PSYCHEMEDICS CORP
Form 10-K
March 25, 2011

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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2010

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

Commission File Number: 1-13738

PSYCHEMEDICS CORPORATION
(Exact Name of Registrant as Specified in Its Charter)

Delaware	58-1701987
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
125 Nagog Park Acton, Massachusetts	01720
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number Including Area Code: (978) 206-8220

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

Common Stock, $0.005 par value

(Title of Class)

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

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Indicate by a check mark if the registrant is a well-known seasoned issuer (as defined in Rule 405 of the Securities Exchange Act of 1934). Yes ¨ No x

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934). Yes ¨ No x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.) Yes ¨ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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 Securities Exchange Act of 1934.

Large Accelerated Filer ¨ Accelerated Filer ¨ Non-Accelerated Filer ¨ Smaller Reporting Company x

(Do not check if a smaller reporting company)

Indicate by a check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities and Exchange Act of 1934). Yes ¨ No x

As of June 30, 2010, there were 5,212,835 shares of Common Stock of the Registrant outstanding. The aggregate market value of the Common Stock of the Registrant held by non-affiliates (assuming for these purposes, but not conceding, that all executive officers, directors and 5% shareholders are "affiliates" of the Registrant) as of June 30, 2010 was approximately $18 million, computed based upon the closing price of $7.98 per share on June 30, 2010.

As of March 22, 2011, there were 5,212,013 shares of Common Stock of the Registrant outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates by reference portions of the Registrant's definitive proxy statement, to be filed with the Securities and Exchange Commission no later than 120 days after the close of its fiscal year; provided that if such proxy statement is not filed with the Commission in such 120-day period, an amendment to this Form 10-K shall be filed no later than the end of the 120-day period.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements under “Business,” “Risk Factors,” “Legal Proceedings,” “Market for Registrant’s Common Stock and Related Stockholder Matters” and “Management Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K (this “Form 10-K”) constitute forward-looking statements under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements made with respect to future earnings per share, future revenues, future operating income, future cash flows, competitive and strategic initiatives, potential stock repurchases and future liquidity needs. These statements involve known and unknown risks, uncertainties and other factors that may cause results, levels of activity, growth, performance, earnings per share or achievements to be materially different from any future results, levels of activity, growth, performance, earnings per share or achievements expressed or implied by such forward-looking statements.

The forward-looking statements included in this Form 10-K and referred to elsewhere are related to future events or our strategies or future financial performance. In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “believe,” “anticipate,” “future,” “potential,” “estimate,” “encourage,” “opportunity,” “g “leader,” “could”, “expect,” “intend,” “plan,” “expand,” “focus,” “through,” “strategy,” “provide,” “offer,” “allow,” “commitm “result,” “increase,” “establish,” “perform,” “make,” “continue,” “can,” “ongoing,” “include” or the negative of such terms or c terminology. All forward-looking statements included in this Form 10-K are based on information available to us as of the filing date of this report, and the Company assumes no obligation to update any such forward-looking statements. Our actual results could differ materially from the forward-looking statements. Important factors that could cause actual results to differ materially from expectations reflected in our forward-looking statements include those described in Item 1A, “Risk Factors.”

TABLE OF CONTENTS

PSYCHEMEDICS CORPORATION
FORM 10-K
ANNUAL REPORT
For the Year Ended December 31, 2010
TABLE OF CONTENTS

PART I

Available Information; Background

Psychemedics Corporation ("the Company" or "Psychemedics") maintains executive offices located at 125 Nagog Park, Acton, MA 01720. Our telephone number is (978) 206-8220. Our stock is traded on the NASDAQ Stock Exchange Market under the symbol "PMD". Our Internet address is www.psychemedics.com . The Company makes available, free of charge, on the Investor Information section of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the Securities and Exchange Commission (the "SEC"). Copies are also available, without charge, from Psychemedics Corporation, Attn: Investor Relations, 125 Nagog Park, Acton, MA 01720. Alternatively, reports filed with the SEC may be viewed or obtained at the SEC Public Reference Room in Washington, D.C., or the SEC's Internet site at www.sec.gov . We do not intend for information contained in our website to be part of this Annual Report on Form 10-K.

Item 1. Business

General

Psychemedics Corporation is a Delaware corporation organized on September 24, 1986 to provide testing services for the detection of abused substances through the analysis of hair samples. The Company's testing methods utilize a patented technology to enzymatically dissolve hair samples and then perform radioimmunoyassays on the hair sampled, with confirmation testing by mass spectrometry.

The Company's primary application of its patented technology is as a testing service that analyzes hair samples for the presence of certain drugs of abuse. Employing radioimmunoassay procedures to drug test hair samples differs from the more commonly used approach in which immunoassay procedures are employed to test urine samples. The Company's tests provide quantitative information that can indicate the approximate amount of drug ingested as well as historical data, which can show a pattern of individual drug use over a longer period of time providing superior detection compared to other types of drug testing. This information is useful to employers for both applicant and employee testing, as well as to physicians, treatment professionals, law enforcement agencies, school administrators, parents concerned about their children's drug use and other individuals or entities engaged in any business where drug use or potential drug use is an issue. The Company provides commercial testing and confirmation by mass spectrometry using industry-accepted practices for cocaine, marijuana, PCP, methamphetamine (including Ecstasy, which is difficult to detect in urine due to sporadic use patterns and rapid clearance from the body) and opiates (including heroin, hydrocodone, hydromorphone and oxycodone).

Testing services are currently performed at the Company's laboratory at 5832 Uplander Way, Culver City, California. The Company's services are marketed under the name RIAH (Radioimmunoassay of Hair), a registered service mark.

Development of Radioimmunoassay of Hair

The application of unique radioimmunoassay procedures to the analysis of hair was initially developed in 1978 by the founders of the Company, Annette Baumgartner and Werner A. Baumgartner, Ph.D. The Baumgartners demonstrated that when certain chemical substances enter the bloodstream, the blood carries these substances to the hair where they become "entrapped" in the protein matrix in amounts approximately proportional to the amount ingested. The Company's patented drugs of abuse testing procedure involves direct analysis of liquefied hair samples by radioimmunoassay procedures utilizing effective reagents and antibodies. The antibodies detect the presence of a specific drug or drug metabolite in the liquefied hair sample by reacting with the drug present in the sample solution,

as well as an added radioactive analog of the drug. The resulting antibody-drug complex is precipitated and analyzed. The amount of drug present in the sample is inversely proportional to the amount of radioactive analog in the precipitate. RIA positive results are then confirmed by Mass Spectrometry. Depending upon the length of head hair, the Company is able to provide historical information on drug use by the person from whom the sample was obtained. Since head hair grows approximately 1.3 centimeters per month, a 3.9 centimeter head hair sample can reflect drug ingestion over the approximate several months prior to the collection of the sample. Another testing option involves sectional analysis of the head hair sample. In this procedure, the hair is sectioned lengthwise to approximately correspond to certain time periods. Each section corresponds to a time period, which allows the Company to provide information on patterns of drug use.

Validation of the Company's Proprietary Testing Method

The process of analyzing human hair for the presence of drugs using the Company's patented method has been the subject of numerous peer-reviewed, scientific field studies. Results from the studies that have been published or accepted for publication in scientific journals are generally favorable to the Company's technology. Some of these studies were performed with the following organizations: Boston University School of Public Health; Citizens for a Better Community Court, Columbia University; Connecticut Department of Mental Health and Addictive Services; Koba Associates-DC Initiative, Harvard Cocaine Recovery Project, Hutzel Hospital, ISA Associates (Interscience America)-NIDA Workplace Study, University of California-Sleep State Organization, Maternal/Child Substance Abuse Project, Matrix Center, National Public Services Research Institute, Narcotic and Drug Research Institute, San Diego State University-Chemical Dependency Center, Spectrum Inc., Stapleford Centre (London), Task Force on Violent Crime (Cleveland, Ohio); University of Miami-Department of Psychiatry, University of Miami-Division of Neonatology, University of South Florida-Operation Par Inc., University of Washington, VA Medical Center-Georgia, U.S. Probation Parole-Santa Ana and Wayne State University. The above studies include research in the following areas: effects of prenatal drug use, treatment evaluation, workplace drug use, the criminal justice system and epidemiology. Many of the studies have been funded by the National Institute of Justice or the National Institute on Drug Abuse ("NIDA"). Several hundred research articles written by independent researchers have been published supporting the general validity and usefulness of hair analysis.

Some of the Company's customers have also completed their own testing to validate the Company's proprietary hair testing method as a prelude to utilizing the Company's services. These studies have consistently confirmed the Company's superior detection rate compared to urinalysis testing. When results based on the Company's patented hair testing method were compared to urine results in side-by-side evaluations, 4 to 10 times as many drug abusers were accurately identified by the Company's proprietary method. In addition to these studies, the Company's proprietary method is validated through the services it offers to the thousands of clients for whom it has performed testing.

In 1998, the National Institute of Justice, utilizing Psychemedics hair testing, completed a Pennsylvania Prison study where hair analysis revealed an average prison drug use level of approximately 7.9% in 1996. Comparatively, urinalysis revealed virtually no positives. After measures to curtail drug use were instituted (drug-sniffing dogs, searches and scanners), the use level fell to approximately 2% according to the results of hair analysis in 1998. Again, the urine tests showed virtually no positives. The study illustrates the usefulness of hair analysis to monitor populations and the weakness of urinalysis.

The Company has received 510k clearance from the United States Food and Drug Administration ("FDA") on all five of its assays used to test human hair for drugs of abuse. As of the date of this report, Psychemedics has received FDA clearance for a five-drug panel test that is not restricted to head hair samples for drugs of abuse.

Advantages of Using the Company's Patented Method

The Company asserts that hair testing using its patented method confers substantive advantages relative to existing means of drug detection through urinalysis. Although urinalysis testing can provide accurate drug use information, the scope of the information is short-term and is generally limited to the type of drug ingested within a few days of the test. Studies published in many scientific publications have indicated that most drugs disappear from urine within a few days.

In contrast to urinalysis testing, hair testing using the Company's patented method can provide long-term historical drug use information resulting in a significantly wider "window of detection." This "window" may be several months or longer depending on the length of the hair sample. The Company's standard test offering, however, uses a 3.9 centimeter length head hair sample cut close to the scalp which measures use for approximately the previous several

months.

This wider window enhances the detection efficiency of hair analysis, making it particularly useful in pre-employment and random testing. Hair testing not only identifies more drug users, but it may also uncover patterns and severity of drug use (information most helpful in determining the scope of an individual's involvement with drugs), while serving as a deterrent against the use of drugs. Hair testing employing the Company's patented method greatly reduces the incidence of "false negatives" associated with evasive measures typically encountered with urinalysis testing. For example, urinalysis test results are adversely impacted by excessive fluid intake prior to testing and by adulteration or substitution of the urine sample. Moreover, a drug user who abstains from use for a few days prior to urinalysis testing can usually escape detection. Hair testing is effectively free of these problems, as it cannot be thwarted by evasive measures typically encountered with urinalysis testing. Hair testing is also attractive to customers since sample collection is typically performed under close supervision yet is less intrusive and less embarrassing for test subjects.

Hair testing using the Company's patented method (with mass spectrometry confirmation) further reduces the prospects of error in conducting drug detection tests. Urinalysis testing is more susceptible to problems such as "evidentiary false positives" resulting from passive drug exposure or poppy seeds. To combat this problem, in federally mandated testing, the opiate cutoff levels for urine testing were raised 667% (from 300 to 2,000 ng/ml) on December 1, 1998 and testing for the presence of a heroin metabolite, 6-AM, was required. These requirements, however, effectively reduced the detection time frame for confirmed heroin with 6-AM in urine down to several hours post drug use. In contrast, the metabolite 6-AM is stable in hair and can be detected for months.

In the event a positive urinalysis test result is challenged, a test on a newly collected urine sample is not a viable remedy. Unless the forewarned individual continues to use drugs prior to the date of the newly collected sample, a re-test may yield a negative result when using urinalysis testing because of temporary abstinence. In contrast, when the Company's hair testing method is offered on a repeat hair sample, the individual suspected of drug use cannot as easily affect the results because historical drug use data remains locked in the hair fiber.

When compared to other hair testing methods, not only are the Company's assays cleared by the FDA, they also employ a unique patented method of enzyme digestion that the Company believes allows for the most efficient release of drugs from the hair without destroying the drugs. The Company's method of releasing drugs from hair is a key advantage and results in superior detection rates.

Disadvantages of Hair Testing

There are some disadvantages of hair testing as compared to drug detection through urinalysis. Because hair starts growing below the skin surface, drug ingestion evidence does not appear in hair above the scalp until approximately five to seven days after use.

Thus, hair testing is not suitable for determining drug presence in "for cause" testing as is done in connection with an accident investigation. It does, however, provide a drug history which can complement urinalysis information in "for cause" testing.

Currently, radioimmunoassay testing using hair samples under the Company's patented method is only practiced by Psychemedics Corporation.

The Company's prices for its tests are generally somewhat higher than prices for tests using urinalysis, but the Company believes that its superior detection rates provide more value to the customer. This pricing policy could, however, adversely impact the growth of the Company's sales volume.

Intellectual Property

Certain aspects of the Company's hair analysis method are covered by six US patents and a number of foreign patents and trade secrets owned by the Company. One U.S. patent expires in 2011 (see risk factors) and two additional patent applications have been filed. The Company believes that its superior technology is protected by this combination of US and foreign patents and trade secrets. The Company's ability to protect the confidentiality of these trade secrets is dependent upon the Company's internal safeguards and upon the laws protecting trade secrets and unfair competition.

Target Markets

1. Workplace

The Company focuses its primary marketing efforts on the private sector, with particular emphasis on job applicant and employee testing.

Most businesses use drug testing to screen job applicants and employees. The Hazeldon Foundation survey from 2007 indicated that 85 percent of human resource professionals believe that drug testing is an effective way to diagnose substance abuse. The prevalence of drug screening programs reflects a concern that drug use contributes to employee health problems and costs (as the same study found that 62 percent of HR professionals believe that absenteeism is the most significant problem caused by substance abuse and addiction, followed at 49 percent by reduced productivity, a lack of trustworthiness at 39 percent, a negative impact on the company's external image at 32 percent and missed deadlines at 31 percent and in certain industries, safety hazards.) It has been estimated that the cost to American businesses is more than $100 billion annually.

The principal criticism of employee drug testing programs centers on the effectiveness of the testing program. Most private sector testing programs use urinalysis. Such programs are susceptible to evasive maneuvers and the inability to obtain confirmation through repeat samples in the event of a challenged result. An industry has developed over the Internet, and through direct mail, marketing a wide variety of adulterants, dilutants, clean urine and devices to assist drug users in falsifying urine test results.

Moreover, scheduled tests such as pre-employment testing and some random testing programs provide an opportunity for many drug users to simply abstain for a few days in order to escape detection by urinalysis.

The Company presents its patented hair analysis method to potential clients as a better technology well suited to employer needs. Field studies and actual client results support the accuracy and effectiveness of the Company's patented technology and its ability to detect varying levels of drug use. This information provides an employer with greater flexibility in assessing the scope of an applicant's or an employee's drug problem.

The Company performs a confirmation test of all presumptive positive results through mass spectrometry. The use of mass spectrometry is an industry accepted practice used to confirm positive drug test results of an initial screen. In an employment setting, mass spectrometry confirmation is typically used prior to the taking of any disciplinary action against an employee. The Company offers its clients a five-drug screen with mass spectrometry confirmation of cocaine, PCP, marijuana, amphetamines (including Ecstasy), and opiates (including heroin and oxycodone).

2. Schools

The Company currently serves hundreds of schools throughout the United States and in several foreign countries. The Company offers its school clients the same five-drug screen with mass spectrometry confirmation that is used with the Company's workplace testing service.

3. Parents

The Company also offers a personal drug testing service, known as "PDT-90"®, for parents concerned about drug use by their children. It allows parents to collect a small sample from their child in the privacy of the home, send it to the Company's laboratory and have it tested for drugs of abuse by the Company. The PDT-90 testing service uses the same patented method that is used with the Company's workplace testing service.

Research

The Company is involved in ongoing studies involving use of drugs of abuse in various populations, including the following: Boston Medical Center, Boston University School of Public Health, University of North Carolina Chapel Hill, Johns Hopkins Bloomberg School Of Public Health, Mclean Hospital, Wayne State University and Chemistry and Drug Metabolism Section, NIDA.

Sales and Marketing

The Company markets its corporate drug testing services primarily through its own sales force. Sales offices are located in several major cities in the United States in order to facilitate communications with corporate employers. The Company markets its home drug testing service, PDT-90, through the Internet and retail distributors.

Competition

The Company competes directly with numerous commercial laboratories that test for drugs primarily through urinalysis testing. Most of these laboratories, such as Laboratory Corporation of America and Quest Diagnostics, have substantially greater financial resources, market identity, marketing organizations, facilities, and numbers of personnel than the Company. The Company has been steadily increasing its base of corporate customers and believes that future success with new customers is dependent on the Company’s ability to communicate the advantages of implementing a drug program utilizing the Company’s patented hair analysis method.

The Company's ability to compete is also a function of pricing. The Company's prices for its tests are generally somewhat higher than prices for tests using urinalysis. However, the Company believes that its superior detection rates, coupled with the customer's ability to test less frequently due to hair testing's wider window of detection (several months versus approximately three days with urinalysis) provide more value to the customer. This pricing policy could, however, lead to slower sales growth for the Company.

Although other laboratories also offer hair testing for drugs of abuse, Psychemedics is the only laboratory with FDA clearance for a five-drug panel test that is not limited to head hair samples for drugs of abuse. To date, no other laboratory engaged in hair testing has received approval or clearance from the FDA on all of its assays for the testing of both head and body hair samples (two other laboratories have either partial FDA clearance or clearance specific to head hair samples only). Additionally, several of these laboratories that purport to test hair samples use a method that the Company presumes includes the use of a form of immunoassay procedures. The Company, however, does not believe that immunoassay testing of hair samples is as effective on a commercial basis without using the Company's unique patented method, which allows for the efficient release of drugs from the hair through enzyme digestion without destroying the drugs.

Government Regulation

The Company is licensed as a clinical laboratory by the State of California as well as certain other states. All tests are performed according to the laboratory standards established by the Department of Health and Human Services, through the Clinical Laboratories Improvement Amendments ("CLIA"), and various state licensing statutes.

A substantial number of states regulate drug testing. The scope and nature of such regulations varies greatly from state to state and is subject to change from time to time. The Company addresses state law issues on an ongoing basis.

In 2000, the FDA issued regulations under the Federal Food, Drug and Cosmetic Act, as amended (the "FDC Act") with respect to companies that market "drugs of abuse test sample collection systems". Under the regulations, companies engaged in the business of testing for drugs of abuse using a test (screening assay) not previously recognized by the FDA are required to submit their assay to the FDA for recognition prior to marketing. In addition, the laboratory performing the tests is required to be certified by a recognized agency. The regulations included a transitional period in order for companies not immediately in compliance with the proposed requirements to obtain the necessary data they needed for submission to the FDA.

By May 3, 2002, the Company had received 510k clearance to market all five of its assays.

In June 2008, Psychemedics also received the first CAP (College of American Pathologists) certification specifically including hair testing.

Research and Development

The Company is continuously engaged in research and development activities. During the years ended December 31, 2010, 2009 and 2008, $481,433, $467,435, and $474,622, respectively, were expended for research and development. The Company continues to perform research activities to develop new products and services and to improve existing products and services utilizing the Company's proprietary technology. The Company also continues to evaluate methodologies to enhance its drug screening capabilities. Additional research using the Company's proprietary technology is being conducted by outside research organizations through government-funded studies.

Research has continued on the interactions of different types of hair with drugs in the environment and from actual drug usage. This work has concentrated on assessments of various published methods for removal of externally

deposited drug from hair surfaces and on methods of extraction of metabolically deposited drugs from the solid hair matrix. Some of the work has been presented at meetings of the Society of Forensic Toxicologists and the European Society of Hair Testing.

Sources and Availability of Raw Materials

Since its inception, the Company has purchased raw materials for its laboratory services from outside suppliers. The most critical of these raw materials are the radio-labeled drugs which the Company purchases from a single supplier, although other suppliers of radio-labeled drugs exist. The Company has entered into an agreement with its principal supplier to purchase certain proprietary information regarding the manufacture of such radio-labeled drugs owned by the supplier in the event that the supplier ceases to be able to supply such radio-labeled drugs to the Company.

Employees

As of December 31, 2010, the Company had 91 full-time equivalent employees, of whom 3 full-time employees were in research and development. None of the Company's employees are subject to a collective bargaining agreement.

Item 1A. Risk Factors

In addition to other information contained in this Form 10-K, the following risk factors should be carefully considered in evaluating Psychemedics Corporation and its business because such factors could have a significant impact on our business, operating results and financial condition. These risk factors could cause actual results to materially differ from those projected in any forward-looking statements.

Companies may develop products that compete with our products and some of these companies may be larger and better capitalized than we are.

Many of our competitors and potential competitors are larger and have greater financial resources than we do and offer a range of products broader than our products. Some of the companies with which we now compete or may compete in the future may develop more extensive research and marketing capabilities and greater technical and personnel resources than we do, and may become better positioned to compete in an evolving industry. Failure to compete successfully could harm our business and prospects.

Increased competition, including price competition, could have a material impact on the Company's net revenues and profitability.

Our business is intensely competitive, both in terms of price and service. Pricing of drug testing services is a significant factor often considered by customers in selecting a drug testing laboratory. As a result of the clinical laboratory industry undergoing significant consolidation, larger clinical laboratory providers are able to increase cost efficiencies afforded by large-scale automated testing. This consolidation results in greater price competition. The Company may be unable to increase cost efficiencies sufficiently, if at all, and as a result, its net earnings and cash flows could be negatively impacted by such price competition. The Company may also face increased competition from companies that do not comply with existing laws or regulations or otherwise disregard compliance standards in the industry. Additionally, the Company may also face changes in fee schedules, competitive bidding for laboratory services or other actions or pressures reducing payment schedules as a result of increased or additional competition. Additional competition, including price competition, could have a material adverse impact on the Company's net revenues and profitability.

Our results of operations are subject in part to variation in our customers' hiring practices and other factors beyond our control.

Our results of operations have been and may continue to be subject to variation in our customers' hiring practices, which in turn is dependent, to a large extent, on the general condition of the economy. Results for a particular quarter may vary due to a number of factors, including:

- economic conditions in our markets in general;
- economic conditions affecting our customers and their particular industries;

- the introduction of new products and product enhancements by us or our competitors; and
- pricing and other competitive conditions.

A failure to obtain and retain new customers, or a loss of existing customers, or a reduction in tests ordered, could impact the Company's ability to successfully grow its business.

The Company needs to obtain and retain new customers. In addition, a reduction in tests ordered, without offsetting growth in its customer base, could impact the Company's ability to successfully grow its business and could have a material adverse impact on the Company's net revenues and profitability. We compete primarily on the basis of the quality of testing, reputation in the industry, the pricing of services and ability to employ qualified personnel. The Company's failure to successfully compete on any of these factors could result in the loss of customers and a reduction in the Company's ability to expand its customer base.

Our business could be harmed if we are unable to protect our proprietary technology.

We rely primarily on a combination of trade secrets, patents and trademark laws and confidentiality procedures to protect our technology. Despite these precautions, unauthorized third parties may infringe or copy portions of our technology. In addition, because patent applications in the United States are not publicly disclosed until either (1) 18 months after the application filing date or (2) the publication date of an issued patent wherein applicant(s) seek only US patent protection, applications not yet disclosed may have been filed which relate to our technology. Moreover, there is a risk that foreign intellectual property laws will not protect our intellectual property rights to the same extent as United States intellectual property laws. One of our patents is due to expire in 2011. In the absence of protections afforded by patents or by trade secrets, we may be vulnerable to competitors who attempt to copy our products, processes or technology.

Our business could be affected by a computer or other IT System failure.

A computer or IT system failure could affect our ability to perform tests, report test results or properly bill customers. Failures could occur as a result of the standardization of our IT systems and other system conversions, telecommunications failures, malicious human acts (such as electronic break-ins or computer viruses) or natural disasters. Sustained system failures or interruption of the Company's systems in one or more of its operations could disrupt the Company's ability to process and provide test results in a timely manner and/or bill the appropriate party. Failure of the Company's information systems could adversely affect the Company's business, profitability and financial condition.

Failure to maintain confidential information could result in a significant financial impact.

The Company maintains confidential information regarding the results of drug tests and other information including credit card and payment information from our customers. The failure to protect this information could result in lawsuits, fines or penalties. Any loss of data or breach of confidentiality, such as through a computer security breach, could expose the Company to a financial liability.

Our future success will depend on the continued services of our key personnel.

The loss of any of our key personnel could harm our business and prospects. We may not be able to attract and retain personnel necessary for the development of our business. We do not have key personnel under contract other than 3 officers who have agreements providing for severance and non compete covenants in the event of termination of employment following a change of control. Further, we do not have any key man life insurance for any of our officers or other key personnel.

We may become exposed to potential risks and related costs as a result of the internal control assessment and attestation process mandated on certain issuers by Section 404 of the Sarbanes-Oxley Act of 2002.

We evaluated, tested and implemented internal controls over financial reporting to enable management to report on such internal controls as required by Section 404 of the Sarbanes-Oxley Act of 2002. At such time we cease qualifying as a "smaller reporting company", under SEC rules (under $75 million market cap), we will be required to provide an auditor attestation on internal controls. The auditor attestation could cause us to incur significant costs, including increased accounting fees and staffing levels. While we believe that we are compliant with the management evaluation requirements of Section 404, if our independent registered public accounting firm were unable to attest in a timely manner to our evaluation, we could be subject to regulatory scrutiny and a loss of public confidence in our internal controls. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

Our reliance on one supplier for certain raw materials used in our testing procedures could harm our business and prospects.

Since its inception, the Company has purchased raw materials for its laboratory services from outside suppliers. The most critical of these raw materials are the radio-labeled drugs, which the Company purchases from a single supplier, although other suppliers of radio-labeled drugs exist. The Company has entered into an agreement with its principal supplier to purchase certain proprietary information regarding the manufacture of such radio-labeled drugs owned by the supplier in the event that the supplier ceases to be able to supply such radio-labeled drugs to the Company. Obtaining alternative sources of supply of the radio-labeled drugs could involve delays and other costs; however, the Company maintains a surplus supply. The failure of the Company's primary or any alternative supplier of radio-labeled drugs to provide such radio-labeled drugs at an acceptable price, or an interruption of supplies from such a supplier and the exhaustion of the Company's current supply on hand could result in lost or deferred sales.

There is a risk that our insurance will not be sufficient to protect us from errors and omissions liability or other claims, or that in the future errors and omissions insurance will not be available to us at a reasonable cost, if at all.

Our business involves the risk of claims of errors and omissions and other claims inherent to our business. We maintain errors and omissions and general liability insurance subject to deductibles and exclusions. There is a risk that our insurance will not be sufficient to protect us from all such possible claims. An under-insured or uninsured claim could harm our operating results or financial condition.

Our research and development capabilities may not produce viable new services or products.

We are attempting to develop further capabilities in the drug testing arena. It is uncertain whether we will be able to develop services that are more efficient, effective or that are suitable for our customers. Our ability to create viable products or services depends on many factors, including the implementation of appropriate technologies, the development of effective new research tools, the complexity of the chemistry and biology, the lack of predictability in the scientific process and the performance and decision-making capabilities of our scientists.

Further, some of our existing patents are due to expire within the next 3 years, including one in 2011. Our research and development teams are working to develop improved processes with the aim of gaining additional patent protection. There is no guarantee that they will be successful in developing these improvements or gaining such additional patent protection. If any or all of our patents expire, there may be increased competition in the marketplace for our service or we might be required to rely to a greater extent on trade secret protection.

Improved testing technologies, or the Company’s customers using new technologies to perform their own tests, could adversely affect the Company’s business.

Advances in technology may lead to the development of more cost-effective technologies such as point-of-care testing equipment that can be operated by third parties o