Grant Life Sciences, Inc.
Form SB-2/A
April 28, 2005

As filed with the Securities and Exchange Commission on April 28, 2005
Registration No. 333-119425

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Amendment No. 2 to
FORM SB-2

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

GRANT LIFE SCIENCES, INC.
(Name of Small Business Issuer in Its Charter)

Nevada	3841	82-0490737
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

64 East Winchester, Suite 205
Murray, Utah 84107
(801) 261-8736

(Address and Telephone Number of Principal Executive Offices)

Stan Yakatan, Chief Executive Officer
64 East Winchester, Suite 205
Murray, Utah 84107
(801) 261-8736

(Name, Address and Telephone Number of Agent for Service)

Copies to:

Gregory Sichenzia, Esq.
Sichenzia Ross Friedman Ference LLP
1065 Avenue of the Americas, 21st Floor
New York, NY 10018
(212) 930-9700
(212) 930-9725

Approximate Date of Commencement of Proposed Sale to the Public:

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box. o

Title of each class of Securities to be Registered	Amount to be registered	Proposed Maximum Offering Price Per Unit (1)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock	24,268,495	$0.70		
			$16,987,946.50	
				$2,152.37
Common Stock				
	1,895,268			
		$0.55		
			$1,042,397	
				$122.69
Total				
	26,163,763			
			$18,323,973.50	
				$2,275.06(2)

(1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based upon the average of the bid and asked prices of the Registrant's common stock on January 21, 2004.

(2) We previously paid $2309.62 for the registration of 26,177,105 shares. We have reduced the number of shares being registered to 26,163,763

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Preliminary Prospectus, subject to Completion, dated April 28, 2005

GRANT LIFE SCIENCES, INC.

26,163,763 Shares

Common Stock

This prospectus relates to the sale of up to 26,163,763 shares of our common stock by selling stockholders. The prices at which the selling stockholders may sell shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any proceeds from the sale of our shares by the selling stockholders.

Our common stock is listed on the Over-the-Counter Bulletin Board under the symbol "GLIF.OB." On April 26, 2005, the last reported bid price of our common stock was $0.35 per share.

INVESTING IN OUR SECURITIES INVOLVES RISKS. SEE "RISK FACTORS" BEGINNING ON PAGE 2.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus is _____, 2005.

64 East Winchester, Suite 205
Murray, Utah 84107
(801) 261-8736

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PROSPECTUS SUMMARY

This summary does not contain all of the information that you should consider before investing in our common stock. You should carefully read the entire prospectus prior to making an investment decision.

About Grant Life Science

We are developing protein-based screening tests to screen women for cervical cancer and pre-cancerous conditions that typically result in 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 blood taken from the patient. In one of our tests, the blood sample is analyzed in a clinical testing laboratory using standard laboratory equipment and analytic software, which generally can produce test results in about 2 hours. Our second generation rapid test is designed to be administered by a health professional in a doctor's office, hospital, clinic or even at home, and can provide easy-to-read results in approximately 15 minutes.

We have not generated any revenues since inception in July 1998. We have a history of losses and we expect to continue to incur losses for the foreseeable future. For the year ended December 31, 2004, we generated no revenues and incurred a net loss of $1,910,350. Cumulative losses since inception total $3,381,339. As a result of recurring losses from operations, a working capital deficit and accumulated deficit, our auditors, in their report dated March 18, 2005, have expressed substantial doubt about our ability to continue as a going concern.

History of Grant Life Sciences

Grant Life Sciences was 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 is a wholly owned subsidiary of Grant Life Sciences. 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 Diagnostics 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, nominees of Impact Diagnostics were appointed to our board of directors and, our standing board of directors resigned.

For accounting purposes, the acquisition of Impact Diagnostics through the Merger is treated and presented as a recapitalization of Impact Diagnostics. The reverse merger is treated and presented as a recapitalization because we did not have any operating activity prior to the acquisition of Impact Diagnostics, ownership of Grant Life Sciences upon the reverse merger was controlled by the stockholders of Impact Diagnostics and the management of Impact Diagnostics controlled our operating activity post-merger. Therefore, in this prospectus, unless otherwise indicated, all historical financial information presented about us is historical financial information of Impact Diagnostics only, the historical audited and unaudited interim financial statements are the financial statements of Impact Diagnostics.

By this prospectus, the selling stockholders are offering up to 26,163,763 shares of our common stock, of which 22,766,393 are shares of common stock currently held by the selling stockholders, 2,979,704 are shares of common stock issuable upon exercise of warrants, and 417,666 are shares issuable upon the conversion of notes held by the selling stockholders. The selling stockholders are not required to sell their shares, and any sales of common stock by the selling stockholders are entirely at the discretion of the selling stockholders.

We will receive no proceeds from the sale of the shares of common stock in this offering. However, if all of the warrants are exercised in full, we would receive $484,048 in proceeds. Any proceeds received upon exercise of the warrants will be used for working capital, administrative expenses and product development.

RISK FACTORS

Investing in our securities involves a material degree of risk. Before making an investment decision, you should carefully consider the risk factors set forth in this prospectus and any accompanying prospectus supplement delivered with this prospectus, as well as other information we include in this prospectus and any accompanying prospectus supplement.

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 is now 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 for the year ended December 31, 2004 and $3,381,339 from inception in 1998 through December 31, 2004. Our accumulated deficit at December 31, 2004 was $3,381.339.

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.

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 need to raise substantial 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.

We believe we have sufficient cash to sustain us through June 2005. Based on our current plan, we will need to raise at least $3,000,000 to fund our operations through April 2006. We plan to raise additional capital through the sale of equity and/or debt securities. We do not currently have any committed sources of financing and we may be unable to obtain financing on acceptable terms or at all. If we are unable to raise sufficient funds, we may have to delay, scale-back or eliminate aspects of our operations or close our business. If we sell additional equity securities, we will dilute our current stockholders' equity interest in us.

Our auditors have qualified their opinion 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. 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.

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.

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 guarantee 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. We may be required to incur significant costs to comply with these laws and regulations. If the US and/or other countries do not issue patents to us, our operating results will suffer and our business may fail.

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. Out 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.

If we are unable to successfully protect our intellectual property or our licensor is unsuccessful in defending the patents on our licensed technology against infringement, our ability to develop, market and sell our tests and any other product we may develop in the future will be harmed.

Our success will partly depend on our ability to obtain patents and licenses from third parties and protect our trade secrets.

We have an exclusive license from Dr. Yao Xiong Hu for certain processes that we currently include in our cervical cancer tests. Some of Dr. Hu's technology 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. In the event a competitor uses our licensed technology, our licensor may be unable to successfully assert patent infringement claims. In that event, we may encounter direct competition using the same technology on which our products are based and we may be unable to compete. If we cannot compete with competitive products, our business will fail. In addition, if any third party claims that our licensed products are infringing their intellectual property rights, any resulting litigation could be costly and time consuming and would divert the attention of management and key personnel from other business issues. We also may be subject to significant damages or injunctions preventing us from selling or using some aspect of our products in the event of a successful patent or other intellectual property infringement claim. In addition, from time to time, we may be required to obtain licenses from third parties for some of the technology or components used or included in our tests. If we are unable to obtain a required license on acceptable terms or at all, our ability to develop or sell our tests may be impaired and our revenue will be negatively affected.

We plan to file patent applications for any additional technology that we create in the future. We cannot guarantee that our patent applications will result in patents being issued in the United States or foreign countries. In addition, the U.S. Patent and Trademark Office may reverse its decision or delay the issuance of any patents that may be allowed. We also cannot guarantee that any technologies or tests that we may develop in the future will be patentable. In addition, competitors may develop products similar to ours that do not conflict with patents we may receive. If our patents are issued, others may challenge these patents and, as a result, our patents could be narrowed or invalidated, which could have a direct adverse effect on our earnings and profitability.

Our confidentiality agreements may not adequately protect our proprietary information, the disclosure of which could decrease our competitive edge.

Our technology and tests may be dependent on unpatented trade secrets. However, trade secrets are difficult to protect. In an effort to protect our trade secrets, we generally require our employees, consultants and advisors to sign confidentiality agreements. 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. However, we cannot guarantee that these agreements will provide us with adequate protection if confidential information is used or disclosed improperly. In addition, in some situations, these agreements may conflict with, or be limited by, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Further, others may independently develop similar proprietary information and techniques, or otherwise gain access to our trade secrets. Any of these adverse consequences could negatively impact our results of operations.

Our products may infringe on the intellectual property rights of others and may result in costly and time-consuming litigation.

Our success will depend partly on our ability to operate without infringing upon the proprietary rights of others, as well as our ability to prevent others from infringing on our proprietary rights. We may be required at times to take legal action in order to protect our proprietary rights. Although we attempt to avoid infringing upon known proprietary rights of third parties, and are not aware of any current or threatened claims of infringement, we may be subject to legal proceedings and claims for alleged infringement by us or our licensees of third-party proprietary rights, such as patents, trade secrets, trademarks or copyrights, from time to time in the ordinary course of business. Any claims relating to the infringement of third-party proprietary rights, even if not successful or meritorious, could result in costly litigation, divert resources and management's attention or require us to enter into royalty or license agreements which are not advantageous to us. In addition, parties making these claims may be able to obtain injunctions, which could prevent us from selling our products. Any of these results could lead to liability, substantial

costs and reduced growth prospects, any or all of which could negatively affect our business.

We do not have any manufacturing facilities and although we have made arrangements with a third party to use its manufacturing facility, the arrangement is subject to a license agreement.

We have no capacity to manufacture our proposed tests. Although we have not established any arrangements with third party manufacturers, we plan to make arrangements pursuant to a licensing agreement to use a manufacturing facility that our licensor has used in the past. If the licensing agreement expires or is terminated, we cannot guarantee that we will be able to enter into any such other arrangements on favorable terms, or at all.

If we are able to market and sell our cervical cancer tests, we may be subject to product liability claims or face product recalls for which our insurance may be inadequate.

If we complete development of our cervical cancer tests and begin to sell them we will be exposed to the risk of product liability claims and product recalls. We currently do not market any products and therefore have obtained only general liability insurance coverage. Any failure to obtain product liability insurance in the future that is not continually available to us on acceptable terms, or at all, or that is sufficient to protect us against product liability claims or recalls, may not have enough funds to pay legal fees and/or any judgments in connection with any such claims which would have an adverse affect on our operating results and could cause our business to fail.

If we are unable to manage our anticipated future growth, we may not be able to implement our business plan.

We currently have seven employees and retain consultants on a part-time basis. In order to complete development of our tests, obtain FDA and other regulatory approval, seek insurance reimbursement, begin to market and sell our tests, begin the production of our tests and continue and expand our research and development programs, we will need to hire significant additional qualified personnel and expand or implement our operating, administrative, information and other systems. We cannot guarantee that we will be able to do so or that, if we do so, we will be able to effectively integrate them into our existing staff and systems. We will also have to compete with other biotechnology companies to recruit, hire and train qualified personnel. If we are unable to manage our growth, we may not be able to implement our business plan and our business could fail.

Risks Related to our Common Stock

There is only a limited market for our common stock and the price of our common stock may be affected by factors that are unrelated to the performance of our business.

Our common stock has not actively traded during the past few years. If any of the risks described in these Risk Factors or other unseen risks are realized, the market price of our common stock could be materially adversely affected. Additionally, market prices for securities of biotechnology and diagnostic companies have historically been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons that are unrelated to the operating performance of any one company. In particular, and in addition to the other risks described elsewhere in these Risk Factors, the following factors can adversely affect the market price of our common stock:

- announcements of technological innovation or improved or new diagnostic products by others;
- general market conditions;
- changes in government regulation or patent decisions;
- changes in insurance reimbursement practices or policies for diagnostic products.

Our common shares have traded on the Over the Counter Bulletin Board at prices below $5.00 for several years. As a result, our shares are characterized as “penny stocks” which could adversely affect the market liquidity of our common stock.

The Securities Enforcement and Penny Stock Reform Act of 1990 requires additional disclosure relating to the market for penny stocks in connection with trades in any stock defined as a penny stock. Securities and Exchange Commission regulations generally define a penny stock to be an equity security that has a market price of less than $5.00 per share, subject to certain exceptions. Such exceptions include any equity security listed on Nasdaq or a national securities exchange and any equity security issued by an issuer that has:

- net tangible assets in excess of $2,000,000, if such issuer has been in continuous operation for three years;
- net tangible assets in excess of $5,000,000, if such issuer has been in continuous operation for less than three years; or
- average revenue of at least $6,000,000, for the last three years.

Unless an exception is available, the regulations require, prior to any transaction involving a penny stock, that a disclosure schedule explaining the penny stock market and the risks associated therewith is delivered to a prospective purchaser of the penny stock. We currently do not qualify for an exception, and, therefore, our common stock is considered to be penny stock and is subject to these requirements. The penny stock regulations adversely affect the market liquidity of our common shares by limiting the ability of broker/dealers to trade the shares and the ability of purchasers of our common shares to sell in the secondary market. In addition, certain institutions and investors will not invest in penny stocks.

Nevada law provides certain anti-takeover provisions for Nevada companies that may prevent or frustrate any attempt to replace or remove our current management by the stockholders or discourage bids for our common stock. These provisions may also affect the market price of our common stock. We have chosen not to opt out of these provisions.

We are subject to provisions of Nevada corporate law that limit the voting rights of a person who, individually or in association with others, acquires or offers to acquire at least 20% of our outstanding voting power unless a majority of our disinterested stockholders elects to grant voting rights to such person. We are also subject to provisions of Nevada corporate law that prohibit us from engaging in any business combination with an interested stockholder, which is a person who, directly or indirectly, is the beneficial owner of 10% or more of our common stock, for a period of three years following the date that such person becomes an interested stockholder, unless the business combination is approved by our board of directors in a prescribed manner. These provisions of Nevada law may make business combinations more time consuming or expensive and have the impact of requiring our board of directors to agree with a proposal before it is accepted and presented to stockholders for consideration. Although we have the ability to opt out of these provisions, we have not chosen not to do so. These anti-takeover provisions might discourage bids for our common stock.

Our board of directors has the authority, without further action by the stockholders, to issue, from time to time, up to 20,000,000 shares of preferred stock in one or more classes or series and to fix the rights and preferences of such preferred stock. The board of directors could use this authority to issue preferred stock to discourage an unwanted bidder from making a proposal to acquire us.

Future sales of a significant number of shares of our common stock by existing stockholders may lower the price of our common stock, which could result in losses to our stockholders.

As of April 26, 2005, we had outstanding 57,639,113 voting shares. Some of our outstanding voting shares are eligible for sale under Rule 144, are otherwise freely tradable or will become freely tradable under Rule 144. Sales of substantial amounts of shares of our common stock into the public market could lower the market price of our common shares.

In general, under Rule 144 as currently in effect, a person (or persons whose shares are required to be aggregated) who has owned shares for at least one year would be entitled to sell within any three-month period a number of shares that does not exceed the greater of (i) 1% of the number of our common shares then outstanding (which equals approximately 576,391 shares of common stock) or (ii) the average weekly trading volume of our common shares during the four calendar weeks preceding the filing of a Form 144 with respect to such sale. Sales under Rule 144 are public information about us. Under Rule 144(k), a person who is not deemed to have been our affiliate at any time during the three months preceding a sale, and who has owned the shares proposed to be sold for at least two years, is entitled to sell his shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

FORWARD LOOKING STATEMENTS

This prospectus includes forward-looking statements. You can identify these forward-looking statements when you see us using words such as “expect,” “anticipate,” “estimate,” “believe,” “intend,” “may,” “predict,” and other similar expressio
These forward looking statements cover, among other items:

- our future capital needs;

- our expectations about our ability to complete development of our cervical cancer tests;

- our expectations about the FDA and other regulatory approval process that will be required for our cervical cancer tests;
- our expectations about reimbursement of our products by health insurance payors;
- our expectations about the future performance of the cervical cancer tests that we are developing;
- our expectations about acceptance in the market of the cervical cancer tests we are developing;
- our expectations about the ability of our planned cervical cancer tests to compete in the market;
- our marketing and sales plans;
- our expectations about our financial performance;
- our intention to develop additional screening tests using our technology;

We have based these forward-looking statements largely on our current expectations. However, forward-looking statements are subject to a number of risks and uncertainties, certain of which are beyond our control. Actual results could differ materially from those anticipated as a result of the factors described under “Risk Factors” including, among others:

- problems that we may face in successfully completing our planned cervical cancer tests;
- our inability to raise additional capital when needed;
- uncertainty of acceptance of our cervical cancer tests in the market;
- reluctance or unwillingness of laboratories and physicians to accept our tests;
- refusal of insurance companies and other third-party payors to reimburse patients, clinicians and laboratories for our tests;
- problems that we may face in marketing and selling our tests;
- the possibility that we may not be able to compete with established companies;
- delays in obtaining, or our inability to obtain, approval by the FDA for our proposed tests;
- delays in obtaining, or our inability to obtain, approval by certain foreign regulatory authorities for our proposed tests;
- problems in acquiring and protecting intellectual property important to our business through patents, licenses and other agreements;
- our ability to successfully defend claims that our tests may infringe the intellectual property rights of others;
- problems that we may face in obtaining product liability insurance or defending product liability claims;
- problems that we may face in manufacturing and distributing our proposed tests;
- the risks we face in potential international markets; and
- the limited market for our common stock and the adverse affect on liquidity that we may face because our common stock is considered a “penny stock”.

We do not undertake any obligation to publicly update or revise any forward-looking statements contained in this prospectus or incorporated by reference, whether as a result of new information, future events or otherwise. Because of these risks and uncertainties, the forward-looking statements and circumstances discussed in this prospectus might not transpire.

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by selling stockholders. Certain of the selling stockholders will receive 2,979,704 shares of our common stock upon conversion of our outstanding warrants that they own. We will receive no proceeds from the sale of shares of common stock in this offering. However, if all of the warrants owned by the selling stockholders are exercised in full, we would receive

$484,048 in proceeds. Any proceeds received upon exercise of the warrants will be used for working capital purposes, administrative expenses and product development.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Some of the information in this Form SB-2 contains forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as "may," "will," "expect," "anticipate," "believe," "estimate" and "continue," or similar words. You should read statements that contain these words carefully because they:

- discuss our future expectations;
- contain projections of our future results of operations or of our financial condition; and
- state other "forward-looking" information.

We believe it is important to communicate our expectations. However, there may be events in the future that we are not able to accurately predict or over which we have no control. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under "Risk Factors," "Business" and elsewhere in this prospectus. See "Risk Factors."

Overview

On July 30, 2004, we acquired Impact Diagnostics through the merger of our wholly owned subsidiary, Impact Acquisition Corporation, into Impact Diagnostics. At the time of the merger, we were an inactive publicly traded shell corporation with no significant assets or operations. In accordance with SFAS No. 141, Impact Diagnostics was the acquiring entity. While the transaction is accounted for using the purchase method of accounting, in substance the merger is a recapitalization of Impact Diagnostic's capital structure. 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.

For accounting purposes, Impact Diagnostics has accounted for the transaction as a reverse acquisition and shall be the surviving entity. Impact Diagnostics did not recognize goodwill or any intangible assets in connection with the transaction and there have been no adjustments to the historical carrying values of the assets and liabilities.

The accompanying financial statements present the historical financial condition, results of operations and cash flows of the Impact Diagnostics prior to the merger with us.

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. Since inception in July 1998, we have incurred cumulative losses of $3,381,339.

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 Financial Accounting Standards Board published Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment ("SFAS 123R"). SFAS 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 123R include stock options, restricted stock plans, performance-based equity awards, stock appreciation rights, and employee share purchase plans. The provisions of SFAS 123R are effective as of the first interim period that begins after December 15, 2005. The Company is adopting this Statement early, for the year 2004. The company incurred expense of $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 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.

Plan of Operations

In connection with the acquisition of Impact Diagnostics, Stan Yakatan was appointed as our Chief Executive Officer and President, John Wilson was appointed as our Chief Financial Officer and Michael Ahlin and Dr. Mark Rosenfeld

were appointed as our Vice Presidents. All of these individuals held these positions with Impact Diagnostics prior to the Merger. Dr. Mark Rosenfeld resigned on Oct 11, 2004. Mr. Wilson resigned on March 31, 2005 and was replaced by Don Rutherford. In addition to these officers, we currently have four employees and have engaged a number of part-time scientific consultants.

During the next year, we expect to acquire laboratory assets to augment our clinical research and development efforts. As part of this effort, we plan to develop a laboratory facility through relocating its offices to California where our Chief Executive Officer and Chief Financial Officer reside. We currently anticipate leasing an office in the Los Angeles area and will seek to secure the necessary mixed-use permits to operate a laboratory facility as part of such office. In conjunction with this relocation, we are subleasing our office space in Raleigh, North Carolina until the lease runs out in September 2005. This address is the address where Mr. John Wilson, our former Chief Financial Officer maintained an office. Effective March 31, 2005, Mr. Wilson resigned as Chief Financial Officer, and Donald Rutherford, a Los Angeles based, experienced financial executive, becoming our Chief Financial Officer. In addition to the termination of our North Carolina office, we also plan to relocate our clinical laboratory presently located in Sandy, Utah to the Los Angeles area.

During the next 12 months, we plan to complete 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 which will be conducted for us by Allogen Laboratories, a subsidiary of the Cleveland Clinic. 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. During the next 12 months, we also anticipate that we will add employees, including scientists and other professionals in the research and development, product development, business development, regulatory, manufacturing, marketing and clinical studies areas.

We plan to invest any excess cash we have in investment grade interest bearing securities. We do not anticipate investing in real estate or interests in real estate, real estate mortgages, or securities of or interests in persons primarily engaged in real estate activities. We do not intend to undertake investments in real estate as a part of our normal operations.

Liquidity and Capital Resources

We do not have sufficient capital to satisfy our cash requirements through the next twelve months. As of December 31, 2004, we had total current assets of $377,768 and total current liabilities of $275,505. These current liabilities include notes payable of $122,500 which converted to shares of common stock in March 2005. Our cash flow deficit from operations was $1,484,935 during the year ended December 31, 2004. Additionally we used $16,873 to acquire new property and equipment during the period. We met our cash requirements in 2004 through a private placement in connection with the Merger. As of March 31, 2005, we have current assets of approximately $248,000 and total current liabilities of approximately $583,000.

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.

Our continuation as a going concern is dependent on our ability to generate sufficient cash flows to meet our obligations on a timely basis and to obtain additional financing as may be required. We plan to raise additional capital in the next three 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. We plan to invest any excess cash we have in investment grade interest bearing securities.

Duncan Bridge Financing

On March 15, 2005, we completed the sale of $200,000 aggregate principal amount of an 8% Senior Secured Note due June 15, 2005 and a warrant to purchase up to an aggregate of 250,000 shares of our common stock to DCOFI Master LDC. The note and warrant were issued in a private placement pursuant to Section 4(2) of the Exchange Act of 1933 and Rule 506. The note bears interest at a rate of 8% per annum, is due and payable on June 15, 2005 and is secured by our assets. Upon the occurrence of an event of default, the full principal amount of the note will become due and payable and we will be required to issue to DCOFI warrants to purchase an aggregate of 250,000 shares of common stock. The note may be prepaid by us at a price equal to 100% of the outstanding principal balance, if within 60 days of the issue date and at a price equal to 106% of the outstanding principal balance if prepaid after 60 days after the issue date. The warrant is exercisable until five years from the date of issuance at a purchase price of $0.40 per share, subject to adjustment. DCOFI may exercise the warrant on a cashless basis if, one year after the issue date,

the shares of common stock underlying the warrant are not then registered pursuant to an effective registration statement. In the event the investors exercise the warrant on a cashless basis, then we will not receive any proceeds. In addition, the exercise price of the warrant will be adjusted in the event we issue common stock at a price below the exercise price of the warrant. Upon an issuance of shares of common stock at a price below the exercise price, the exercise price of the warrant will be reduced to the price such shares of common stock were issued. The exercise price of the warrant will also be adjusted in certain circumstances such as if we pay a stock dividend, subdivide or combine outstanding shares of common stock into a greater or lesser number of shares, or take such other actions as would otherwise result in dilution of DCOFI's ownership. We received net proceeds of $165,000, which was used for working capital.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as of the December 31, 2004 or as of the date of this prospectus.

MARKET FOR COMMON STOCK

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, 2002 through March 31, 2005, as reported by the OTC Bulletin Board. 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 2003	$0.04	$0.04
Second Quarter 2003	$0.04	$0.04
Third Quarter 2003	$0.04	$0.04
Fourth Quarter 2003	$0.04	$0.04
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	$0.82	$0.40

On April 26, 2005, the last reported bid price of our common stock as reported on the OTC Bulletin Board was $0.35 per share. As of April 26, 2005, we had approximately 140 shareholders of record. Certain of the shares of common stock are held in "street" name and may be held by numerous beneficial owners.

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.

Our planned cervical cancer test uses proprietary technology to detect the presence of specific antibodies associated with cervical pre-cancers and cancer. We believe that in the future we may be able to use that technology to develop rapid tests for other diseases and cancers.

As part of our expansion of our diagnostic mission, we have also acquired exclusive rights to a rapid testing product for HIV-1, HIV-2 and dengue fever as well as a proprietary colloidal gold reagent from AccuDx Corp., a California biotechnology corporation.

Cervical Cancer

Invasive cervical cancer affects over 500,000 women worldwide annually, and approximately 300,000 women die each year from this disease (National Institutes of Health Notices, Federal Press Release Library Assession Number A00295; Cleveland Clinic Journal of Medicine, 70:641). Cervical cancer is second only to breast cancer as the leading `cause of cancer death among women (Cancer Journal, 9:348). 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 Latin America, 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, a microscopic examination of cells scraped from the cervix, have been the most prevalent cervical cancer screening method for more than 50 years. In recent years, gene- or DNA-based HPV tests have been introduced as an adjunct to the Pap Test. In the United States, more than 82% of women 25 years or older have gotten Pap Tests over the last three years (Cancer, 97:1528), equated to a total of more than 50 million Pap Tests performed each year (CDC Morbidity and Mortality Weekly Report, 49:1001). An equivalent number of Pap Tests are performed annually across 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 (United States Census Bureau International Data Base statistics). 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. Under these circumstances, in some nations, the mortality rate of cervical cancer is not unlike that for incidence of cervical cancer (Journal of American Medical Association, 285:3107; Annals of Oncology, 16:489). In other words, the mortality rate for those with cervical cancer may approach 100% in some places.

Virtually all-cervical cancer is 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 are increasing in incidence (Canadian Medical Association Journal, 164:1151) but often goes undetected by Pap Tests. The missing of adenocarcinomas is largely due to problems in collecting and interpreting the correct cervical cells (Cancer [Cancer Cytopathology], 99:324 and 102:280).

Traditional Testing for Cervical Cancer

Pap Tests

The most common means of screening for cervical cancer is the Pap Test, or papanicolaou smear cytology, 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, a technician trained in the microscopic examination and identification of cellular abnormalities of the cervix, 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, a physician specialized in assessing cervical cells, verifies the interpretation. A second generation Pap Test, known as a "Liquid Pap Test", involves as special procedures for placing cells onto a microscopic slide in a manner that is intended to allow for more clear-cut scrutiny by cytotechnologists and cytopathologists.

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. Cancerous and precancerous lesions may then be removed with a cauterizing device or scalpel, and in some cases women may have to 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 2-7% of cases, or maybe even more cases (Cancer [Cervical Cytopathology], 72:3002). 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, the overwhelming majority of women with ASC-US who then experience these costly follow-up procedures to ascertain their heath conditions, do not have either precancerous, high-grade cervical dysplasias or cervical cancer (Cancer [Cervical Cytopathology], 72:3002; Medscape Medical News, November 8, 2004 - http://www.medscape.com/viewarticle/493298).

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 (American Journal of Obstetrics and Gynecology, 175-1110).

- false positive results — Distinguishing between cervical cancer or pre-cancerous states and benign conditions mimicking them can be difficult via Pap Tests. (Singapore Medical Journal, 42:351).

- inability to detect adenocarcinomas — Pap Tests appear deficient for detecting the presence of the more virulent adenocarcinoma (Cancer [Cervical Cytopathology], 102:282).

- invasive procedure — Pap Tests require healthcare professionals to extract cells from the cervix by inserting a collecting 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 the microscopic examination of chemically stained cells, 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 DNA from the cancer-causing ones. The only HPV Test approved by the United States Food and Drug Administration (FDA) is the HC2 High-Risk HPV DNA Test, manufactured by Digene Corporation of Gaithersburg, Maryland. 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 presence in all forms as opposed to just the HPV DNA associated with cervical cancer and/or associated pre-cancerous lesions. In fact, the FDA-approved HC2 High-Risk HPV DNA Test yields a positive predictive value as low as 19% for ascertaining precancerous lesions or cervical cancer (Acta Cytologica, 49:120).

• 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 (American Journal of Obstetrics and Gynecology, 177:930). Following a positive test result, colposcopy and biopsies are required, thus further elevating diagnostic costs (Journal of the American Medical Association, 287:2382).

Our Planned Cervical Cancer Test

We are developing cervical cancer tests that will detect the presence or absence of specific antibodies 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.

We believe that our tests will efficiently and accurately screen for cervical cancer. When completed, we believe that our tests will differ in several important respects from the Pap Tests and HPV tests that are currently in use:

· Our tests are done with patient's blood from either a finger prick or veinous puncture, a procedure universally considered as safe and minimally invasive). In contrast, the Pap and HPV tests require cervical cells harvested by inserting a collecting device into a woman's cervix.

· Our tests will be done in a laboratory by a technician using standard, readily available laboratory equipment, or by a doctor or other healthcare provider at the point-of-care as a self-contained, easy-to-use test. Virtually any trained laboratory technician can do our tests. By contrast, Pap Test specimens must be examined under a microscope by a

specially-trained cytotechnologist to assess the presence of cancerous or pre-cancerous cells. The HPV tests now available require dedicated, expensive laboratory equipment and sophisticated analytical computer software for interpreting results.

- Our tests will detect antibodies only if a woman has cervical cancer or those pre-cancerous conditions that typically lead to cervical cancer. In preliminary trials that used one version of our test to analyze blood from patients already diagnosed with cervical cancer or pre-cancerous lesions, our test was able to detect cervical cancer or pre-cancerous conditions when such conditions existed, but otherwise ruled out cervical disease when it did not exist.

- Pap tests results may be limited by inefficiencies in sampling cervical cells and the subjective nature of cytology. Pap tests frequently fail to detect cervical cancer or pre-cancerous conditions when actually present (Cancer [Cervical Cytopathology], 72:3002) and otherwise do not permit the differentiation of cancerous or pre-cancerous states from benign conditions mimicking them (American Journal of Clinical Pathology, 94:754). Woman with abnormal Pap tests must often experience a colposcopy (a visual examination of the cervix by means of a special microscope) and a biopsy. This triage is quite inefficient, as evidenced by colposcopy with biopsy not revealing cervical cancer or precursor lesions most of the time (Cancer [Cervical Cytopathology], 72:3002; Medscape Medical News, November 8, 2004 - http://www.medscape.com/viewarticle/493298).

· The human papillomavirus, or HPV, causes virtually all cervical cancers. There are more than 100 types of HPV, but the scientific community considers only 7 to 15 of these responsible for this disease. Gene- or DNA-based HPV tests actually detect HPV infection, but infection and cervical cancer are not the same In fact, cervical HPV infections clear or become undetectable for 90% of afflicted women within two years and only a small proportion individuals experience a persistent HPV infection and subsequently cervical cancer (CDC**,** National Center for HIV, STD and TB Prevention**,** Division of Sexually Transmitted Diseases, STD Prevention, Genital HPV Infection, http://www.cdc.gov/std/HPV/STDFact-HPV.htm).

Our tests involve the analysis of a small amount of blood taken from the patient. The collection of small volumes of blood is accepted virtually everywhere as being of "minimal risk". Importantly, 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, our tests logically have inherently broad acceptability and/or desirability. Our tests involve a few readily done 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 results will be available in 10 to 15 minutes.

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 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 plan to conduct validation studies on a refined version of our cervical cancer test in the next few months. Allogen Laboratories, a wholly owned subsidiary of the Cleveland Clinic Foundation, has agreed to conduct these studies for us. Although it is possible that these later studies may not support the results of the initial validation studies, preliminary indications have been positive. Allogen Laboratories will also assist us in developing 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.

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 to be 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 determination by the FDA of controls needed to ensure the safety and effectiveness of the device or diagnostic test. Class I devices are devices

which are deemed to be of minimal potential for harm to the user and include items, such as elastic bandages and cholesterol and pregnancy tests. As with the majority of diagnostic products, we anticipate that our planned cervical cancer tests will be classified as Class II or Class III devices. A medical device is classified as Class II if general controls alone are insufficient to assure safety and effectiveness, but methods are available to provide assurance. Class III devices are those for which insufficient information exists in to order to assure safety and effectiveness from other controls. Categorization is predicated by an FDA assessment of the complexity and safety of doing the test as well as on intended use. With regard to intended use, a test used in conjunction with other laboratory or clinical methods to monitor for cancer may be given Class II status. The same test used alone or solely to diagnose or screen for cancer might be classified as Class III. For FDA purposes, our planned cervical cancer tests will be used in consort with other clinical methods like Pap smear cytology. Furthermore, our planned cervical cancer tests are of lesser complexity, either to be performed as an Enzyme-Linked Immunosorbent Assay (ELISA) in the laboratory, a common or routine procedure, or as a rapid immunotest, with a processing complexity requiring almost no training and/or expertise to successfully perform. Hence, anticipation of Class II status is not inappropriate.

For our planned cervical cancer tests, we are required to submit to the FDA either a premarket approval (PMA) or a premarket notification (510(k)) application for