for U.S. deferred taxes has been provided. Any earnings of the foreign subsidiary would be considered to be permanently invested.

**7. LEASE OBLIGATIONS**

The Company leases its corporate facility under an operating lease effective through September 2011. The Company has the option to extend the lease for three additional five-year periods. The lease agreement required a

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

\$1,000,000 upfront payment and requires the Company to provide the landlord an irrevocable standby letter of credit of \$1,300,000, which is collateralized by a certificate of deposit included in short-term investments. Ongoing rent payments increase during the lease term. Rent expense is being recorded by the Company on a straight-line basis over the amended lease term. At December 31, 2005 and 2004, long-term other assets includes approximately \$798,000 and \$938,000, respectively, of prepaid rent. In addition, at December 31, 2005 and 2004, other long-term liabilities includes approximately \$1,159,000 and \$1,099,000, respectively, of deferred rent.

In 2005 and 2004, the Company entered into multiple capital leases for computer equipment, office equipment and furniture, totaling approximately \$184,000 and \$230,000, respectively.

Future minimum lease payments as of December 31, 2005 by year are as follows:

	<u>Capital Leases</u>	<u>Operating Leases</u>
2006 .....	\$138,100	\$ 1,879,000
2007 .....	116,417	1,954,000
2008 .....	53,463	2,032,000
2009 .....	36,531	2,113,000
2010 .....	12,176	2,198,000
2011 .....	<u>0</u>	<u>1,714,000</u>
Total minimum lease obligations .....	<u>356,687</u>	<u>\$11,890,000</u>
Less amounts representing interest .....	<u>50,070</u>	
Present value of minimum lease payments .....	306,617	
Less current portion of long-term lease obligations .....	<u>114,693</u>	
	<u>\$191,924</u>	

Rent expense was approximately \$2,167,000, \$2,165,000, and \$2,149,000 in 2005, 2004 and 2003, respectively.

**8. RESTRUCTURING AND OTHER CHARGES**

During the third quarter of 2002, we announced a restructuring plan designed to simplify product development and manufacturing operations and reduce operating expenses. The restructuring charges recorded were determined based upon plans submitted by the Company's management and approved by the Board of Directors using information available at the time. The restructuring charge included \$2.5 million for the consolidation of facilities, \$500,000 for prepayment penalties mainly under capital lease arrangements, an impairment charge of \$7.2 million for abandoned leasehold improvements and equipment to be sold and \$900,000 of other costs related to the restructuring. The Company also recorded a \$1.1 million charge within cost of goods sold related to inventory that was considered obsolete based upon the restructuring plan.

The facilities charge contained estimates based on the Company's potential to sublease a portion of its corporate office. The Company has offered the corporate office space for sublease, but has been unable to sublease the space. Accordingly, the Company decreased its estimate of the amount of sublease income it expects to receive. The estimated lease and operating expenses were also reduced, based on a portion of the office space being utilized.

The following table shows the changes in the restructuring accrual through December 31, 2005. The remaining restructuring balance of \$1.0 million is for rent payments on a non-cancelable lease, net of estimated sublease income, which will continue to be paid over the lease term through 2011. The current portion of the accrual of

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

\$182,389 is included in other accrued liabilities on the balance sheets and the remainder is included in other long-term liabilities.

	<u>Facilities</u>	<u>Equipment and Leasehold Improvements Disposals</u>	<u>Prepayment Penalties</u>	<u>Other</u>	<u>Total</u>
Charge in 2002 . . . . .	\$2,470,438	\$ 7,175,995	\$ 494,930	\$ 945,870	\$11,087,233
Payments made . . . . .	(312,400)	—	(469,300)	—	(781,700)
Non-cash charges . . . . .	—	(7,175,995)	(25,630)	(140,290)	(7,341,915)
Accrued restructuring balance at December 31, 2002 . . . . .	2,158,038	—	—	805,580	2,963,618
Payments made . . . . .	(674,809)	—	—	(874,765)	(1,549,574)
Revision to estimate . . . . .	(69,185)	—	—	69,185	—
Accrued restructuring balance at December 31, 2003 . . . . .	1,414,044	—	—	—	1,414,044
Payments made . . . . .	(199,196)	—	—	—	(199,196)
Revision to estimate . . . . .	(98,000)	—	—	—	(98,000)
Accrued restructuring balance at December 31, 2004 . . . . .	1,116,848	—	—	—	1,116,848
Payments made . . . . .	(159,285)	—	—	—	(159,285)
Accrued restructuring balance at December 31, 2005 . . . . .	\$ 957,563	\$ —	\$ —	\$ —	\$ 957,563

**9. LICENSE AGREEMENTS**

The Company entered into an exclusive license agreement (research license) in March 1994 to make, use and sell products utilizing the licensed patents in the research market. Under the research license, the Company is required to pay a royalty at a rate not to exceed a certain percentage of the selling price on licensed component sales. There have been no sales of licensed components through December 31, 2005. The research license will continue until the licensed patents expire or until the agreement is terminated by either party, whichever is earlier, as defined in the agreement. The Company also entered into an equity agreement with the licensor in March 1994 whereby it issued 115,200 shares of common stock in exchange for the research license and diagnostic market option, which is an exclusive license agreement to make, use and sell products utilizing the licensed patents in the diagnostic market. In October 1998, the Company issued 103,200 shares to the licensor to exercise the diagnostic market option. The shares issued in 1994 and 1998 were valued at amounts considered to approximate the fair value of common stock at the time of each issuance.

Under this agreement, the Company granted the licensor a put option to sell a specified number of shares back to the Company anytime after March 1, 1998. The total number of shares that can be put to the Company cannot exceed the number of shares necessary to achieve a purchase price of \$200,000. At December 31, 2005, the price per share to be paid if the put option is exercised is \$11.00. Accordingly, the Company has classified \$200,000 of additional paid-in capital outside of shareholders' equity in other liabilities in the accompanying balance sheets.

In October 2001, the Company entered into a development, license and supply agreement with RIKEN, Inc. (RIKEN). The Company licensed certain patent rights relating to polymorphism in genes that encode drug metabolizing enzymes from RIKEN for a nonrefundable fee which is being amortized over its estimated useful life (7.5 years). In 2003, the Company and RIKEN entered into an additional license for similar content. The Company also pays royalties based upon net sales of licensed products in exclusive and nonexclusive territories.

**Third Wave Technologies, Inc.**

**Notes to Consolidated Financial Statements — (Continued)**

In December 2005, the Company entered into a nonexclusive sublicense agreement for certain patent rights involving multiplex polymerase chain reaction (PCR) technology for a nonrefundable fee of \$2,000,000. This technology permits the Company to develop and market multiplex Invader Plus products. The estimated present value of the fee of \$1.8 million will be amortized over its estimated useful life (8 years). The future payments under this license arrangement are as follows:

2006 .....	\$ 425,000
2007 .....	450,000
2008 .....	450,000
2009 .....	450,000
2010 .....	<u>225,000</u>
Total payments .....	<u>2,000,000</u>
Less amount representing interest .....	<u>227,828</u>
Present value of payments .....	\$1,772,172

In addition, the Company licensed rights to patents and/or patent applications covering genetic variations associated with certain diseases for which the Company has designed clinical diagnostic products.

**10. COLLABORATIVE AGREEMENTS**

In December 2000, the Company entered into a development and commercialization agreement with BML, Inc. (BML). Under this agreement, the Company developed assays in accordance with a mutually agreed development program for use in clinical applications by BML. In 2000, BML paid the Company a nonrefundable fee of \$3 million, which was recognized as revenue on a straight-line basis over the expected term of development services being performed by the Company. The Company recorded revenue related to the upfront fee from BML of \$917,000 in 2003. Additionally, in 2005, 2004 and 2003, BML paid the Company \$575,000, \$1,915,000, and \$1,500,000, respectively, for product and specified services performed in these respective years, which was recognized as revenue as the product was shipped and services were performed.

On October 16, 2002, the Company entered into a license and supply agreement with Aclara Biosciences, Inc., which was acquired by Monogram Biosciences (formerly Virologics, Inc.) in December 2004. Under this agreement, Monogram has the non-exclusive right to incorporate the Company's Invader™ technology and Cleavase® enzyme with Monogram's eTag™ technology to offer the eTag Assay System for multiplexed gene expression applications for the research market. In exchange, Monogram made certain upfront payments and will make royalty payments to the Company on sales of eTag-Invader gene expression assays. The Company has also provided Monogram with certain manufacturing materials for use in manufacturing Invader products. The Company received royalty revenue of \$250,000, \$150,000, and \$100,000 in 2005, 2004, and 2003 respectively.

**11. 401(k) PLAN**

The Company has a 401(k) savings plan (the Plan) which covers substantially all employees. The Plan provides for Company contributions of 50% of employee contributions up to 6% of their compensation. Company contributions to the plan were approximately \$377,000, \$329,000, and \$311,000 in 2005, 2004 and 2003, respectively.

**12. SEGMENT DISCLOSURE**

The Company operates in one industry segment. Product revenues to international end-users accounted for 27%, 70% and 78% of product revenues in 2005, 2004 and 2003, respectively. At December 31, 2005 and 2004,

approximately \$783,000 and \$2,681,000, respectively, of receivables are denominated in Yen. Product revenues by geographic area in 2005, 2004 and 2003, were as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
United States . . . . .	\$17,027,952	\$13,759,367	\$ 7,668,573
Japan . . . . .	5,107,455	31,361,485	26,983,342
Other . . . . .	<u>1,035,398</u>	<u>895,275</u>	<u>496,382</u>
	<u>\$23,170,805</u>	<u>\$46,016,127</u>	<u>\$35,148,297</u>

### 13. QUARTERLY FINANCIAL DATA (UNAUDITED)

The following sets forth selected quarterly financial and stock price information for the years ended December 31, 2005 and 2004 (in thousands, except per share data). The operating results are not necessarily indicative of results for any future period.

	<u>Quarter Ended</u>			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
2005:				
Net revenues . . . . .	\$ 7,126	\$ 5,772	\$ 5,222	\$ 5,786
Gross margin . . . . .	5,126	3,960	3,646	4,070
Net loss . . . . .	(4,421)	(5,514)	(7,380)	(5,031)
Basic and diluted net loss per share . . . . .	\$ (0.11)	\$ (0.13)	\$ ( 0.18)	\$ (0.12)
2004:				
Net revenues . . . . .	\$15,276	\$12,632	\$10,479	\$ 8,106
Gross margin . . . . .	11,105	8,939	8,144	5,813
Net income (loss) . . . . .	2,848	(106)	24	(4,708)
Basic and diluted net income (loss) per share . . . . .	\$ 0.07	\$ (0.00)	\$ 0.00	\$ (0.12)

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

On May 31, 2005, the Company dismissed Ernst & Young LLP as its independent registered public accounting firm and engaged Grant Thornton LLP to serve as the Company's independent registered public accounting firm for 2005. Information regarding the change in the Company's principal accountants was provided in the Company's Current Report on Form 8-K, filed June 6, 2005. The letter from Ernst & Young LLP stating the firm's agreement with the information provided in the Current Report on Form 8-K was filed as an exhibit thereto.

**ITEM 9A. CONTROLS AND PROCEDURES**

**EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES**

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) under the Securities Exchange Act of 1934. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of the end of the period covered by this report. There have been no significant changes during the period covered by this report in the Company's internal control over financial reporting or in other factors that could significantly affect internal control over financial reporting.

**EVALUATION OF INTERNAL CONTROL OVER FINANCIAL REPORTING**

The management of Third Wave Technologies is responsible for establishing and maintaining adequate internal control over financial reporting. Third Wave's internal control system was designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Third Wave's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework. Based on management's assessment, management believes that, as of December 31, 2005, the Company's internal control over financial reporting is effective.

Third Wave's independent auditors have issued an audit report on management assessment of the Company's internal control over financial reporting, which is included herein.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To The Board of Directors and Shareholders  
of Third Wave Technologies, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Third Wave Technologies, Inc. (a Delaware corporation) and subsidiaries maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

In our opinion, management's assessment that Third Wave Technologies, Inc. and subsidiaries maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Third Wave Technologies, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Third Wave Technologies, Inc. and subsidiaries as of December 31, 2005, and the related consolidated statements of operations, shareholders' equity and cash flows for the year ended December 31, 2005, and our report dated February 20, 2006 expressed an unqualified opinion on those financial statements.

GRANT THORNTON LLP

Madison, Wisconsin  
February 20, 2006

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

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

The Company incorporates by reference the information required by this Item from the Company's definitive proxy statement for its annual meeting of shareholders scheduled to be held on June 13, 2006 (the "Proxy Statement"), which will be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the Company's fiscal year.

**ITEM 11. EXECUTIVE COMPENSATION**

The Company incorporates by reference the information required by this Item from the Proxy Statement.

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

The Company incorporates by reference the information required by this Item from the Proxy Statement.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The Company incorporates by reference the information required by this Item from the Proxy Statement.

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

The Company incorporates by reference the information required by this Item from the Proxy Statement.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES**

(a) Documents Filed as a Part of this Report.

1. Financial Statements. The financial statements required to be filed as part of this Report are listed on page 32.

2. Financial Statement Schedules. The following financial statement schedule required to be filed as part of this Report is included on page 61.

*Schedule II — Valuation and Qualifying Accounts.* Schedules not included have been omitted because they are not applicable.

3. Exhibits. The exhibits required to be filed as a part of this Report are listed in the Exhibit Index.

## 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, on March 9, 2006.

THIRD WAVE TECHNOLOGIES, INC.

By: /s/ Kevin T. Conroy

Kevin T. Conroy  
Chief Executive Officer

## POWER OF ATTORNEY

We, the undersigned directors and executive officers of Third Wave Technologies, Inc., hereby severally constitute and appoint of Rodman Hise our true and lawful attorney and agent, with full power to him to sign for us, and in our names in the capacities indicated below, any and all amendments to the Annual Report on Form 10-K of Third Wave Technologies, Inc. filed with the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorney to any and all amendments to said Annual Report on Form 10-K.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ David A. Thompson David A. Thompson	Chairman of the Board Chief Executive Officer President, and Director	March 10, 2006
/s/ Kevin T. Conroy Kevin T. Conroy	(Principal Executive Officer)	March 9, 2006
/s/ James J. Herrmann James J. Herrmann	Vice President of Finance (Principal Financial Officer)	March 10, 2006
/s/ James Connelly James Connelly	Director	March 8, 2006
/s/ Gordon F. Brunner Gordon F. Brunner	Director	March 10, 2006
/s/ Lawrence Murphy Lawrence Murphy	Director	March 8, 2006
/s/ John Neis John Neis	Director	March 10, 2006
/s/ Lionel Sterling Lionel Sterling	Director	March 8, 2006

## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference to</u>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, dated as of August 16, 2000	Exhibit 3.1(b) to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
3.2	Amended and Restated Bylaws of the Registrant, dated as of July 25, 2005	
4.1	Investors' Rights Agreement, dated as of July 24, 2000	Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
4.2	Rights Agreement between the Registrant and EquiServe Trust Company N.A., dated as of October 24, 2001	Exhibit 4.9 to the Registrant's Registration Statement on Form 8-A, File No. 000-31745, filed on November 30, 2001
4.3	Amendment No. 1 to the Rights Agreement between the Registrant and EquiServe Trust Company N.A., dated February 18, 2003	Exhibit 4.2 to the Registrant's Registration Statement on Form 8-A/A, File No. 000-31745, filed on February 19, 2003
10.1*	Incentive Stock Option Plan	Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
10.2*	1997 Incentive Stock Option Plan	Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
10.3*	1997 Nonqualified Stock Option Plan	Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
10.4*	1998 Incentive Stock Option Plan	Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
10.5*	1999 Incentive Stock Option Plan	Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
10.6*	1999 Nonqualified Stock Option Plan	Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
10.7*	2000 Stock Plan	Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference to</u>
10.8*	2000 Employee Stock Purchase Plan	Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
10.9*	Form of Director and Executive Officer Indemnification Agreement	Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
10.10	Lease Agreement, dated as of April 1, 1997, between the Registrant and University Research Park Facilities Corp. and amendment, dated as of September 1, 2001	Exhibit 10.18 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
10.11	Amendment to Lease between Registrant and University Research Park Facilities Corp. dated as of September 1, 2002	Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002
10.12	Development and Commercialization Agreement, dated as of December 29, 2000, between the Registrant and BML, Inc.	Exhibit 10.26 to the Registrant's Registration Statement on Form S-1, Registration No. 333-42694, filed on July 31, 2000, as amended
10.13	License Agreement dated as of October 15, 2002 between Registrant and Aclara Biosciences, Inc.	Exhibit 10.14 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002
10.14*	Employment Agreement between Lance Fors and Third Wave Technologies, Inc. dated October 16, 2003	Exhibit 10.16 to Registrant's Annual Report on Form 10-K for the fiscal year ended on December 31, 2003
10.15*	Employment Agreement between John Puisis and Third Wave Technologies, Inc. dated September 19, 2001 and Amendment dated July 17, 2003	Exhibit 10.17 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003
10.16*	Amendment No. 2 to Employment Agreement between John Puisis and Third Wave Technologies, Inc. effective June 14, 2004	Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004
10.17*	Severance Agreement between John Puisis and Third Wave Technologies, Inc. effective December 20, 2005	
10.18*	Third Wave Technologies, Inc. Amended LTIP 1	Exhibit 10.17 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2004
10.19*	Third Wave Technologies, Inc. Amended LTIP 2	
10.20*	Employment Agreement between Maneesh Arora and Third Wave Technologies, Inc. dated May 10, 2005	Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005
10.21*	Employment Agreement between Lander Brown and Third Wave Technologies, Inc. dated May 10, 2005	Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005
10.22*	Employment Agreement between Vecheslav Elagin and Third Wave Technologies, Inc. dated May 10, 2005	Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference to</u>
10.23*	Employment Agreement between Jacob Orville and Third Wave Technologies, Inc. dated May 10, 2005	Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005
10.24*	Amended and Restated Employment Agreement between Kevin T. Conroy and Third Wave Technologies, Inc. dated December 23, 2005	Exhibit 10.1 to Registrant's Current Report on Form 8-K filed December 30, 2005
10.25*	Employment Agreement between James J. Herrmann and Third Wave Technologies, Inc. dated March 14, 2005	Exhibit 10.23 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004
10.26*	Severance Agreement between James J. Herrmann and Third Wave Technologies, Inc. dated January 31, 2006	
10.27*	Amendment No. 1 to Employment Agreement between Lance Fors and Third Wave Technologies, Inc. dated June 14, 2004	Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004
10.28*	Amendment No. 2 to Employment Agreement between Lance Fors and Third Wave Technologies, Inc. dated July 25, 2005	Exhibit 10.1 to Registrant's Current Report on Form 8-K filed July 28, 2005
10.29*	Third Wave Technologies, Inc. LTIP 3 dated February 14, 2006	
21	List of Subsidiaries	
23.1	Consent of Independent Registered Public Accounting Firm — Grant Thornton LLP	
23.2	Consent of Independent Registered Public Accounting Firm — Ernst & Young LLP	
24	Powers of Attorney (contained in the signature page hereto)	
31.1	CEO's Certification Pursuant to Section 302 of the Sarbanes Oxley Act of 2002	
31.2	Principal Financial Officer Certification pursuant to Section 302 of the Sarbanes Oxley Act of 2002	
32.1	CEO's Certification pursuant to 18 U.S.C. Section 1350, of Chapter 63 of Title 18 of the United States Code	
32.2	Principal Financial Officer's Certification pursuant to 18 U.S.C Section 1350, of Chapter 63 of Title 18 of the United States Code	

\* Indicated a management contract or compensatory plan or arrangement.

**SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS**  
**YEARS ENDED DECEMBER 31, 2005, 2004, AND 2003**

<u>Description</u>	<u>Balance At Beginning of Year</u>	<u>Additions Charged to Expense</u>	<u>(1) Deductions</u>	<u>Balance At End of Year</u>
		(Dollars in thousands)		
Allowance for doubtful accounts receivable:				
2003 .....	\$ 465	\$ 402	\$ 727	\$140
2004 .....	\$ 140	\$ 177	\$ 17	\$300
2005 .....	\$ 300	\$ 107	\$ 207	\$200
Allowance for excess and obsolete inventory:				
2003 .....	\$3,050	\$1,308	\$3,608	\$750
2004 .....	\$ 750	\$ 805	\$ 905	\$650
2005 .....	\$ 650	\$ 968	\$ 943	\$675

(1) Represents amounts written off or disposed, net of recoveries.

**CERTIFICATION**

I, Kevin T. Conroy, President and Chief Executive Officer of Third Wave Technologies, Inc. (the “registrant”), certify that:

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

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Kevin T. Conroy

Date:

**CERTIFICATION**

I, James J. Herrmann, principal financial officer of Third Wave Technologies, Inc. (the “registrant”), certify that:

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

\_\_\_\_\_  
/s/ JAMES J. HERRMANN  
James J. Herrmann

Date: March 10, 2006

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
OF CHAPTER 63 OF TITLE 18  
OF THE UNITED STATES CODE**

I, Kevin T. Conroy, President and Chief Executive Officer of Third Wave Technologies, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that on the date of this Certification:

1. the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2005, (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Kevin T. Conroy

Date:

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
OF CHAPTER 63 OF TITLE 18  
OF THE UNITED STATES CODE**

I, James J. Herrmann principal financial officer of Third Wave Technologies, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that on the date of this Certification:

1. the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2005, (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ JAMES J. HERRMANN

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James J. Herrmann

Date: March 10, 2006

## BOARD OF DIRECTORS

### David A. Thompson

Chairman of the Board, Third Wave Technologies, Inc.  
Retired; Former President, Diagnostic Division,  
Abbott Laboratories

### Gordon F. Brunner

Retired; Former Senior Vice President, Chief Technology  
Officer and Director, Procter & Gamble Co.

### James P. Connelly

Partner, Foley & Lardner

### Kevin T. Conroy

President & Chief Executive Officer,  
Third Wave Technologies, Inc.

### Lawrence J. Murphy

Independent Business Consultant  
Focused on Mergers and Acquisitions

### John Neis

Managing Director, Venture Investors LLC

### Lionel N. Sterling

President, Equity Resources, Inc.

## EXECUTIVE OFFICERS

### Kevin T. Conroy

President & Chief Executive Officer

### Maneesh K. Arora

Senior Vice President & Chief Financial Officer

### Cindy S. Ahn

Vice President & General Counsel

### John A. Bellano

Vice President, Sales

### Jorge A. Garces, Ph.D.

Vice President, Platform & Product Development

### Gregory K. Hamilton

Vice President, Finance

### Rodman P. Hise

Vice President, Corporate Affairs

### Ivan D. Trifunovich, Ph.D.

Senior Vice President

## INVESTOR RELATIONS

For further information about Third Wave,  
additional copies of this report, Form 10-K,  
or other financial information, please contact:

### Investor Relations

Third Wave Technologies, Inc.  
502 South Rosa Road  
Madison, WI 53719  
(608) 663-7098

Communications concerning transfer  
requirements, lost certificates and changes  
of address should be directed to the  
transfer agent.

## TRANSFER AGENT

Computershare  
Chicago, IL

## INDEPENDENT ACCOUNTANTS

Grant Thornton LLP  
Madison, WI

## CORPORATE COUNSEL

Kennedy Covington Lobdell & Hickman, LLP  
Charlotte, NC

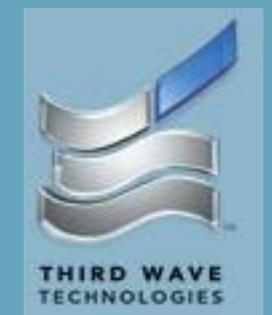
## NOTICE OF ANNUAL MEETING

June 13, 2006

9:00 a.m. CDT

Third Wave Technologies, Inc.  
502 South Rosa Road  
Madison, WI 53719

This annual report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. When used in this annual report by management from time to time, the words "believe," "anticipates," "intends," "plans," "estimates," and similar expressions are forward-looking statements. Such forward-looking statements contained in this annual report are based on current expectations. Forward-looking statements may address the following subjects: results of operations; customer growth and retention; development of technologies and products; losses or earnings; operating expenses, including, without limitation, marketing expense and technology and development expense; and revenue growth. We caution investors that there can be no assurance that actual results, outcomes or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, among others, our limited operating history, unpredictability of future revenues and operating results, competitive pressures and also the potential risks and uncertainties set forth in the "Overview" section and in the "Risk Factors" section of our annual report on 2005 Form 10-K filed with the Securities and Exchange Commission, on March 15, 2006, which factors are specifically incorporated herein by this reference. You should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission. Except, as required by law, we undertake no obligation to update any forward-looking statements.





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