Grant Life Sciences, Inc.
Form 10KSB
April 17, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-KSB

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

For the fiscal year ended December 31, 2005

o TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

COMMISSION FILE NO. 000-50133

Grant Life Sciences, Inc.
(Name of Small Business Issuer in Its Charter)

Nevada	82-0490737
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
3550 Wilshire Blvd., Ste 1700, Los Angeles, CA (Address of Principal Executive Offices)	90010 (Zip Code)

(213) 637-5692
(Issuer's Telephone Number, Including Area Code)

SECURITIES REGISTERED UNDER SECTION 12(b) OF THE EXCHANGE ACT: NONE

SECURITIES REGISTERED UNDER SECTION 12(g) OF THE EXCHANGE ACT:

Common Stock, $.001 Par Value Per Share

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. x
Check whether the Issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 o

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained herein, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. x

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

State issuer’s revenues for the most recent fiscal year: $72,675.

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of a specified date within the past 60 days. As of March 9, 2006: $3,282,154 (117,219,774 shares at $0.028/share).

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 126,486,518 shares of common stock, $.001 par value per share, as of March 31, 2006.

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STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

In this annual report, references to “Grant Life Sciences,” “GLIF,” “the Company,” “we,” “us,” and “our” refer to Grant Sciences, Inc.

Except for the historical information contained herein, some of the statements in this Report contain forward-looking statements that involve risks and uncertainties. These statements are found in the sections entitled "Business," "Management's Discussion and Analysis or Plan of Operation," and "Risk Factors." They include statements concerning: our business strategy; expectations of market and customer response; liquidity and capital expenditures; future sources of revenues; expansion of our proposed product line; and trends in industry activity generally. In some cases, you can identify forward-looking statements by words such as "may," "will," "should," "expect," "plan," "could," "anticipate," "intend," "believe," "estimate," "predict," "potential," "goal," or "continue" or similar terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including, but not limited to, the risks outlined under "Risk Factors," that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. For example, assumptions that could cause actual results to vary materially from future results include, but are not limited to: our ability to successfully develop and market our products to customers; our ability to generate customer demand for our products in our target markets; the development of our target markets and market opportunities; our ability to manufacture suitable products at competitive cost; market pricing for our products and for competing products; the extent of increasing competition; technological developments in our target markets and the development of alternate, competing technologies in them; and sales of shares by existing shareholders. Although we believe that the expectations reflected in the forward looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Unless we are required to do so under US federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements

Item 1. Description of Business

Overview of Our Business

We are developing protein-based screening tests to screen woman for cervical cancer and pre-cancerous conditions that become cervical cancer. Our tests detect the presence of certain antibodies that appear only when cervical cancer or certain pre-cancerous conditions are present in the body. Our tests are performed by analyzing a small amount of the patient’s blood.

In one version of our test, the blood sample is analyzed in a clinical setting using standard laboratory equipment and analytic software, which generally can produce completed results in about 2 hours. Our rapid test provides easy-to-read results in approximately 15 minutes and is designed to be administered by a health professional in a doctor’s office, hospital, and clinic or even at home. This planned cervical cancer test uses proprietary technology to detect the presence of specific antibodies associated with cervical pre-cancers and cancer. We continue to test the validity of the results and believe that if they prove valid that in the future we may be able to use that technology to develop rapid tests for other diseases and cancers.

In January 2006 we announced the signing of a Memorandum of Understanding with Drs. Sveshnikov and Kiselev of the Russian Republic, for the in-licensing of certain of their technologies that are highly complementary to our antibody-based test for detecting cervical cancer. The technology is used to detect specific cervical cancer-causing proteins. The test utilizes antibodies against these cancer-causing proteins for detection. Thus far, the test is designed to detect specific cancer-causing proteins and once fully validated and expanded would be synergistic and complementary test to existing Pap technology. It would provide for very low-cost HPV testing as currently performed in Western countries, without the need for additional cervical specimens beyond what is now taken. In

addition, large capital outlays would not be required, since most laboratories can readily do the necessary testing.

Sveshnidov/Kiselev have already tested their technology in Russia and we will be further validating their tests with more specimens from Russia and the United States in controlled clinical settings.

We also have the exclusive worldwide rights to diagnostic devices for HIV-1, HIV-2 and dengue fever testing and a proprietary diagnostic reagent a key ingredient commonly used by leading manufacturers of rapid tests. We acquired these rights from AccuDx Corporation in March 2005 for a period of ten years.

History of Grant Life Sciences

We were incorporated in Idaho in 1983 as Grant Silver Inc. In 2000, we reincorporated in Nevada. On July 30, 2004, we acquired Impact Diagnostics, Inc, a Utah corporation, through the merger of our wholly owned subsidiary into Impact Diagnostics. We sometimes refer to that transaction as the "Merger". As a result of the Merger, Impact Diagnostics became our wholly owned subsidiary. Impact Diagnostics was formed in 1998 and has been developing a cervical cancer test. For several years prior to our acquisition of Impact Diagnostics, we engaged in no business.

Impact Diagnostics was formed in 1999 to license and develop certain technologies as owned by Dr. Yao Xiong Hu. Initial funding provided by the founders, and supplemented by two additional rounds of private funding, was used to fund the collection of patient samples and validation study costs of the technology. Once the technology was verified, Dr. Mark Rosenfeld drafted and applied for patents. In early 2004, Impact Diagnostics received its first patent.

Pursuant to the merger, each issued and outstanding share of common stock of Impact Diagnostic was converted into the right to receive one share of our common stock. In addition, each option to purchase one (1) share of common stock of Impact Diagnostics was converted into the right to receive an option to purchase one (1) share of our common stock. Upon completion of the merger, our then standing board of directors resigned and the nominees of Impact Diagnostics were appointed to our board of directors.

Cervical Cancer

Invasive cervical cancer affects over 500,000 women worldwide annually, and approximately 300,000 women die each year from this disease. Cervical cancer is the second highest cause of cancer death among women. In the United States, Western Europe and other countries where there is widespread screening and a well developed testing or diagnostic infrastructure, invasive cervical cancer is less prevalent. In China, India and many other countries, there is a much higher incidence of invasive cervical cancer because of the lack of testing and limited or diagnostic testing infrastructure.

Pap Tests have been the most prevalent cervical cancer screening method for more than 50 years. In recent years, gene- or DNA-based HPV tests has been introduced as an adjunct to the Pap Test. Today, approximately 60 million Pap Tests are performed annually in the United States, and an additional 60 million Pap Tests are performed annually in the rest of the world, mainly in Canada, Western Europe and Japan. Outside the United States, approximately 1.7 billion women do not undergo regular cervical cancer testing. In many cases, this scarcity of testing is the result of a lack of economic resources, as well as social, cultural and/or religious factors which may contribute to women not undergoing cervical cancer screening.

Cervical cancer is predominantly caused by humanpapilloma virus or HPV. However, of the more than 100 specific types of HPV, the scientific community believes only 7 to 15 are positively correlated with most cervical cancers. There are two types of cervical cancer. Squamous cell carcinoma, a cancer of the flat, scale-like cells that coat the cervix, is the most prevalent type. Adenocarcinoma is a more virulent cancer that stems from cervical cells with glandular or secretory properties that is increasing in incidence and often is undetectable by Pap Tests. Missing adenocarcinomas is largely caused by problems in collecting the correct cervical cells.

Traditional Testing for Cervical Cancer

Pap Tests

The most common means of screening for cervical cancer is the Pap Test, which has been used as the primary screen for over 50 years. The Pap Test is performed by swabbing the cervical surface to collect cells that are then placed on a microscopic slide for examination. A specially- trained licensed cytotechnologist, usually in a hospital or pathology

laboratory, observes the cells using a microscope and other specialized equipment to determine whether abnormal cells are present. When a cytotechnologist identifies a potential abnormality, a cytopathologist verifies the interpretation. A second generation Pap Test, known as a "Liquid Pap Test", involves as special procedure that puts cells onto a microscopic slide in a manner that is intended to allow for more clear-cut scrutiny by the cytotechnologist.

Women whose Pap test results are normal do not undergo further inspection, but instead characteristically return for routine Pap screening on an annual basis. However, women with abnormal Pap test results may be subjected to follow-up Pap tests, colposcopy (a visual examination of the cervix with the aid of a distinctive microscope) and biopsy to clearly identify cancerous conditions. Advanced lesions may then be removed with a cauterizing device or scalpel, and in some cases women undergo a hysterectomy, or removal of the entire cervix. If a patient's Pap Test cannot specifically be classified as normal or abnormal, the result is classified as "equivocal", or Atypical Squamous Cells of Undetermined Significance (ASC-US). This occurs in approximately 5-7% of cases in the United States (Modern Pathology, 12:335). Patients with equivocal Pap Test results typically will undergo multiple repeat Pap Tests. Many of these patients will also undergo a colposcopy and a biopsy. However, 80% of women with ASC-US who undergo an expensive colposcopy do not have cervical disease or develop cervical cancer (Journal of Medical Screening, 3:29).

While Pap Tests have been an important screening tool for many years and have helped reduce deaths caused by cervical cancer, they still have some significant shortcomings, including:

· limited predictive value — in the United States, each year several million colposcopies are performed on patients with abnormal Pap Test results, but only 20% of the colposcopies reveal cervical cancer or pre-cancerous lesions (Journal of the American Medical Association, 287:2382).

· false negative results — in the United States**,** Pap Tests fail to diagnose cervical cancer or pre-cancerous conditions that often lead to cervical cancer in approximately 30% to 60% (depending on whether a Liquid Pap Test or a regular Pap Test is used) of the cases where cervical cancer or pre-cancerous conditions are present (Archives of Pathology & Laboratory Medicine, 122:139).

· false positive results — Distinguishing between cervical cancer or pre-cancerous states and benign conditions mimicking them can be difficult via Pap Tests. (Diagnostic Cytopathology, 28:23).

· inability to detect adenocarcinomas — Pap Tests are unable to detect the presence of the more virulent adenocarcinoma (Clinical Laboratory Medicine, 20:140).

· invasive procedure — Pap Tests require healthcare professional to extract cells from the cervix by inserting a colleting device into the cervix. In some non-Western countries, women may be inhibited from undergoing this procedure for social, cultural or religious reasons.

· high costs — highly trained physicians and other specialists are required to collect, examine and interpret the Pap Test specimen, which contributes to a higher cost structure for the Pap Test. Following a positive test result, colposcopies and biopsies are required, raising the overall potential cost of screening.

Some of these deficiencies may be due primarily to visual limitations associated with microscopic examination, the inadequate or inappropriate sampling of cells or other technical problems and to the subjective nature of cytology interpretation.

HPV Tests

In the past few years, HPV testing has been introduced as another element of the cervical cancer screening process. The HPV Test is a gene-based test that detects the presence or absence of certain cancer-causing HPV. Like the Pap Test, it is performed by swabbing the cervix to extract cells. The specimen is then analyzed using expensive specialized equipment and software programs in a laboratory.

In the United States, women with ASC-US results from an initial Pap Test often undergo an HPV Test to determine if HPV is present. That test can be performed using the same sample taken for a Liquid Pap Test or a stand-alone one. HPV testing has also been introduced in conjunction with Pap Tests as an optional screening protocol for women 30 years of age and older, even in the absence of ASC-US or worse results.

While HPV Tests are helpful in detecting the presence of HPV, which is a precursor for virtually all cervical cancer, they too suffer from some significant shortcomings:

· limited predictive value — HPV tests actually detect virus infection and not cervical cancer and/or associated pre-cancerous lesions. Although HPV is an obligate cause of cervical cancer, only 2% of patients testing positive for HPV will eventually progress to the disease (Journal of Clinical Microbiology, 42:2470).

· invasive procedure — Like Pap smear cytology, the HPV test requires that the attending healthcare professional get cells by inserting a collection device into the cervix. As earlier stated, women in certain non-Western cultures may be prohibited from undergoing such a procedure for social, cultural or religious reasons

· high cost and complex — The HPV test specimen must be processed by special and dedicated, expensive laboratory equipment and interpretational computer software by highly trained technicians, thus the higher costs associated with HPV tests. Following a positive test result, colposcopy and biopsies are required, thus further elevating diagnostic costs.

Our Planned Cervical Cancer Test

We are developing cervical cancer tests that if proven will detect the presence or absence of specific antibodies and proteins that are produced only if cancer-causing HPV is present in the body, and consequent oncogenic, or cancer-promoting, changes have occurred. Cancer-causing HPV have unique proteins that trigger the disease. Upon disease onset, the body makes large numbers of antibodies to these unique proteins. By detecting specific antibodies to cancer-causing HPVs, we believe that our tests will be able to more reliably determine whether a patient has cervical cancer or pre-cancerous lesions than can Pap smear cytology or HPV testing.

Our tests involve the analysis of a small amount of blood taken from the patient. The collection of small volumes of blood is widely accepted as being of "minimal risk". It is not necessary to probe the cervix to get results. Given the previously discussed socio-religious hesitance or prohibitions as to getting cells from the cervix, we believe our tests will have greater acceptability and/or desirability than tests that involve obtaining cells from the cervix. Our tests involve the following, readily completed steps:

· The sample is placed into a receptacle coated with proprietary detection proteins of a specific nature.
· Only certain antibodies to cancer-causing HPVs can adhere to these proteins.

· The container is then rinsed, thus removing everything but antibodies that have adhered to the proteins.

· A special solution is added to the container. This solution includes "detector" antibodies that attach to those specific antibodies to cancer-causing HPVs adhered to the special detector proteins. The solution changes color with attachment of the "detector" antibodies, an indicator of a positive result (i.e., cervical cancer or a pre-cancerous condition present).

We are developing two tests. One, known as the Enzyme Linked Immunosorbent Assay Test (ELISA), is designed to be run in a laboratory. The blood specimen is sent to the laboratory, where a laboratory technician runs the test using standard, readily available laboratory equipment. No unique analytic or diagnostic software is required, while such software is essential for HPV testing. While test results typically are available in about two hours, we anticipate that the typical turnaround time from the laboratory to the doctor will be approximately one day. We believe that a doctor will be able to order this test as one of a battery of tests that is run on a patient's blood sample after a typical office visit.

Our second generation rapid test is designed to be a point-of-care test that will be able to be administered in the hospital, physician's office, clinic or even at home or in outdoor settings. The test kit will contain the required container and reagents, with a color change will indicate the presence of cancer-causing proteins. We anticipate that the test will be able to produce results within 10 to 15 minutes after administration of the test.

We have not yet completed the development of our cervical cancer tests. We are continuing to refine the existing proteins and processes currently used in our tests and are testing other proteins and processes, which may be included in our tests in the future.

We believe that, when completed, our tests will be a more accurate and efficient way to diagnose cervical cancer for the following reasons:

· greater accuracy — Our cervical cancer tests will detect specific antibodies present only if cancer-causing HPV is present and cancer-related cellular changes have occurred. As a result, we believe our tests will be able to more accurately diagnose cancer or pre-cancerous conditions than do Pap and HPV tests, thus making for fewer false positive or false negative results.

· ability to detect adenocarcinomas - Our antibody detection approach is well suited for finding adenocarcinomas as well as squamous cell carcinomas since cell samples are not required.

· non-invasive — Our tests require a small amount of blood, which may be quickly and safely taken via a finger prick or from a vein in the arm. We believe that in countries where women are reluctant to allow a healthcare professional to sample their cervix there will be greater willingness to allow blood sampling to ascertain cervical disease.

· reduced costs — We believe that because our tests will be run by laboratory technicians using standard, readily available equipment or by a healthcare professional using a point-of-care test, overall costs for our screening tests will be less than experienced with Pap or HPV tests. In addition, by providing more accurate results, we believe that our tests may reduce the number of repeated cervical cancer tests of any sort along with expensive colposcopies, biopsies and related medical procedures.

Initial Cervical Cancer-associated HPV Antibody Validation Studies

We have conducted initial studies to validate our planned cervical cancer tests.

In the United States, the Institutional Review Board (IRB) governs collection and use of patient specimens for research and testing purposes. The IRB Committee at Intermountain Health Care, the largest hospital facility in the intermountain western United States, and at St. Mark's Hospital in Salt Lake City, Utah, approved the evaluation of our technology for screening blood serum from patients, some of whom had negative Pap Tests and some of whom had previously been diagnosed with cervical cancer or intraepithelial lesions, the immediate precursor to cervical cancer. These initial non-blind studies were performed in May 2003 by Ameripath, Inc. on a total of 65 American patient samples from these IRB approved sources. Our tests detected cervical cancer or pre-cancerous conditions 94% of the time such conditions existed, and were able to rule out cervical cancer or pre-cancerous conditions 82% of the time the patient did not have these conditions.

Similar testing was done in April 2003, under a Chinese IRB equivalent, at the China Cancer Institute, China Academy of Medical Sciences on 70 samples, of which over half were from cervical cancer patients. Our tests detected cervical cancer or pre-cancerous conditions 97% of the time such conditions existed and were able to rule out cervical cancer or pre-cancerous conditions 85% of the time the patient did not have these conditions.

The initial studies conduced by Ameripath and in China used a "cut off" value or measurement standard to differentiate benign from cancerous or pre-cancerous conditions that is higher than would typically be used in a commercially available test. We currently are refining our technology in order to enable our tests to achieve similar results using a measurement standard appropriate for a commercial cervical cancer diagnostic test.

We are reformatting the assay platform and will conduct validation studies on the refined version of our cervical cancer test in the next few months. We have leased a facility in Los Angeles to conduct these studies. Once the test is validated we will develop a proposed protocol of clinical trials and other studies that will be used to support the submissions we intend to make to the FDA and other foreign regulatory authorities.

Cervical Cancer-associated HPV Antigen Detection Immunoassay Program

We have signed a Memorandum of Agreement (MOU) with Drs. Peter Sveshnikov and Vsevolod Kiselev of the Russian Republic, for the in licensing of technologies highly complimentary to Grants' antibody-based test for detecting cervical cancer. The Sveshnikov/Kiselev Technology comes to Grant from the US State Department through its Bio-Industry Initiative (BII) program. The BII is designed to foster medical and other biological research and development in the former Soviet Union, to convert former biowarfare scientists to productive peacetime activities. .

Sveshnikov/Kiselev have developed an Enzyme-linked Immunosorbent Assay (ELISA) to detect specific cancer-causing proteins from the human papillomavirus (HPV), the obligate cause of cervical cancer, in cervical mucous and cells (which make up liquid-based pap samples). The test utilizes certain monoclonal antibodies against these cancer-causing HPV proteins for detection. So far, the test is designed to detect cancer-causing proteins from HPV types 16 and 18, which collectively are responsible for most cervical disease. This type-specific antigen test, once fully validated, and expanded to include additional types of HPV associated with cervical dysplasia and cancer, would be a very synergistic compliment test to existing Pap technology. It will provide for very low cost HPV testing as currently performed in Western countries, without the need for additional cervical specimens beyond what is now taken. In addition, large capital outlays would not be required since most laboratories can readily do ELISA testing.

Sveshnidov/Kiselev have already looked at their technology with 1000 Russian samples to confirm the potential of this technology. Grant will be further validating with more specimens from Russia and with the many cervical specimens obtained in the United States under Institutional Review Board approval in controlled clinical settings.

Together, when validated, Grant will have two complementary cervical dysplasia or cancer diagnostic tests that will work on blood serum or cervical mucous and cells. A blood-based test is eminently suitable for the 1.7 billion women worldwide currently are not tested by Pap smear cytology.

Regulatory Approval

In the United States, our planned cervical cancer tests will be subject to regulation by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act. Governmental agencies in other countries also regulate medical devices. These domestic and foreign regulations govern the majority of the commercial activities we plan to perform, including the purposes for which our proposed tests can be used, the development, testing, labeling, storage and use of our proposed tests with other products and the manufacturing, advertising, promotion, sales and distribution of our proposed test for the approved purposes. Compliance with these regulations could prove expensive and time-consuming.

Products that are used to diagnose diseases in people are considered medical devices, which are regulated in the United States by the FDA. To obtain FDA authorization for a new medical device, a company may have to submit data relating to safety and efficiency based upon extensive testing. This testing, and the preparation and processing of necessary applications, are expensive and may take up to a few years to complete. Whether a medical device requires FDA authorization and the data that must be submitted to the FDA varies depending on the nature of the medical device.

Medical devices fall into one of three classes (Class I, II, or III), in accordance with the FDA's determination of controls necessary to ensure the safety and effectiveness of the device or diagnostic. As with most diagnostic products, we anticipate that our planned cervical cancer tests will be classified by the FDA as a Class II device. By definition, his means that there could be a potential for harm to the consumer if the device is not designed properly and/or otherwise does not meet strict standards. To market and sell a class II medical device, a company must first submit a 510(k) premarket notification, also known as a 510(k). The 510(k) application is intended to demonstrate substantial equivalency to a Class II device already on the market. The FDA will still require that clinical studies of device safety and effectiveness be completed.

In the United States, prior to approval by the FDA, under certain conditions, companies can sell investigational or research kits to laboratories under the Clinical Laboratory Improvement Amendment (CLIA) of 1988. Under CLIA, companies can sell diagnostic assays or tests to "high complexity" laboratories for validation as an "analyte specific reagent". An analyte specific reagent is the active ingredient of an "in-house" diagnostic test.

We intend to sell the ELISA version of our cervical cancer test to high complexity laboratories for validation as an analyte specific reagent or for use by such laboratories in their own homebrew (or in-house) diagnostic assays. Such sales would not require FDA approval, but we are aware that the FDA might deny approval under CLIA for sales of our product as an analyte specific reagent.

We have not yet submitted an application for approval to the FDA or regulatory agencies in any other countries of the cervical cancer tests we are developing. It is highly likely that we will have to conduct clinical trials and other studies to generate data that the FDA and other regulatory authorities will require in support of our application. We have not yet designed or initiated any of these trials. We anticipate it will take a minimum oft one to two years to complete the review and approval process.

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In addition to any government requirements as to authorizing the marketing and sales of medical devices, there are other FDA requirements. The manufacturer must be registered with the FDA. The FDA will inspect what is being done on a routine basis to ascertain compliance with those regulations prescribing standards for medical device quality and consistency. Such standards refer to but are not limited to manufacturing, testing, distribution, storage, design control and service activities. The FDA also prohibits promoting a device for unauthorized uses and routinely reviews labeling accuracy. If the FDA finds failures in compliance, it can institute a range of enforcement actions, from a public warning letter to more severe sanctions like withdrawal of approval; denial of requests for future approval; fines, injunctions and civil penalties; recall or seizure of the product; operating restrictions, partial suspension or total shutdown of production; and criminal prosecution.

The FDA's medical device reporting regulation also will require the reporting of information on deaths or serious injuries associated with the use of our tests, as well as product malfunctions that are likely to cause or contribute to death or serious injury if the malfunction were to recur.

Regardless of FDA approval status in the U.S, we will need to obtain certification of our tests from regulatory authorities in other countries prior to marketing and selling in such countries. The amount of time needed to achieve foreign approval varies from country to country and regulatory, approval by regulatory authorities of one country cannot by itself determine acceptance by another country's regulatory body. Additionally, implementation of more stringent requirements or the adoption of new requirements or policies could adversely affect our ability to sell our proposed tests in other countries in the world. We may be required to incur significant costs to comply with these laws and regulations.

In addition to the rules and regulations of the FDA and similar foreign agencies, we may also have to comply with other federal, state, provincial and local laws, rules and regulations. Our tests could be subject to rules pertaining to the disposal of hazardous or toxic chemicals or potentially hazardous substances, infectious disease agents and other materials, and laboratory and manufacturing practices used in connection with our research and development activities. If we fail to comply with these regulations, we could be fined, may not be allowed to operate certain portions of our business, or otherwise suffer consequences that could materially harm our business.

Competition

We are not aware of other companies that are developing a protein-based screening test that detects antibodies to cervical cancer. However, when completed, we expect that our cervical cancer tests will compete with the Pap Tests, which have been widely accepted by the medical community for over 50 years. Approximately 60 million Pap Tests are performed annually in the United States, and an additional 60 million Pap Tests are performed annually in the rest of the world. Manufacturers of Pap Tests include Cyctc Corporation, TriPath Imaging, Inc. and several other companies.

Our cervical cancer test also will compete with HPV Tests, which are becoming increasingly accepted in the medical community. Manufacturers of HPV Tests include Digene Corporation, Ventana Medical Systems, Roche Diagnostics, Abbott Laboratories, and Bayer Corporation.

All of the companies who make Pap Tests and HPV Tests have far greater financial, technical, research and development, sales and marketing, administrative and other resources than we do.

For our proposed tests to become accepted in the medical community, we will need to convince those who use established tests that our proposed tests are more reliable for the screening of cervical cancer, either as stand-alone tests or in conjunction with the Pap Test and/or HPV Tests.

In addition, we will need to obtain reimbursement coverage for our proposed cervical cancer tests. In the United States, the American Medical Association assigns specific Current Procedural Terminology, or CPT, codes necessary for reimbursement. Third-party payors and managed care entities that provide health insurance coverage to approximately 225 million people in the United States currently authorize almost universal reimbursement for the Pap Test, and the Pap Test is nearly fully reimbursed in other markets where we will sell our proposed tests. The HPV Test now has full reimbursement for certain uses. We will attempt to obtain reimbursement for our planned cervical cancer tests to the same degree as the Pap Test, but it is possible that we will be unable to obtain third-party reimbursement for these tests.

Sales and Marketing

When we have completed the development of our cervical cancer tests and received any required regulatory approval, we plan to market and sell our ELISA test to laboratories in the United States, Canada, Western Europe, Japan and other countries with established cervical cancer screening programs for use as a screening test. Initially, we do not plan to sell our test in these countries directly to primary healthcare providers.

In developing nations and other markets where cervical cancer screening is not widespread and where there are few laboratories or other testing facilities, we plan to market and sell our rapid test to primary healthcare providers as a stand alone point-of-care test. In some of these countries, we plan to sell our proposed test directly to the governments or to other national healthcare distributors who distribute tests to national healthcare providers.

We do not currently have a marketing or sales force or a distribution arrangement in place. We will need to expend resources to develop our own marketing and sales force or enter into third party distribution arrangements.

License AccuDx Rapid Point-of-Care Diagnostic Tests

In conjunction with our primary diagnostic cervical cancer blood test that we are developing, during the year we acquired exclusive worldwide rights to diagnostic devices for HIV-1, HIV-2 and dengue fever and proprietary colloidal gold reagent, a key ingredient commonly used by leading manufacturers of rapid tests as a detectable label. We acquired these rights from AccuDx. An estimated 40 million people are now living with HIV/AIDS of which nearly 18 million are women and 2 million children. Over 5 million new infections were reported in 2004.

As access to antiretroviral treatment is scaled up in low income countries, there is a critical opportunity to expand access to HIV prevention. Among the interventions which play a critical role both in treatment and prevention, HIV testing and counseling stands out as paramount. An estimated 40 million people are now living with HIV/AIDS of which nearly 18 million are women and 2 million children. Just in year 2004 over 5 million new infections were reported. Serological determination of the specific anti-HIV antibodies still forms the primary screening/diagnostic procedure for HIV infection.

The AccuDx AIDS test device consists of a sample addition pad containing HIV-antigen gold conjugate, a capillary membrane with three capture lines with HIV-1, HIV-2 and a control line and a fluid absorption pad. When test strips are placed in the tube containing test serum or plasma, the liquid migrates upwardly by capillary action. Colloidal gold conjugates of HIV antigen react with anti-HIV-1 and anti-HIV-2 antibodies in the sample which then are captured on specific antigen lines as they migrate up the membrane and into the fluid absorption pad. The results are visual and easy to interpret. For example, a single pink line corresponding to control is a negative, two lines corresponding to control and HIV-1 is an HIV-1 positive sample. In the cases where all two lines corresponding to HIV-2 and control would be an HIV-2 infection. Recombinant fusion proteins consisting of envelope proteins (gp120 and gp41), a recombinant protein covering the antigenic epitopes of HIV-1 envelope gp36 and a recombinant O-subtype are used for signal as well as capture Ligands in a “double antigen immuno-chromatographic assay” format. The test is simple to use and performance characteristics are comparable to Laboratory based assays. The Company believes that extensive utilization of HIV antibody point-of-care tests should aid combat the current HIV/AIDS pandemic world-wide.

Another global illness, dengue fever, which is transmitted by mosquitoes has increased dramatically in recent decades. Dengue fever, dengue haemorrhagic fever (DHF) and dengue shock syndrome (DDS) occur in over 100 countries and territories and threaten the health of more than 2.5 billion people in urban, peri-urban and rural areas of the tropics and subtropics. The disease is endemic in Africa, the Americas, the Eastern Mediterranean, South-East Asia and the Western Pacific. Although the major disease burden is in South-East Asia and the Western Pacific, rising trends are also reflected in increased reporting of dengue fever and DHF cases in the Americas. In 1998, a total of 1.2 million cases of dengue and DHF were reported to WHO including 15,000 deaths. Globally, the annual number of infections

is much higher than is indicated by the number of reported cases. Based on statistical modeling methods there are an estimated 51 million infections each year.

Dengue is a Flavivirus that is transmitted by mosquito, principally Aedes aegypti. There are four known serotypes and serology is a useful aid in the diagnosis of dengue infections. Rapid and reliable tests for primary and secondary infections of dengue are essential for patient management. Primary Dengue infection is associated with mild to high fever, headache, muscle pain and skin rash. Immune response includes antibodies denoted as IgM which are produced by 5th day of symptoms and persists for 30-60 days and antibodies denoted as IgG which appear by the 14th day and persist for life. Secondary infections often result in high fever and in many cases with haemorrhagic events and circulatory failure. Secondary infections induce IgM response after 20 days of infection and IgGs rise within 1-2 days after the onset of symptoms. A reliable and sensitive rapid test that can simultaneously detect the presence of anti-dengue IgG and IgM is of great clinical utility. The Immunochromatographic format provides an excellent immune capture method for specific detection of anti-dengue IgG and IgM. The presence of high titers of IgGs does not interfere with the IgM detection in the AccuDx format. A mixture of highly purified recombinant proteins corresponding to dengue virus e-proteins from type 2 and 3 and covering antigenic epitopes of all 4 serotypes is conjugated to colloidal gold. The Immunochromatographic device is sensitized with goat anti-human IgG (corresponding to a band just below the mark “G”), goat anti-human IgM (corresponding to a band just below the mark “M”) and anti-dengue E protein monoclonal antibodies (corresponding to the band just below the mark “C”).

The AccuDx test utilizes a specimen sample consisting of serum or plasma which is added to a test tube with the buffer solution provided. IgGs and IgMs in the specimen sample react with colloidal gold conjugates of recombinant dengue envelope proteins that detect Dengue Types 1, 2, 3 and 4 as they travel up the test strip and are captured by the relevant IgG and or IgM test bands. If there are anti-dengue IgGs or IgMs present within the specimen sample, signal conjugates will bind to them and produce a pale or dark pink band at either the "G" for IgGs or "M" for IgMs. In all cases the conjugate in the specimen sample conjugate mixture in the test tube will bind with the anti-dengue monoclonal antibody band, and serves as a positive control. The intensity of the bands will vary depending upon the antibody titer (IgM and IgG). In the cases of very high titer IgG and IgM, the control band may appear fainter in its intensity. Extensive utilization of point-of-care testing of Dengue IgM/IgG tests could in the Company's view save millions of lives worldwide.

The agreement with AccuDx grants us the right to manufacture the AccuDx Tests in AccuDx's 'maquiladora'-modeled contract manufacturing facility in Tijuana, Mexico which facility is registered with the FDA and is ISO 9002-certified. We will seek recertification approval in Southeastern countries where the AccuDx Tests had previously received certificates of resale and we will seek governmental approval in other countries including China, Brazil and India. We plan on generating revenues from the sale of AccuDx Tests in the last quarter of 2005, provided that we receive such recertifications in a timely manner.

We have also acquired exclusive rights to AccuDx's proprietary colloidal gold reagent, a key ingredient commonly used by leading manufacturers of rapid tests as a detectable label. The need for uniform size colloidal conjugates in diagnosis and nanotechnology cannot be over emphasized. AccuDx has developed and perfected technologies to particles of colloidal manufacture large quantities of uniform size colloidal gold. Colloidal gold conjugates are currently used in various applications including in in vitro diagnostic devices, electron microscopy and various nanotechnology applications. Conjugates of various specific Ligands will be made available as research reagents and OEM products.

Grant Life Sciences has shipped its first order of *Malaria* rapid diagnostic tests, to India. This product, along with rapid tests for *Dengue Fever*, *HIV-1* and *HIV-2*, among others, was licensed earlier this year from AccuDx Corp., a biotechnology company based in La Jolla, Calif., founded by Ravi Pottahil, Ph.D., one of the world's leading authorities in the field of HIV/AIDS diagnostics and therapeutics. Grant Life Sciences owns the exclusive rights to AccuDx's rapid tests.

While this initial order totaling $75,000 is admittedly small, nonetheless it is evidence that we are executing our strategy to revitalize AccuDx's distributor networks in overseas markets. While we expect revenues to continue to increase, seasonal fluctuations due to the nature of specific diseases will effect monthly sales. For example, Malaria and Dengue Fever are highly seasonal diseases. However, to offset seasonal fluctuations, we plan on broadening our family of diagnostic tests utilized at both the point-of-care as well as in the laboratory setting.

The Company's goal is to have a global distributorship network in place, along with the requisite manufacturing capacity, so that we can begin selling our core product, the immunological serum-based test for detecting Cervical Cancer and its precursors, as soon as it is ready for commercialization .

Intellectual Property

We rely on patents, licenses from third parties, trade secrets, trademarks, copyright registrations and non-disclosure agreements to establish and protect our proprietary rights in our technologies and products.

We entered into an exclusive license with Dr. Yao Xiong Hu on July 20, 2004 for certain processes that we currently include in our cervical cancer tests based on antibodies. Some of the technology owned by Dr. Hu is covered by a United States patent that has been issued, and some of the technology is covered by a United States patent application that has been filed and is pending. The agreement with Dr. Hu also covers technology included in foreign applications presently pending as PCT applications in China and India. We entered into the license agreement with Dr. Hu on July 20, 2004. The initial term of this license is 17 years, and it automatically renews for successive one-year periods unless voluntarily terminated by us or by Dr. Hu in the event of our insolvency. Under the license agreement, we are required to pay Dr. Hu a minimum licensing fee of $48,000 per year, which is paid on a monthly basis of $4,000 per month. If the annual royalty exceeds, $48,000, we will also be required to pay to Dr. Hu royalties on a quarterly basis ranging from 1% to 3% depending on the net sales of our product. We have the option to purchase the licensed technology for $250,000 within two years from the date of the agreement. As of the date of this report we have made $24,000 in license fee payments to Dr. Hu.

We plan to file patent applications for any additional technology that we create in the future.

We anticipate that we may need to license additional technology for use in our planned cervical cancer tests from other third parties. We may be unable to obtain these licenses on acceptable terms or at all.

Our technology is also dependent upon unpatented trade secrets. However, trade secrets are difficult to protect. In an effort to protect our trade secrets, we have a policy of requiring our employees, consultants and advisors to execute non-disclosure agreements. These agreements provide that confidential information developed or made known to an individual during the course of their relationship with us must be kept confidential, and may not be used, except in specified circumstances. In addition, our employees are parties to agreements that require them to assign to us all inventions and other technology that they create while employed by us.

On March 7, 2005, we entered into an Exclusive License Agreement with AccuDx Corporation for a period of ten years, pursuant to which AccuDx granted us the exclusive right to its rapid tests for HIV-1, HIV-2 and dengue fever and its colloidal gold reagent. The license agreement also granted us the ability to manufacture these products at AccuDx's FDA/GMP-compliant contract manufacturing maquiladora facility in Tijuana, Mexico. In consideration for the license, we agreed to pay AccuDx $15,000 in cash and deliver a promissory note in the principal amount of $35,000 payable in equal quarterly installments for a two-year period and bearing 6% interest on the unpaid principal. We also agreed to pay AccuDx a 3% royalty on net sales of the products under the license.

On April 10, 2006 we announced the signing of a memorandum of understanding (MOU) with Diagnostic Technologies LTD. ("DTL"), a company incorporated under the laws of the State of Israel whereby DTL will carry out a short-term assessment in order to evaluate the feasibility and viability of the results for DTL to enter in a new product development, and we would grant DTL an irrevocable, worldwide, exclusive, royalty-bearing license to use our Licensed Properties to develop, manufacture, and sell our product for the duration of the patent. In return, we would receive an up-front license fee and royalties on all sales.

Research and Development

Our research and development program is focused on completing development of our cervical cancer tests. We continue to refine existing technology and develop further improvements to our tests.

We believe that in the future we may be able to apply our technology to develop rapid tests for other diseases and certain other cancers. We plan to pursue development of these other tests.

For the fiscal years ended December 31, 2005 and 2004, we spent approximately $502,325 and $450,540, respectively, on research and development.

Manufacturing

We outsource the manufacture of the products sold under license from AccuDx and plan to outsource the manufacturing and assembly of our planned cervical cancer tests to third parties. We do not currently have arrangements in place with any such third parties for the latter.

Suppliers

We develop the processes including proteins and other technology that we use in our proposed tests, and license certain other technology from third parties. We believe that the reagents and other supplies we will use to manufacture our test may be readily obtained from multiple suppliers.

Employees

As of March 31, 2006, we had five employees and retained three consultants on a part-time basis. Our employees consist of our three executive officers, a director of international marketing and one administrative assistant. During the next 12 months, we anticipate that we may add employees, including scientists and other professionals in the research and development, product development, business development, regulatory, manufacturing, marketing and clinical studies areas.

Item 2. Properties

We currently lease our principal executive offices in Los Angeles and office space in Murray, Utah. Part of our Utah office space is subleased for $800 per month on a month to month basis. We believe that our existing facilities will be adequate for our current needs and that additional space will be available as needed. The material terms of our property leases are set forth in the table below.

Location	Use	Square Feet	Rent Payments	Term	Leased From
3550 Wilshire Blvd., Ste 1700, Los Angeles CA 90010	Principal Executive Offices	Approximately 500 square feet	$979 per month	month to month	Wilshire Business Center, LLC
64 East Winchester Suite 205 Murray, Utah 84107	Offices	Approximately 1330 square feet	$1,663 per month	Month to month	Plaza 6400, LLC

Item 3. Legal Proceedings

We are not currently a party to any litigation.

Item 4. Submission of Matters to a Vote of Security Holders

There were no matters submitted to a vote of our security holders during the fourth quarter of the year ended December 31, 2005.

Items 5. Market for Registrant's Common Equity and Related Security Holder Matters

Our common stock is quoted on the OTC Bulletin Board under the symbol "GLIF.OB." The following table sets forth, for the calendar periods indicated, the range of the high and low last reported bid prices of our common

stock from January 1, 2004 through December 31, 2005, as reported by the OTC Bulletin Board. The stock was not actively traded in the first ½ of 2004. The quotations represent inter-dealer prices without retail mark-ups, mark-downs or commissions, and may not necessarily represent actual transactions. The quotations may be rounded for presentation.

Period	High	Low
First Quarter 2004	$ 0.04	$ 0.04
Second Quarter 2004	$ 0.04	$ 0.04
Third Quarter 2004	$ 0.80	$ 0.04
Fourth Quarter 2004	$ 1.40	$ 0.64
First Quarter 2005	$ 0.90	$ 0.30
Second Quarter 2005	$ 0.53	$ 0.13
Third Quarter 2005	$ 0.17	$ 0.006
Fourth Quarter 2005	$ 0.039	$ 0.005

On April 7, 2006, the last reported bid price of our common stock as reported on the OTC Bulletin Board was $0.025 per share. As of March 31, 2006, we had approximately 165 shareholders of record.

We have never declared nor paid cash dividends and do not expect to pay dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table gives information about the Company's common stock that may be issued upon the exercise of options, granted to employees, directors and consultants, under its 2004 Stock Incentive Plan as of December 31, 2005.

Equity Compensation Plan Information

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plan
Equity Compensation approved by Security Holders	4,170,952	$	0.18	20,829,048
Equity Compensation not approved by Security Holders (1)	250,000	$	0.18	N/A
TOTAL	4,420,952	$	0.18	

(1) Includes 250,000 warrants to purchase shares at $0.18 issued to a consultant for performing research services for performed on our behalf, prior to the Merger in July 2004.

Item 6. Management's Discussion and Analysis or Plan of Operation

Overview

On July 30, 2004, we acquired Impact Diagnostics through the merger of our wholly owned subsidiary, Impact Acquisition Corporation, into Impact Diagnostics. As a result of the Merger, each issued and outstanding share of common stock of Impact Diagnostics was converted into one share of our common stock, and Impact Diagnostics became a wholly owned subsidiary of our company. We now own, indirectly though Impact Diagnostics, all of the assets of Impact Diagnostics.

We are considered a development stage company. In 2003 and 2004, we had no revenues and incurred net losses of $253,881 and $1,910,350, respectively. In 2005, we had revenues of $72,675 and incurred net losses of $4,634,331. Since inception in July 1998, we have incurred cumulative losses of $8,015,670.

Application of Critical Accounting Policies

Our consolidated financial statements and accompanying notes are prepared in accordance with generally accepted accounting principles in the United States. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. These estimates and assumptions are affected by management's application of accounting policies. We believe that understanding the basis and nature of the estimates and assumptions involved with the following aspects of our consolidated financial

statements is critical to an understanding of our financials.

Stock-Based Compensation

On December 16, 2004, the FASB published Statement No. 123 (Revised 2004), “Share-Based Payment” (“SFAS No. 123R”). SFAS No. 123R requires that compensation cost related to share-based payment transactions be recognized in the financial statements. Share-based payment transactions within the scope of SFAS No. 123R include stock options, restricted stock plans, performance-based equity awards, stock appreciation rights, and employee share purchase plans. The provisions of SFAS No. 123R are effective as of the first interim period that begins after December 15, 2005. The Company adopted this Statement early, for the year 2004. The company incurred expense of $976,986 in 2005 and $426,081 in 2004 for the stock options granted under its 2004 Stock Incentive Plan. The Company anticipates continuing to incur such costs in order to conserve its limited financial resources. The determination of the volatility, expected term and other assumptions used to determine the fair value of equity based compensation issued to non-employees under SFAS No. 123 involves subjective judgment and the consideration of a variety of factors, including our historical stock price, option exercise activity to date and the review of assumptions used by comparable enterprises.

Accounting for Derivatives

In June 1998, FASB issued SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities.” The Statement establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, (collectively referred to as derivatives) and for hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value.

In June 2005, the Company obtained a commitment from accredited investors to purchase convertible debt with warrants. The Company evaluated the transaction as a derivative transaction in accordance with SFAS No. 133. The transactions, to the extent that it is to be satisfied with common stock of the Company, would normally be included as equity obligations. However, in the instant case, due to the indeterminate number of shares which might be issued under the embedded convertible host debt conversion feature, the Company is required to record a liability for the fair value of the detachable warrants and the embedded convertible feature of the note payable (included in the liabilities as a "derivative liability").

The Company accounts for warrants and embedded conversion features as described in SFAS 133, EITF 98-5, 00-19, and 00-27, and APB 14 as follows:

- The Company allocated the proceeds received between the convertible debt and the detachable warrants based upon the relative fair market values on the dates the proceeds were received.
    - Subsequent to the initial recording, the change in the fair value of the detachable warrants, determined under the Black-Scholes option pricing formula, and the change in the fair value of the embedded derivative in the conversion feature of the convertible debentures at each reporting date are recorded as adjustments to the liabilities.
    - The expense relating to the change in the fair value of the Company's stock reflected in the change in the fair value of the warrants and derivatives is included as other income (expense).

Plan of Operations

During the next year, we expect we may acquire laboratory assets to augment our clinical research and development efforts, which are presently outsourced, and may continue to be outsourced. We have relocated our offices to California where our chairman, president and our chief financial officer reside. In conjunction with this relocation, we have terminated our lease of our office in Raleigh, North Carolina

During the next 12 months, we plan to continue the development of our cervical cancer screening tests. We intend to continue to validate the effectiveness of the processes that we currently use in the tests we are developing through trials. In the near term, we plan to meet with regulatory agencies in the United States and in other countries to determine the clinical trials and studies we will have to undertake and the data and other information we will be required to submit to them to support our future applications for authority to market and sell our planned cervical cancer tests in those countries. We also plan to:

- begin studies and clinical trials in the United States and other countries that will be required in connection with our regulatory applications.
- validate the HPV antigen detection immunoassay. We intend to continue the development of this project once the assay is verified in its current format.
- register the HIV-1/II rapid test in India and several other Asia countries. The sales of HIVI/II, malaria, dengue fever tests in Asia are expected to increase significantly.

During the next 12 months, we anticipate that we may add employees, including scientists and other professionals in the research and development, product development, business development, regulatory, manufacturing, marketing and clinical studies areas. We also intend to explore alternate means of developing and marketing our cervical cancer tests by other means such as alliances, joint development, and licensing.

Liquidity and Capital Resources

We do not have sufficient capital to satisfy our cash requirements through the next twelve months. As of December 31, 2005, we had total current assets of $987,481 and total current liabilities of $478,595. Our cash flow used in operations was $1,499,163 during the year ended December 31, 2005. Additionally we used $5,743 to acquire new property and equipment during the period. We met our cash requirements during the year 2005 through the placement of $2,000,000 of convertible notes payable.

Our auditors have added an explanatory paragraph to their opinions to our financial statements because of concerns about our ability to continue as a going concern. These concerns arise from the fact that we have not yet established an ongoing source of revenues sufficient to cover our operating costs and that we must raise additional capital in order to continue to operate our business.

In connection with the Merger, between July 30, 2004 and August 19, 2004, we sold 1,912,125 units in a private placement, at a purchase price of $0.9175 per unit ($0.1835 per share), resulting in gross proceeds to our company of $1,754,375, or $1,494,937 net after deduction of offering costs. Net proceeds after legal, accounting, printing and other fees was approximately $1,437,000. Each unit was comprised of five (5) shares (or 9,560,625 shares) of our common stock and a warrant to purchase one (1) share of our common stock at an exercise price of $0.1835 per share. During the year 2005, we sold 567,000 shares of our common stock for a total consideration of $14,420 through the exercise of stock options and warrants.

We plan to raise additional capital in the next twelve months through the sale of equity and/or debt securities to support our development plan in the medical diagnostics industry. However, we currently do not have any committed sources of financing. We may not be able to raise additional financing on acceptable terms when we need to, or we may be unable to raise additional financing as all.

On March 7, 2005, we entered into an Exclusive License Agreement with AccuDx Corporation (“Licensor”) for a period of ten years, pursuant to which we were granted the exclusive right to Licensor’s rapid tests for HIV-1, HIV-2 and Dengue Fever and its colloidal gold reagent. The Agreement also granted us the right to manufacture these products at the Licensor’s FDA/GMP-compliant contract manufacturing maquiladora facility in Tijuana, Mexico. In consideration for the License, we agreed to pay Licensor $15,000 in cash and deliver a promissory note in the principal amount of $35,000 payable in equal quarterly installments for a two-year period and bearing 6% interest on the unpaid principal. We also agreed to pay the Licensor a 3% royalty on net sales of the products under the License. We also entered into a Consulting Agreement with Ravi Pottahil and Indira Pottahil in support of the License in exchange for 310,000 shares of our common stock, which were to be issued as follows: one-third on September 7, 2005, one-third on March 7, 2006 and one-third on September 7, 2006. No shares have yet been issued.

On March 15, 2005, we issued an 8% Senior Secured Note due June 15, 2005, in the aggregate principal amount of $200,000 (the “Note”) and a warrant to purchase up to an aggregate of 250,000 shares of the our common stock (the “Warrant”) to DCOFI Master LDC, for net proceeds of $165,000. The Note and Warrant were issued in a private placement pursuant to Section 4(2) of the Exchange Act of 1933 and Rule 506. Proceeds from the sale were used for working capital and general corporate purposes. The Note bore interest at a rate of 8% per annum, and was secured by the assets of the Company. Interest was payable in cash monthly. The Warrant was exercised during the fourth quarter of 2005 and the note repaid on June 15, 2005.

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We entered into a Securities Purchase Agreement with New Millennium Capital Partners II, LLC, AJW Qualified Partners, LLC, AJW Offshore, Ltd. and AJW Partners, LLC on June 14, 2005 for the sale of (i) $2,000,000 in callable secured convertible notes and (ii) stock purchase warrants to buy 7,692,308 shares of our common stock.

- On June 15, 2005, the investors purchased $700,000 in callable secured convertible notes and received warrants to purchase 2,692,307 shares of the Company's common stock.
- On August 18, 2005, the investors purchased $600,000 in callable secured convertible notes and received warrants to purchase 2,307,692 shares of the Company's common stock.
- On August 30, 2005, the investors purchased $700,000 in callable secured convertible notes and received warrants to purchase 2,692,307 shares of the Company's common stock.

The Notes bear interest at 10%, mature three years from the date of issuance, and, subject to the filing of an amendment to the Company's certificate of incorporation increasing its authorized stock, are convertible into our common stock, at the investors' option, at a conversion price equal to the lower of (i) $0.40 or (ii) 50% of the average of the three lowest intraday trading prices for our common stock during the 20 trading days before, but not including, the conversion date. As of February 28, 2006, the average of the three lowest intraday trading prices for our common stock during the preceding 20 trading days as reported on the Over-The-Counter Bulletin Board was $.0184 and, therefore, the conversion price for the secured convertible notes was $.009. As of February 28, 2006 the outstanding principal for the foregoing notes is $1,529,688, Therefore based on this conversion price, the callable secured convertible notes, excluding interest, would be convertible into 166,270,435 shares of our common stock.

In January 2006, the Company was served with a default notice by the holders of the $2,000,000 convertible notes. The default was the result of the Company's not having maintained an effective registration statement for sufficient shares to permit the noteholders to continue conversion of the notes to common shares. In February 2006, the notice of default was withdrawn in exchange for an agreement with the Company whereby the rate at which the notes could be converted was reduced from 50% to 43% of the average of the three lowest intraday trading prices for the common stock on a principal market for the 20 trading days before but not including conversion date.

We may prepay the callable secured convertible notes in the event that no event of default exists, there are a sufficient number of shares available for conversion of the callable secured convertible notes and the market price is at or below $.40 per share. The full principal amount of the callable secured convertible notes is due upon default under the terms of callable secured convertible notes. In addition, the Company has granted the investors a security interest in substantially all of its assets and intellectual property.

The Warrants are exercisable until five years from the date of issuance at a purchase price of $0.45 per share. In addition, the exercise price of the warrants is adjusted in the event the Company issues common stock at a price below market.

The investors have contractually agreed to restrict their ability to convert the callable secured convertible notes and exercise the warrants and receive shares of the Company's common stock such that the number of shares of the Company common stock held by them and their affiliates after such conversion or exercise does not exceed 4.99% of the Company's then issued and outstanding shares of common stock.

We plan to raise additional capital in the next twelve months through the sale of equity and/or debt securities to support our development plan in the medical diagnostics industry. However, we currently do not have any committed sources of financing. We may not be able to raise additional financing on acceptable terms when we need to, or we may be unable to raise additional financing as all.

Risks Related to our Business

We are a development stage company and we have no meaningful operating history on which to evaluate our business or prospects.

We acquired Impact Diagnostics on July 30, 2004. For several years prior to that acquisition, we did not engage in any business. Impact Diagnostics was formed in 1998 and has been developing a cervical cancer screening test. This in addition to the limited sale of the AccuDx products and investigation of additional technology related to cervical cancer screening is our only business. Impact Diagnostics has only a limited operating history and has generated no revenue. The limited operating history of Impact Diagnostics makes it difficult to evaluate our business prospects and future performance. Our business prospects must be considered in light of the risks, uncertainties, expenses and difficulties frequently encountered by companies in their early stages of development, particularly companies in new and rapidly evolving markets, such as the biotechnology market.

We have not completed the development of our planned cervical cancer tests and we are not currently developing any other products. We may not successfully develop our cervical cancer tests or any other products.

The cervical cancer tests are the only products we are developing. We have no other products. We may never successfully complete the development of our cervical cancer tests. If we do not complete the development of our cervical cancer tests or develop other products, we will not be able to generate any revenues or become profitable and you may lose your entire investment in us.

We have incurred net losses to date and expect to continue to incur net losses for the foreseeable future. We may never become profitable.

We have had substantial operating losses since our inception and have never earned a profit. We incurred net losses of $646,201 in fiscal 2002, $253,881 in fiscal 2003, $1,910,350 in fiscal 2004, $4,634,331 for the year ended December 31, 2005, and $8,015,670 from inception in 1998 through December 31, 2005. Our accumulated deficit at December 31, 2005 was $8,015,670.

Our losses have resulted principally from:

· expenses associated with our research and development programs and development or our cervical cancer tests;

· expenses associated with the Merger; and

· administrative and facilities costs which include significant charges resulting from the required accounting for loans and stock options.

We expect to incur significant and increasing operating losses for the next few years as we complete development of our cervical cancer tests, initiate clinical trials, seek regulatory approval, expand our research and development, advance other product candidates into development and, if we receive regulatory approval, market and sell our products. We may never become profitable.

We will be required to raise additional capital to fund our operations, and if we are unable to obtain funding when needed, we may need to delay completing the development of our planned cervical cancer tests, scale back our operations or close our business.

Our auditors have added an explanatory paragraph to their opinions to our financial statements because of concerns about our ability to continue as a going concern. These concerns arise from the fact that we have not yet established an ongoing source of revenues sufficient to cover our operating costs and that we must raise additional capital in order to continue to operate our business. If we are unable to continue as a going concern, you could lose your entire investment in us.

We will not be able to sell our planned cervical cancer tests and generate revenues if laboratories and physicians do not accept them.

If we successfully complete development of our cervical cancer tests and obtain required regulatory approval, we plan to market and sell our tests initially to clinical testing laboratories in the United States, Western Europe and other countries in which there is widespread cervical cancer screening and a sophisticated testing infrastructure. We plan to market and sell the rapid test to physicians, hospitals, clinics and other healthcare providers in some developing countries where cervical cancer screening is not widespread and where there is limited or non-standardized testing infrastructure. In order to successfully commercialize our tests, we will have to convince both laboratories and

healthcare providers that our proposed tests are an effective method of screening for cervical cancer, whether as an independent test, used in conjunction with Pap Tests and/or HPV Tests or as a follow-up screening method for women with equivocal Pap Tests. Pap Tests have been the principal means of cervical cancer screening for over 50 years and, in recent years, HPV Tests have been introduced primarily as an adjunct to Pap Tests. Failure to achieve any of these goals, could have an adverse material effect on our business, financial condition or results of operation.

Our planned cervical cancer tests rely on an approach that is different from the underlying technology of the Pap Tests and the HPV Tests and of healthcare professionals, women's advocacy groups and other key constituencies may not view our planned tests as an accurate means of detecting cervical cancer or pre-cancerous conditions. In addition, some parties may view using our proposed test along with the Pap Tests and/or HPV Tests for primary screening as adding unnecessary expense to the already accepted cervical cancer screening protocol, which could cause our product revenue to be negatively affected.

If third-party health insurance payors do not adequately reimburse healthcare providers or patients for our proposed cervical cancer tests, we believe it will be more difficult for us to sell our tests.

We anticipate that if government insurance plans (including Medicare and Medicaid in the United States), managed care organizations and private insurers do not adequately reimburse users for use of our tests, it will be more difficult for us to sell our tests to laboratories and healthcare providers. Third-party payors and managed care entities that provide health insurance coverage to approximately 225 million people in the United States currently authorize almost universal reimbursement for the Pap Tests, and Pap Tests are nearly fully reimbursed in other markets where we plan to market and sell our proposed tests. HPV Tests also are almost fully reimbursed for certain uses. We will attempt to obtain reimbursement coverage in all markets in which we plan to sell our proposed cervical cancer tests to the same degree as the Pap Test.

Our management will be required to expend significant time, effort and expense to provide information about the effectiveness of our planned cervical cancer tests to health insurance payors who are willing to consider reimbursement for our tests. However, reimbursement has become increasingly limited for medical diagnostic products. Health insurance payors may not reimburse laboratories, healthcare providers or patients in the United States or elsewhere for the use of our planned tests, either as a stand-alone test or as an adjunct to Pap Tests or HPV Tests, which would make it difficult for us to sell our tests, which could make our business less profitable and cause our business to fail.

We currently have no sales force or distribution arrangement in any market where we intend to market and sell our tests.

We currently have no sales or marketing organization for our cervical cancer tests. When we complete the development of our cervical cancer tests and receive the required regulatory approvals, we will attempt to market and sell our tests to laboratories and directly to physicians, hospitals, clinics and other healthcare providers. We plan to market and sell our tests to laboratories in the United States and globally through third party distributors. We do not currently have any arrangements with any distributors and we may not be able to enter into arrangements with qualified distributors on acceptable terms or at all. If we are unable to enter into distribution agreements with qualified distributors on acceptable terms, we may be unable to successfully commercialize our tests.

Our competitors are much larger and more experienced than we are and, even if we complete the development of our tests, we may not be able to successfully compete with them.

The diagnostic testing industry is highly competitive. When completed, we expect that our cervical cancer tests will compete with the Pap Tests, which have been widely accepted by the medical community for many years. Approximately 60 million Pap Tests are performed annually in the United States, and an additional 60 million Pap Tests are performed annually in the rest of the world. Manufacturers of Pap Tests include Cyctc Corporation and several other companies. Future improvements to the Pap Test could hinder our efforts to introduce our tests into the market.

Our cervical cancer tests also will compete with HPV Tests, which are becoming increasingly accepted in the medical community. Manufacturers of HPV Tests include Digene Corporation, Ventana Medical Systems, Roche Diagnostics,

Abbott Laboratories, and Bayer Corporation. If market acceptance of HPV Tests becomes greater, it may be more difficult for us to introduce our tests into the market.

All of the companies who manufacture Pap Tests and HPV Tests are more established than we are and have far greater financial, technical, research and development, sales and marketing, administrative and other resources than we do. Even if we successfully complete the development of our tests, we may not be able to compete effectively with these much larger companies and their more established products.

We will need to obtain regulatory approval before we can market and sell our planned tests in the United States and in many other countries.

In the United States, our planned cervical cancer tests will be subject to regulation by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act. Governmental agencies in other countries also regulate medical devices. These domestic and foreign regulations govern the majority of the commercial activities we plan to perform, including the purposes for which our proposed tests can be used, the development, testing, labeling, storage and use of our proposed tests with other products and the manufacturing, advertising, promotion, sales and distribution of our proposed test for the approved purposes. Compliance with these regulations could prove expensive and time-consuming.

Products that are used to diagnose diseases in people are considered medical devices, which are regulated in the United States by the FDA. To obtain FDA authorization for a new medical device, a company may have to submit data relating to safety and efficiency based upon extensive testing. This testing, and the preparation and processing of necessary applications, are expensive and may take up to a few years to complete. Whether a medical device requires FDA authorization and the data that must be submitted to the FDA varies depending on the nature of the medical device.

Medical devices fall into one of three classes (Class I, II, or III), in accordance with the FDA's determination of controls necessary to ensure the safety and effectiveness of the device or diagnostic. As with most diagnostic products, we anticipate that our planned cervical cancer tests will be classified by the FDA as a Class II device. By definition, this means that there could be a potential for harm to the consumer if the device is not designed properly and/or otherwise does not meet strict standards. To market and sell a Class II medical device, a company must first submit a 510(k) premarket notification, also known as a 510(k). The 510(k) application is intended to demonstrate substantial equivalency to a Class II device already on the market. The FDA will still require that clinical studies of device safety and effectiveness be completed.

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