Pharma-Bio Serv, Inc.
Form 10-K
January 31, 2011

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

FORM 10-K

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

For the fiscal year ended October 31, 2010

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

For the transition period from _____ to _____

Commission File No. 000-50956

PHARMA-BIO SERV, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	20-0653570 (IRS Employer Identification No.)
Pharma-Bio Serv Building, #6 Road 696 Dorado, Puerto Rico (Address of Principal Executive Offices)	00646 (Zip Code)

787-278-2709
(Registrant'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, par value $0.0001 per share

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting companyx

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

The approximate aggregate market value of common stock held by non-affiliates of the registrant, based on the closing price for the registrant's common stock on April 30, 2010 (the last business day of the second quarter of the registrant's current fiscal year), was $3,140,152.10.

The number of shares of the registrant's common stock outstanding as of January 27, 2011 was 20,751,215.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement relative to the 2011 Annual Meeting of Stockholders are incorporated by reference in Part III hereof.

PHARMA-BIO SERV, INC.
FORM 10-K
FOR THE YEAR ENDED OCTOBER 31, 2010

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PART I

ITEM 1. BUSINESS.

GENERAL

Pharma-Bio Serv, Inc. is a Delaware corporation, organized in 2004 under the name Lawrence Consulting Group, Inc. In February 2006, our corporate name was changed to Pharma-Bio Serv, Inc.

On January 25, 2006, pursuant to an agreement and plan of merger among us, Plaza Acquisition Corp., Pharma-Bio Serv PR, Inc. (then known as Plaza Consulting Group, Inc. and referred to as "Pharma-PR"), and the then sole stockholder of Pharma-PR, Plaza Acquisition Corp. was merged into Pharma-PR, with the result that Pharma-PR became our wholly-owned subsidiary and our sole business became the business of Pharma-PR.

Pharma-PR business was established as a sole proprietorship in 1993 and incorporated in 1997 to offer compliance consulting services to the pharmaceutical industry. The business operations provide services to the pharmaceutical, biotechnology, medical device and chemical manufacturing companies principally in Puerto Rico, the United States and Europe.

Our executive offices are located at Pharma-Bio Serv Building, #6 Road 696, Dorado, Puerto Rico 00646. Our telephone number is (787) 278-2709.

Our website is www.pharmabioserv.com. Information on our website or any other website is not part of this Annual Report on Form 10-K.

References to "we," "us," "our" and similar words in this Annual Report on Form 10-K refer to Pharma-Bio Serv, Inc. and its subsidiaries.

OVERVIEW

We are a compliance and technology transfer services consulting firm with a laboratory testing facility with headquarters in Puerto Rico, servicing the Puerto Rico, United States and Europe markets. The compliance consulting service sector in those markets consists of local compliance and validation consulting firms, United States dedicated validation and compliance consulting firms and large publicly traded and private domestic and foreign engineering and consulting firms. We provide a broad range of compliance related consulting services. We also provide microbiological testing services and chemical testing services through our laboratory testing facility ("Lab") in Puerto Rico. We also provide information technology consulting services and technical trainings/seminars, which services are not currently significant to our operating results. We market our services to pharmaceutical, chemical, biotechnology and medical devices, and allied products companies in Puerto Rico, the United States and Europe. Our team includes more than 135 experienced engineering and life science professionals, and includes former quality assurance managers or directors, and experienced and trained professionals with bachelors, masters and doctorate degrees in health sciences and engineering.

We have a well-established and consistent relationship with the major pharmaceutical, biotechnology, medical device and chemical manufacturing companies in Puerto Rico and the United States, which provides us access to affiliated companies in other markets. We seek opportunities in markets that could yield profitable margins using our professional consulting force and also provide new services such as those performed by our new microbiological testing laboratory facility, our information technology service division, Integratek, and our technical training division, Pharma Serv Academy.

Integratek provides a variety of information technology services such as web pages and portals development, digital art design, intranets, extranets, software development including database integration, Windows and web applications development, software technical training and learning management systems, technology project management, and compliance consulting services, among others. Our Pharma Serv Academy division, through a network of leading industry professional experts in their field, which include resources of our own, provides technical seminars/training that incorporates the latest regulatory trends and standards as well as other related areas. Although these services are not currently significant to our operating results, our goal is to broaden the portfolio of services that we can provide to our customer base and also target other potential customers in other industries.

We believe the most significant factors to achieving future business growth includes our ability to: (i) continue to provide quality value-added compliance services to our clients; (ii) recruit and retain highly educated and experienced professionals; (iii) further expand our products and services to address the expanding needs of our clients; and (iv) expand our market presence in the United States, Europe and possibly other emerging pharmaceutical markets in order to respond to the international compliance needs of our clients. Since our business is conducted mainly in Puerto Rico, our business is affected to the extent that Puerto Rico's current economic downturn affects the decision of our clients and potential clients to establish operations in Puerto Rico or to continue or expand their existing operations.

Our revenue is derived from (i) time and materials contracts (representing approximately 85% of total revenues), where the clients are charged for the time, materials and expenses incurred on a particular project or service, (ii) fixed-fee contracts or from "not to exceed" contracts (approximately 8% of total revenues), which are generally short-term contracts, in which the value of the contract cannot exceed a stated amount, and (iii) laboratory testing (representing approximately 7% of total revenues) which generally is completed and certified within days of sample receipt. For time and materials contracts, our revenue is principally a function of the number of resources and the number of hours billed per professional. To the extent that our revenue is based on fixed-fee or "not to exceed" contracts, our ability to operate profitably is dependent upon our ability to estimate accurately the costs that we will incur on a project and to manage and monitor the project. If we underestimate our costs on any contract, we could sustain a loss on the contract or its profitability might be reduced.

The principal components for our consulting costs of services are resource compensation (salaries and wages, independent contractors' fees, taxes and benefits) and expenses relating to the performance of the services. In order to ensure that our pricing is competitive yet minimize the impact in our margins, we manage increasing labor costs by (i) selecting resources according to our cost for specific projects, (ii) negotiating, where applicable, rates with the resource, (iii) subcontracting labor and (iv) negotiating and passing rate increases to our customers, as applicable. Although this strategy has been successful in the past, we cannot give any assurance that such strategy will continue to be successful. As for our testing laboratory operation, the major costs of services components are salaries and wages, occupancy and depreciation expenses, plus consumable goods usage.

We have established quality systems for our employees which include:

- Training Programs - including a Current Good Manufacturing Practices exam prior to recruitment and periodic refreshers;

- Recruitment Full Training Program - including employee manual, dress code, time sheets and good project management and control procedures, job descriptions, and firm operating and administration procedures;

- Safety Program - including OSHA, Environmental Health and Safety; and

- Code of Ethics and Business Conduct - a code of ethics and business conduct is used and enforced as one of the most significant company controls on personal behavior.

In addition, we have implemented procedures to respond to client complaints and customer satisfaction survey procedures. As part of our employee performance appraisal annual process, our clients receive an evaluation form for employee project performance feedback, including compliance with our code of ethics.

BUSINESS STRATEGY AND OBJECTIVES

We are actively pursuing new markets as part of our growth strategy. We have a well-established and consistent relationship with the major pharmaceutical, biotechnology, medical device and chemical manufacturing companies in

Puerto Rico and the United States which provides us access to affiliated companies in other markets. We seek opportunities in markets that could yield profitable margins using our professional consulting force and also provide new services such as those performed by our microbiological testing laboratory facility and our acquired information technology service firm.

Our business strategy is based on a commitment to provide premium quality and professional consulting services and reliable customer service to our customer base. Our business strategy and objectives are as follow:

- Continue growth in consulting services in each technical service, quality assurance, regulatory compliance, technology transfer, validation, engineering, laboratory testing and manufacturing departments by achieving greater market penetration from our marketing and sales efforts;

- Continue to enhance our technical consulting services through internal growth and acquisitions that provide solutions to our customers' needs;

- Motivate our professionals and support staff by implementing a compensation program which includes both individual performance and overall company performance as elements of compensation;

- Create a pleasant corporate culture and emphasize operational quality safety and timely service;

- Continue to maintain our reputation as a trustworthy and highly ethical partner; and

- Efficiently manage our operating and financial costs and expenses.

2006 U.S. Validation Compliance Service Business Acquisition

In January 2006, we acquired a validation compliance service business which serves mainly the United States East Coast market. We host our U.S. market expansion plans from this organization.

2007 Entrance to Ireland Market

In September 2007, we entered into the Ireland market through the formation of an 80%-owned subsidiary. Currently, we provide the Ireland market the same services we are currently providing in the Puerto Rico and United States markets.

2008 Integratek Acquisition

On December 2008, we acquired through one of our subsidiaries the operations and assets of Integratek Corp. ("Integratek"), an information technology services and consulting firm based in Puerto Rico. With this acquisition we broaden the portfolio of services to our customer base and also target other potential customers in other industries.

2009 Laboratory Testing Facility

Our laboratory testing facility ("Lab") located in Puerto Rico, with an investment of $1.5 million for microbiology, chemical and environmental testing, commenced operations in early fiscal 2009. The Lab incorporates the latest technology and test methodologies meeting pharmacopoeia industry standards and regulations. It offers testing and related services to our core industries already serviced as well as the cosmetic and food industries.

2010 Minority Controlled Company Certification

In line with the strategy to penetrate the United States market, on September 1, 2010 we obtained the renewal of the certification as a "minority-controlled company" as defined by the National Minority Supplier Development Council and Growth Initiative ("NMSDC"). The certification allows us to participate in corporate diversity programs available from various potential customers in the United States and Puerto Rico. The certification is subject to renewal on

September 1, 2011.

TECHNICAL CONSULTING SERVICES

We have established a reputation as a premier technical consulting services firm to the pharmaceutical, biotechnology, medical device and chemical manufacturing industries in Puerto Rico. These services include regulatory compliance, validation, technology transfer, engineering, project management and process support. We have approximately 25 clients that are among the largest pharmaceutical, chemical manufacturing, medical device and biotechnology companies in Puerto Rico. We are actively participating in exhibitions, conferences, conventions and seminars as either exhibitors, sponsors or conference speakers.

MARKETING

We conduct our marketing activities in Puerto Rico as well as the United States and other marketplaces. We actively utilize our project managers and leaders who are currently managing consulting service contracts at various client locations to also market consulting and laboratory testing services to their existing and past client relationships. Our senior management is also actively involved in the marketing process, especially in marketing to major accounts. Our senior management and staff also concentrate on developing new business opportunities and focus on the larger customer accounts (by number of professionals or dollar volume) and responding to prospective customers' requests for proposals.

PRINCIPAL CUSTOMERS

We provide a substantial portion of our services to three customers, each of whom accounted for 10% or more of our revenues in the years ended October 31, 2010 and 2009. During the years ended October 31, 2010 and 2009, these customers accounted for, in the aggregate, 45% and 48% of total revenue, respectively. In spite of the fact that just a few customers represent a significant source of revenue, our functions are not a continuous process, accordingly, the client base for which our services are typically rendered, on a project-by-project basis, changes regularly. Therefore, in any given year a small number of customers could represent a significant source of our revenue for that year. The loss of or significant reduction in the scope of work performed for any major customer or our inability to replace customers upon completion of contracts could adversely affect our revenue and impair our ability to operate profitably.

COMPETITION

We are engaged in a highly competitive and fragmented industry. Some of our competitors are, on an overall basis, larger than we are or are subsidiaries of larger companies, and therefore may possess greater resources than we do. Furthermore, because the technical professional aspects of our consulting business do not usually require large amounts of capital, there is relative ease of market entry for a new entrant possessing acceptable professional qualifications. Accordingly, we compete with regional, national, and international firms. Within the Puerto Rico, United States and Ireland markets, certain competitors, including local competitors, may possess greater resources than we do as well as better access to clients and potential clients.

Competition for validation and consulting services used to be primarily based on reputation, track record, experience, and quality of service. However, given the economic recession and our clients' strategies to reduce costs, price of service has become a major factor in sourcing our services. We believe that we enjoy significant competitive advantages over other consulting service firms because of our historical market share within Puerto Rico (18 years), brand name, reputation and track record with many of the major pharmaceutical, biotechnology, medical device and chemical manufacturing companies which have presence in the markets we are pursuing.

The market of qualified and experienced professionals that are capable of providing technical consulting services is very competitive and consists primarily of our competitors as well as companies in the pharmaceutical, chemical, biotechnology and medical device industries who are our clients and potential clients. In seeking qualified personnel we market our name recognition in the Puerto Rico market, our reputation with our client, salary and benefit package, company stock options and a low turnover of qualified employees.

RAW MATERIALS

We require the use of various raw materials, including culture media, DNA reagents, LAL reagents and biological indicators, in our testing laboratory facility. We purchase these raw materials from various suppliers. At times, we concentrate orders among a few suppliers in order to strengthen our supplier relationships and receive quantity discounts. Raw materials are generally available from multiple suppliers at competitive prices, and amounts kept in stock are not significant.

ENVIRONMENTAL REGULATIONS

Activities in our microbiological testing laboratory facility are regulated under Puerto Rico and U.S. federal laws designed to protect workers and the environment. Some of these laws include the Occupational Safety and Health Act and the Resource Conservation and Recovery Act. These laws apply to the use, handling and disposal of various biological and chemical substances used in our processes. We believe we are in material compliance with these laws and that continued compliance will not have a materially adverse effect on our business. No specific accounting for environmental compliance has been maintained or projected by us at this time.

INTELLECTUAL PROPERTY RIGHTS

We have no proprietary software or products. We rely on non-disclosure agreements with our employees to protect the proprietary software and other proprietary information of our clients. Any unauthorized use or disclosure of this information could harm our business.

EMPLOYEES

We currently employ 95 full time employees. None of our employees are represented by a labor union, and we consider our employee relations to be good.

EXECUTIVE OFFICERS

The following table sets forth certain information with respect to our executive officers.

Name	Age	Position
Elizabeth Plaza	47	President, Chairman of the Board and Director
Nélida Plaza	43	President of Puerto Rico Operations and Secretary
Pedro J. Lasanta	51	Chief Financial Officer and Vice President - Finance and Administration

Elizabeth Plaza has been the president and sole director of Pharma-PR since 1997, when the Company was incorporated after operating as a sole proprietorship since 1993, and she has been our president and chief executive officer since January 25, 2006. Ms. Plaza holds a B.S. in Pharmaceutical Sciences, magna cum laude, from the School of Pharmacy of the University of Puerto Rico. She was a 40 under 40 Caribbean Business Award recipient in 2002, the 2003 recipient of Ernst & Young's Entrepreneur of the Year Award in Health Science, one of the 2003 recipients of the Puerto Rico Powerful Business Women Award, elected as Puerto Rico Manufacturers Association 2004 (Metropolitan-West Region) Executive of the Year, Puerto Rico 2008 Executive of the Year, and is member of the Board for the Puerto Rico Commerce & Export Company.

Nélida Plaza has been the vice president of operations of Pharma-PR since January 2004, our secretary since January 25, 2006, and our President of Puerto Rico Operations since December 31, 2009, in charge of Scienza Labs, Pharma Academy and Pharma-PR. Ms. Plaza served as our vice president from January 25, 2006 to December 31, 2009. In July 2000, Ms. Plaza joined Pharma-PR as a project management consultant. In the past, Ms. Plaza was a unit operations leader and safety manager at E.I. DuPont De Nemours where she was involved with the development, support and audit of environmental, safety and occupational health programs. Ms. Plaza holds a M.S. in Environmental Management from the University of Houston in Clear Lake and a B.S. in Chemical Engineering from the University of Puerto Rico. Nélida Plaza was recognized by Casiano Communications as one of the 40 under 40 distinguished executives in Puerto Rico.

Pedro J. Lasanta has been our chief financial officer and vice president - finance and administration since November 2007. From 2006 until October 2007, Mr. Lasanta was in private practice as an accountant, tax and business counselor. From 1999 until 2006, Mr. Lasanta was the Chief Financial Officer for Pearle Vision Center PR, Inc. In the past, Mr. Lasanta was also an audit manager for Ernst & Young, formerly Arthur Young & Company. He is a cum laude graduate in business administration (accounting) from the University of Puerto Rico. Mr. Lasanta is a certified public accountant.

Elizabeth Plaza and Nélida Plaza are sisters.

ITEM 1A. RISK FACTORS.

This Annual Report on Form 10-K includes "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, including, in particular, certain statements about our plans, strategies and prospects. Although we believe that our plans, intentions and expectations reflected in or suggested by such forward-looking statements are reasonable, we cannot assure you that such plans, intentions or expectations will be achieved. Important factors that could cause our actual results to differ materially from our forward-looking statements include those set forth in this Risk Factors section.

If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations, cash flows or prospects could be materially adversely affected.

Risks That Relate to our Business

Because our business is concentrated in the pharmaceutical industry in Puerto Rico, and to a lesser extent in the United States and other countries, any changes in that industry or in those markets could impair our ability to generate revenue and realize a profit.

Since most of our business is performed in Puerto Rico, and to a lesser extent in the United States and other countries, for pharmaceutical, biotechnology, medical device and chemical manufacturing companies, our ability to generate

revenue and realize a profit could be impaired by factors impacting those markets. For example, changes in tax laws or regulatory, political or economic conditions, which discourage businesses from operating in the markets we serve, which affect the need for services such as those provided by us, could impair our ability to generate revenue and realize a profit.

Puerto Rico government enacted ACT 154 of October 22, 2010 which may adversely affect the willingness of our customers to do business in Puerto Rico and consequently adversely affect our business.

On October 22, 2010, Act No. 154 was enacted by the Puerto Rico government. The Act primarily affects the industry we serve and consequently our customer base. Act 154 extends the circumstances under which a nonresident alien individual or a non resident corporation or partnership can be treated as doing business in Puerto Rico and is deriving income from sources within Puerto Rico for purposes of income tax. It also provides for the imposition of a temporary excise tax on some acquisitions by non-resident individuals, corporations or partnerships, of products total or partially manufactured or produced in Puerto Rico and of related services to said products of affiliated entities with the buyer. It basically adopts a modified income sourcing rule and a temporary excise tax that will be enforced for a period of six (6) years and will decrease gradually during this time.

The impact of the Act, if any, over the industry and its willingness to do business in Puerto Rico is unknown. Consequently, our ability to generate revenue in Puerto Rico may be impaired.

Changes in tax benefits may affect the willingness of companies to continue or expand their operations in Puerto Rico.

Until 1996, the Internal Revenue Code provided certain tax benefits to pharmaceutical companies operating in Puerto Rico by enabling their Puerto Rico operations to operate free from federal income taxes. Partly as a result of the tax benefits, numerous pharmaceutical companies established facilities in Puerto Rico. In 1996, this tax benefit was eliminated, although companies that had facilities in Puerto Rico could continue to receive these benefits for ten years, at which time the benefits were set to expire. In order to promote business activities in Puerto Rico, in May 2008 the Puerto Rico government enacted a tax incentive law (“Act 73”). Act 73 provides tax exemption from various taxes, including income tax, and investment credits for activities similar to those of our customers and our company. The change in the tax laws may affect favorably or unfavorably the willingness of pharmaceutical companies to continue or to expand their Puerto Rico operations. To the extent that pharmaceutical companies choose to develop and manufacture products outside of Puerto Rico, our ability to generate new business may be adversely impaired.

Puerto Rico’s economy, including its governmental financial crisis, may affect the willingness of businesses to commence or expand operations in Puerto Rico.

As a result of Puerto Rico’s governmental financial crisis, businesses may be reluctant to establish or expand their operations in Puerto Rico. Further, since Puerto Rico’s economy is petroleum-based, the fluctuating price of oil, combined with Puerto Rico’s high level of debt, may make Puerto Rico a less attractive place to expand existing operations or commence new business activities. To the extent that companies in the pharmaceutical and related industries decide not to commence new operations or not to expand their existing operations in Puerto Rico, the market for our services may decline.

Other factors, including economic factors, may affect the decision of businesses to continue or expand their operations in Puerto Rico.

Companies in the pharmaceutical and related industries for which we perform service are subject to economic pressures, which affect their global operations and which may influence the decision to reduce or increase the scope of their operations in Puerto Rico. These companies consider a wide range of factors in making such a decision, and may be influenced by a need to consolidate operations, to reduce expenses, to increase their business in geographical regions where there are large customer bases, tax, regulatory and political considerations and many other factors. We cannot assure you that our customers and potential customers will not make extensive reductions or terminate their operations in Puerto Rico entirely, which could significantly impair our ability to generate revenue.

Because our business is dependent upon a small number of clients, the loss of a major client could impair our ability to operate profitably.

Our business has been dependent upon a small number of clients. During the years ended October 31, 2010 and 2009, a very small number of clients accounted for a disproportionately large percentage of our revenue. In the years ended October 31, 2010 and 2009, three customers accounted for, in aggregate, approximately 45% and 48% of total revenue, respectively. The loss of or significant reduction in the scope of work performed for any major customer could impair our ability to operate profitably. We cannot assure you that we will not sustain significant decreases in revenue from our major customers or that we will be able to replace any major customers or the resulting decline in revenue.

Customer procurement and sourcing practices intended to reduce costs could have an adverse affect on our margins and profitability.

In an effort to reduce their costs, many of our customers are establishing or extending the scope of their procurement departments to include consulting and project services such as ours. As a result, we have less interaction with the end user of our services (typically labs or production units) when bidding on a project, which we believe decreases the focus on the quality of service provided and increases the emphasis on cost of the service. This may cause us to lower the price of our bids, which would reduce the margins in a given project. Also, some customers have established vendor management programs with third-parties (some of whom are also our competitors). Because these vendor management programs may receive a percentage of our fees, without a corresponding increase in the fee itself, our margins would decline. In addition, where a vendor management program is a competitor for a particular service we provide, we may have difficulty securing that particular project, which would adversely impact revenue.

Since our business is dependent upon the development and enhancement of patented pharmaceutical products or processes by our clients, the failure of our clients to obtain and maintain patents could impair our ability to operate profitably.

Companies in the pharmaceutical industry are highly dependent on their ability to obtain and maintain patents for their products or processes. We are aware of some pharmaceutical companies with operations in Puerto Rico whose patent rights may expire in the near future. The inability to obtain new patents and the expiration of active patents may reduce the need for our services and thereby impair our ability to operate profitably.

We may be unable to pass on increased labor costs to our clients.

The principal components of our cost of revenues are employee compensation (salaries, wages, taxes and benefits) and expenses relating to the performance of the services we provide. We face increasing labor costs which we seek to pass on to our customers through increases in our rates. To remain competitive, we may not be able to pass these increased costs on to our clients, and, to the extent that we are not able to pass these increased costs on to our clients, our gross margin will be reduced.

Consolidation in the pharmaceutical industry may have a harmful effect on our business.

In recent years, the pharmaceutical industry has undergone consolidation, and may in the future undergo further substantial consolidation which may reduce the number of our existing and potential customers. The consolidation in the pharmaceutical industry may have a harmful effect on our business and or ability to maintain and replace customers.

Because the pharmaceutical industry is subject to government regulations, changes in government regulations relating to this industry may affect the need for our services.

Because government regulations affect all aspects of the pharmaceutical, biotechnology, medical device and chemical manufacturing industries, including regulations relating to the testing and manufacturing of pharmaceutical products and the disposal of materials which are or may be considered toxic, any change in government regulations could have a profound effect upon not only these companies but companies, such as ours, that provide services to these industries. If we are not able to adapt and provide necessary services to meet the requirements of these companies in response to changes in government regulations, our ability to generate business may be impaired.

If we are unable to protect our clients' intellectual property, our ability to generate business will be impaired.

Our services either require us to develop intellectual property for clients or provide our personnel with access to our clients' intellectual property. Because of the highly competitive nature of the pharmaceutical, biotechnology, medical device and chemical manufacturing industries and the sensitivity of our clients' intellectual property rights, our ability to generate business would be impaired if we fail to protect those rights. Although all of our employees and contractors are required to sign non-disclosure agreements, any disclosure of a client's intellectual property by an employee or contractor may subject us to litigation and may impair our ability to generate business either from the affected client or other potential clients. In addition, we are required to enter into confidentiality agreements and our failure to protect the confidential information of our clients may impair our business relationship.

We may be subject to liability if our services or solutions for our clients infringe upon the intellectual property rights of others.

It is possible that in performing services for our clients, we may inadvertently infringe upon the intellectual property rights of others. In such event, the owner of the intellectual property may commence litigation seeking damages and an injunction against both us and our client, and the client may bring a claim against us. Any infringement litigation would be costly, regardless of whether we ultimately prevail. Even if we prevail, we will incur significant expenses and our reputation would be hurt, which would affect our ability to generate business and the terms on which we would be engaged, if at all.