

Averion International Corp.
Form SB-2
June 15, 2007
As filed with the Securities and Exchange Commission on June 15, 2007

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM SB-2

**REGISTRATION STATEMENT UNDER THE
SECURITIES ACT OF 1933**

(Amendment No.)

AVERION INTERNATIONAL CORP.

(Name of small business issuer in its charter)

Delaware
(State or jurisdiction of
incorporation or organization)

8731
(Primary Standard Industrial
Classification Code Number)

20-4354185
(I.R.S. Employer
Identification No.)

225 Turnpike Road

Southborough, Massachusetts 01772

(508) 597-6000

(Address and telephone number of principal executive offices and principal place of business)

Philip T. Lavin

Chief Executive Officer

Averion International Corp.

225 Turnpike Road

Southborough, Massachusetts 01772

(508) 597-6000

(Name, address and telephone number of agent for service)

Copy to:

Adam C. Lenain, Esq.

Foley & Lardner LLP

402 W. Broadway, Suite 2100

San Diego, CA 92101

(619) 234-6655

Approximate Date of Commencement of Proposed Sale to the Public: From time to time after the effective date of this registration statement as determined by the selling stockholders.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. X

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

CALCULATION OF REGISTRATION FEE

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Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per share(1)	Proposed maximum aggregate offering price(1)	Amount of registration fee
Shares of common stock, par value \$0.001	30,623,995	\$ 0.123	\$ 3,766,751.39	\$ 115.64

(1) Estimated pursuant to Rule 457(c) solely for the purpose of calculating the amount of the registration fee, using the average of the bid and asked prices of our common stock as reported on the Over-the-Counter Bulletin Board on June 12, 2007.

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. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities nor does it solicit an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION DATED June 15, 2007

AVERION INTERNATIONAL CORP.

30,623,995 Shares of Common Stock

This prospectus relates solely to the offer and sale by the selling stockholders identified in this prospectus of up to 30,623,995 shares of our common stock held by the selling stockholders. Of these shares, 27,333,329 are currently issued and outstanding and 3,290,666 are issuable upon exercise of warrants held by selling stockholders. The selling stockholders are offering all of the shares to be sold in the offering, but they are not required to sell any of these shares. We will not receive any of the proceeds from the sale of our common stock by the selling stockholders, although we will receive proceeds from the exercise of warrants to the extent they are exercised for cash. We will bear all expenses (other than selling commissions and fees and expenses of counsel or other advisors to the selling stockholders) relating to this offering.

The selling stockholders may sell these shares from time to time in various types of transactions, including in the principal market on which the stock is traded or listed or in privately negotiated transactions. If any broker-dealers are used by the selling stockholders, any commissions paid to broker-dealers and, if broker-dealers purchase any shares of our common stock as principals, any profits received by such brokers-dealers on the resale of shares of our common stock, may be deemed to be underwriting discounts or commissions under the Securities Act of 1933, as amended, or the Securities Act. In addition, any profits realized by the selling stockholders may be deemed to be underwriting commissions if any such selling stockholder is deemed an underwriter as defined in the Securities Act.

Our common stock is traded on the Over-the-Counter Bulletin Board under the symbol AVRO.OB. The average of the high and low bid price per share of our common stock as reported by the Over-the-Counter Bulletin Board on June 12, 2007, was \$0.123.

Investing in our common stock involves significant risks. See Risk Factors beginning on page 6 to read about factors you should consider before buying our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

You should rely only on the information contained in this prospectus. Neither we nor the selling stockholders have authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

Prospectus dated , 2007

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PROSPECTUS SUMMARY

You should read the following summary together with the more detailed information regarding us, the sale of our common stock in this offering by the selling stockholders, our consolidated financial statements and the notes to those consolidated financial statements that appear elsewhere in this prospectus.

Our Business

We are a contract research organization, or a CRO, focused on providing our clients with services and solutions throughout the drug development process. We operate in two business segments: clinical research and staffing services. We serve a variety of clients in the pharmaceutical, biotechnology and medical device industries.

Our clinical research operation assists our clients with strategic and regulatory planning, clinical trial design and protocol development, investigator qualification and recruitment, site identification and management, clinical trial implementation and management, data management, biometrics and reporting. We have the resources to directly implement or manage Phase I through Phase IV clinical trials and have clinical trial experience across a wide variety of therapeutic areas such as oncology, dermatology, nephrology, critical care, and medical devices. Our staffing services operation assists our clients by providing them the expertise necessary to evaluate, structure, implement and maintain effective quality programs and processes that ensure compliance with the Food and Drug Administration, or FDA, regulations throughout the product development and manufacturing lifecycle.

Company Information

We were originally organized under the name Clinical Trials Assistance Corporation, or Clinical Trials, by the filing of Articles of Incorporation with the Secretary of State of the State of Nevada on April 22, 2002. On June 14, 2004, Clinical Trials acquired IT&E International Corporation and amended its Articles of Incorporation to change the corporate name from Clinical Trials to IT&E International Group. In November 2005, we acquired substantially all the assets of Millennix, Inc., or Millennix, a CRO based in the State of New York that provides comprehensive clinical research services for Phase I through Phase IV clinical trials in oncology (see Note 4 to our Consolidated Financial Statements). On March 2, 2006, with the written consent of holders of the majority of our shares of common stock, we reincorporated into Delaware and filed a Certificate of Incorporation to change our corporate name to IT&E International Group, Inc. On July 31, 2006 we acquired Averion Inc. (see Note 5 to our Consolidated Financial Statements), a CRO. In August 2006, we formed Averion Europe GmbH, our European division, or Averion Europe, which will allow us to assist our clients that wish to run clinical trials and gain access to patients internationally (see Note 7 to our Consolidated Financial Statements). On September 21, 2006, we filed an amendment to our Certificate of Incorporation to change our corporate name to Averion International Corp. Our common stock symbol was changed from ITER.OB to AVRO.OB in conjunction with the name change.

Our corporate headquarters are located at 225 Turnpike Road, Southborough, MA 01772. We also have offices in New York, Pennsylvania, and California, as well as in Germany, the United Kingdom and Austria. Our principal executive offices are located at 225 Turnpike Road, Southborough, MA 01772. Our telephone number is (508) 597-6000. The address of our website is www.averionintl.com. Information contained on our website is not a part of this prospectus.

The Offering

Common stock offered in this offering 30,623,995 shares

Common stock to be outstanding after this offering 529,128,325(1)

Use of proceeds All of the net proceeds from the sale of our common stock covered by this prospectus will be received by the selling stockholders who offer and sell shares of our common stock. We will not receive any proceeds from the sale of our common stock offered by the selling stockholders, although we will receive proceeds from the exercise of warrants held by selling stockholders to the extent they are exercised for cash (2). The proceeds we would receive if all the warrants were exercised for cash would be approximately \$628,280. These proceeds, if any, will be used for general corporate purposes.

OTC Bulletin Board symbol AVRO.OB

(1) Unless the context indicates otherwise, all share and per-share information in this prospectus is based on 498,504,330 shares of our common stock outstanding as of June 8, 2007. Shares of common stock to be outstanding after this offering assumes that all shares registered under this prospectus are sold by the selling stockholders. Unless the context indicates otherwise, all other share and per-share information in this prospectus assumes no exercise of warrants or other rights to acquire our common stock outstanding as of June 8, 2007.

(2) Please note that one of the warrants described in this registration statement, a warrant to purchase 1,366,666 shares of our common stock, contains a cashless exercise provision whereby the holder, at its option, may exercise the warrant by surrender and cancellation of a portion of the shares of common stock issuable upon the exercise of the warrant based on the then current market price of our common stock. If the holder of the warrant elected to exercise the warrant pursuant to this provision, we would not receive any proceeds from the exercise of the warrant but instead would issue fewer shares of our common stock.

Summary Financial Information

In the table below, we provide you with historical summary financial data for the two years ended December 31, 2006 and 2005, derived from our audited consolidated financial statements included elsewhere in this prospectus. We also provide below financial data for, and as of the end of, the three months ended March 31, 2007 and 2006, derived from our unaudited consolidated financial statements included elsewhere in this prospectus. Historical results are not necessarily indicative of the results that may be expected for any future period. When you read this historical summary financial data, it is important that you read along with it the historical consolidated financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

	Year ended December 31,		Three months ended	
	2006	2005	March 31, 2007 (unaudited)	2006 (unaudited)
Statement of Operations Data:				
Net Service Revenue	\$ 25,551,378	\$ 17,798,591	\$ 8,803,675	\$ 4,638,976
Operating Expenses	(32,406,842)	(19,553,978)	(11,187,524)	(5,989,337)
Net Income (loss) applicable to common stockholders	(9,195,190)	(10,974,622)	(1,943,730)	(975,957)
Net Income (loss) per share basic and fully diluted	(0.07)	(0.41)	(0.00)	(0.02)

The table below sets forth a summary of our consolidated balance sheet data as of December 31, 2006, derived from our audited consolidated financial statements included elsewhere in this prospectus. We also provide below financial data for, and as of, the end of the three months ended March 31, 2007, derived from our unaudited consolidated financial statements included elsewhere in this prospectus.

	December 31, 2006	March 31, 2007 (unaudited)
Balance Sheet Data:		
Cash and cash equivalents	\$ 8,097,577	\$ 6,785,475
Working Capital	6,658,148	4,710,268
Total Assets	44,761,588	41,016,373
Total Stockholders' Equity	28,561,902	26,692,576

RISK FACTORS

Investment in our common stock involves a high degree of risk. You should carefully consider the risks described below together with all of the other information included in this prospectus before making an investment decision with respect to our securities. If any of the following risks actually occur, our business, financial condition or results of operations could suffer. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

In addition, the following risk factors may contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, will, may, and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. We wish to caution readers that these forward-looking statements are only predictions and that our business is subject to the risk factors described below.

RISKS RELATED TO OUR BUSINESS

We may not be able to attract, retain or integrate key personnel, which may prevent us from successfully operating our business.

We may not be able to retain our key personnel or attract other qualified personnel in the future. We believe that our continued success will depend to a significant extent upon the efforts and abilities of our senior management team, including Dr. Philip Lavin, our Chief Executive Officer. These individuals possess industry knowledge and have successfully built strong working relationships with our clients. Our failure to retain Dr. Lavin or to attract and retain additional qualified personnel, could adversely affect our operations.

Our success depends on our ability to attract and retain scientific and technical personnel.

Our ability to operate successfully and manage our future growth depends in significant part upon the continued service of key scientific and technical personnel, as well as our ability to attract and retain additional highly qualified personnel in these fields. Competition for this personnel is significant, and we may not be able to attract or retain key employees when necessary, which could limit our operations and growth.

We may bear financial losses because our contracts may be delayed or terminated or reduced in scope for reasons beyond our control.

Our contracts generally may be terminated or reduced in scope either immediately or upon short notice. Clients may terminate or delay their contracts for a variety of reasons, including, but not limited to, the failure of products to satisfy safety requirements, unexpected or undesired clinical results relating to safety, merger or potential merger-related activities, client budget constraints, the client's decision to terminate the development of a particular product or to end a particular study, insufficient patient enrollment in a study, insufficient investigator recruitment, manufacturing problems resulting in shortages of the product, or our failure to perform our obligations under the contract. This risk of loss or delay of contracts potentially has greater effect as we pursue larger outsourcing arrangements with global pharmaceutical companies. Also, over the past several years we have observed that clients may be more willing to delay, cancel or reduce contracts more rapidly than in the past. If this trend continues, it could become more difficult for us to balance our resources with demands for our services and our financial results could be materially and adversely affected.

In addition, companies may proceed with fewer clinical trials or conduct them without assistance of CROs as a result of changing priorities or other internal considerations. These factors may cause such companies to cancel contracts with CROs.

In general, our contracts entitle us to receive the costs of winding down a terminated project, as well as all fees earned by us up to the time of termination. The loss, reduction in scope or delay of a significant contract or the loss or delay of multiple contracts could materially and adversely affect our business, results of operations

and financial condition. To counter this potential downside, we maintain an aggressive posture in soliciting new opportunities and in generating bids.

We may pursue strategic acquisitions or investment in new markets and may encounter risks associated with these activities that could harm our business and operating results.

We may pursue acquisitions of, or investments in, businesses and assets in new markets that we believe will complement or expand our existing business or our client base. Our acquisition strategy involves a number of risks, including:

- difficulty in successfully integrating acquired operations, personnel, technology, clients, partner relationships, services and businesses with our operations;
- loss of key employees of acquired operations or inability to hire key employees necessary for our expansion;
- diversion of our capital and management attention away from other business issues;
- an increase in our expenses and working capital requirements; and
- other financial risks, such as potential liabilities of the businesses we acquire.

Our growth may be limited and our competitive position may be harmed if we are unable to identify, finance and complete future acquisitions. There can be no assurance that we will be able to identify, negotiate or finance future acquisitions successfully. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities, and amortization expense related to intangible assets, a decrease in profitability, or future losses. The incurrence of debt in connection with any future acquisitions could restrict our ability to obtain working capital or other financing necessary to operate our business. Our future acquisitions or investments may not be successful, and if we fail to realize the anticipated benefits of these acquisitions or investments, our business and operating results could be harmed.

We are significantly influenced by our directors and executive officers.

Our directors and officers beneficially own a majority of our outstanding common stock. Mr. Falk, one of our directors, is the Managing Partner of ComVest, and as such may be deemed to have indirect beneficial ownership of all shares owned by ComVest. Mr. Falk disclaims any beneficial ownership of such shares owned by ComVest. These stockholders, acting together, would be able to exert significant influence on substantially all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or acquisitions and other business transactions.

The failure to successfully integrate any business acquired in a future acquisition could harm our business and operating results.

If we acquire businesses in the future and are unable to integrate successfully these businesses, it could harm our business and operating results. In order to remain competitive or to expand our business, we may find it necessary or desirable to acquire other businesses, products or technologies. We may be unable to identify appropriate acquisition candidates. If we identify an appropriate acquisition candidate, we may not be able to negotiate the terms of the acquisition successfully, to finance the acquisition or to integrate the acquired businesses, products or technologies into our existing business and operations. Further, completing a potential acquisition and integrating an acquired business, including that of Averion Inc., may strain our resources and require significant management time. In addition, we may be required to amortize significant amounts of finite life intangible assets in connection with future acquisitions which would harm our operating results.

We depend on a finite number of clients for our business, and the loss of one of our significant clients could cause revenues to drop quickly and unexpectedly.

We provide services to the pharmaceutical, biotechnology and medical device industries and our revenue is highly dependent on expenditures on the services we provide to clients in these industries. Our operations could be materially and adversely affected if:

- our clients reduce their research and development expenditures or reduce the rate of growth in their research and development expenditures;
- consolidation in the pharmaceutical, biotechnology or medical device industries leads to a smaller client base for us;
- one or more significant studies are terminated as a result of the failure of the product to satisfy safety requirements, unexpected or undesired clinical results, or other reasons; or
- our clients' businesses experience financial problems or are affected by a general economic downturn.

We expect that a relatively small number of clients will continue to represent a significant percentage of our net service revenue. The contracts with our clients generally can be terminated on short notice. The loss of business from any significant client or our failure to continue to obtain new business would have a material and adverse effect on our business and revenues.

We may be responsible for maintaining sensitive patient information, and any unauthorized use or disclosure could result in substantial damage and harm to our reputation.

We collect and utilize data derived from various sources to recruit patients for clinical studies. We may have access to names and addresses of potential patients who may participate in these studies. As a result, we may know what studies are taking place, and who may be participating in these studies. Due to these privacy concerns, we must take steps to ensure patient lists remain confidential. Any unauthorized disclosure or use could result in a claim against us for substantial damages and could harm our reputation.

If we do not keep pace with rapid technological changes, our products and services may become less competitive or obsolete.

The biotechnology, pharmaceutical and medical device industries generally, and clinical research specifically, are subject to increasingly rapid technological changes. Our competitors or others might develop technologies, products or services that are more effective or commercially attractive than our current or future technologies, products or services, or render our technologies, products or services less competitive or obsolete. If competitors introduce superior technologies, products or services and we cannot make enhancements to our technologies, products and services necessary to remain competitive, our competitive position will be harmed. If we are unable to compete successfully, we may lose clients or be unable to attract new clients, which could lead to a decrease in revenue.

Our operating results have fluctuated between quarters and years and may continue to fluctuate in the future, which could affect the price of our common stock.

Our quarterly and annual operating results have varied and will continue to vary in the future as a result of a variety of factors. We incurred net operating losses of \$5,151,235 and \$1,116,294 for the years ended December 31, 2006 and 2005, respectively. We incurred net operating losses of \$1,895,755 and \$1,030,609 for the quarters ended March 31, 2007 and 2006, respectively. Factors that can cause these variations in our operating results include:

- the level of new business authorizations in a particular quarter or year;
- the timing of the initiation, progress, or cancellation of significant projects;

- the mix of services offered in a particular quarter or year;
- the timing of the opening of new offices;
- the costs and the related financial impact of acquisitions;
- the timing of internal expansion;
- the timing and amount of costs associated with integrating acquisitions;
- the amount of effort necessary to integrate operations;
- the timing and amount of startup costs incurred in connection with the introduction of new products, services or subsidiaries; and
- the incurrence of debt and certain costs associated with such debt.

Many of these factors, such as the initiation of new projects between quarters or years, are beyond our control.

A significant portion of our operating costs relate to personnel, which accounted for approximately 81% of our total operating costs in fiscal year 2006, versus 85% of our total operating costs in fiscal year 2005. As a result, the effect on our revenues of the timing of the completion, delay or loss of contracts, or the progress of client projects, could cause our operating results to vary substantially between reporting periods. If our operating results do not match the expectations of securities analysts and investors as a result of these factors, the trading price of our common stock will likely decrease.

Our backlog may not be indicative of future results.

At March 31, 2007, our backlog was approximately \$42.3 million. Backlog represents anticipated net service revenue from uncompleted projects with our clients. We cannot be certain that the backlog we have reported will be indicative of our future results. A number of factors may affect our backlog, including: the ability of clients to reduce or expand the size and duration of the projects (some are performed over several years); the termination or delay of projects; and a change in the scope of work during the course of a project.

Also, if clients delay projects, the projects will remain in backlog, but will not generate net service revenue at the rate originally expected. Accordingly, historical indications of the relationship of backlog to net service revenues may not be indicative of future results.

If we do not adequately protect the confidential information of clients and other third parties in our possession, our business may suffer.

In the course of providing our services to the pharmaceutical, biotechnology and medical device industries, we may have access to proprietary and confidential information belonging to our clients. As a result, we must take steps to protect the confidential information of clients and other parties in our possession. We have entered into confidentiality and non-disclosure agreements with many of our clients, employees, contractors, and other parties with whom we conduct business, in order to limit access to and disclosure of proprietary and confidential information in our possession. Any unauthorized or inappropriate disclosure or use of such information could harm our business and reputation and could result in a claim against us for substantial damages.

If we are unable to attract suitable willing volunteers for the clinical trials of our clients, our results could be materially and adversely affected.

One of the factors on which we compete is the ability to recruit independent investigators who can identify volunteers for the clinical studies we manage on behalf of our clients. These clinical trials rely upon the ready accessibility and willing participation of volunteer subjects. These subjects generally include volunteers from the communities in which the studies are conducted, which to date have provided an adequate pool of potential subjects for research studies. Some of our contracts include specific milestone payments directly tied to the

recruitment of study subjects. The trials we manage and our operating results could be materially and adversely affected if we are unable to attract suitable and willing volunteers on a consistent basis.

Our revenues and earnings are exposed to exchange rate fluctuations as well as international economic, political and other risks.

The percentage of our net service revenues that are derived from contracts denominated in currencies other than U.S. dollars will increase as a result of our expansion into Europe and our stated acquisition strategy. Our financial statements are denominated in U.S. dollars. As a result, factors associated with international operations, including changes in foreign currency exchange rates, could affect our results of operations and financial condition.

We offer many of our services on a worldwide basis and we are therefore subject to risks associated with doing business internationally. We expect that net service revenues from international operations will increase in the future and represent a greater percentage of total net service revenues. As a result, our future results could be negatively affected by a variety of factors, including changes in a specific country's political or economic conditions, potential negative consequences from changes in tax laws, difficulty in staffing and managing widespread operations, and unfavorable labor regulations applicable to our international operations.

If we are unable to develop and market new services successfully in the United States, Europe and internationally, our results could be materially and adversely affected.

An element of our growth strategy is the successful development and marketing of new services that complement or expand our existing business. If we are unable to develop new services and create demand for those newly developed services, we may not be able to implement this element of our growth strategy, and our future business, results of operations and financial condition could be materially and adversely affected. In addition, we are considering expanding our international operations through acquisition or by other means, such as commencing business partnerships or clinical studies in countries where we do not have subsidiaries. The profitability of our international subsidiaries and operations depends, in part, on client acceptance and use of our services. There can be no assurance that our international subsidiaries or operations will be profitable in the future or that any revenue resulting from them will be sufficient to recover the investment in them. If our international operations or subsidiaries do not develop as anticipated, our business, financial condition and results of operations may be materially and adversely affected.

RISKS RELATED TO OUR INDUSTRY

We operate in a market that is highly competitive, and if we are unable to compete successfully, our revenue could decline and we may be unable to gain market share.

The market for clinical research outsourcing is highly competitive. Our future success will depend on our ability to adapt to changing technologies, evolving industry standards, product offerings, evolving demands of the marketplace and to expand our client base through long-term contracts. Some of our competitors have longer operating histories and larger client bases, which means they have more experience in completing clinical trials in order to obtain regulatory approvals. In the staffing services area, we compete against RCM Technologies, Teratec, and Comsys (Venturi Partners). In the clinical research services area, we compete against Quintiles, Covance, Pharmanet Development Group, ICON, Kendle, and Parexel, among others. Our competitors have greater marketing capabilities which have helped them establish stronger name recognition and longer relationships with clients. We may not be able to compete with those companies effectively.

Our competitors may also be better positioned to address technological and market developments or may react more favorably to technological changes. If we fail to gain market share or lose existing market share, our financial condition, operating results and business could be adversely affected and the value of your investment in us could be reduced significantly. We may not have the financial resources, technical expertise, marketing, distribution or support capabilities to compete successfully.

Changes in outsourcing trends in the pharmaceutical and biotechnology industries could materially and adversely affect our operating results and growth rate.

Industry trends and economic factors that affect our clients in the pharmaceutical, biotechnology and medical device industries also affect our business. Our revenues depend greatly on the expenditures made by the pharmaceutical, biotechnology and medical device industries in research and development. The practice of many companies in these industries has been to hire outside organizations like us to conduct clinical research projects. This practice has grown significantly in the last decade, and we have benefited from this trend. However, if this trend were to change and companies in these industries were to reduce the number of research and development projects they outsource, our business could be materially and adversely affected. For example, over the past year, mergers and other factors in the pharmaceutical industry appear to have slowed decision-making by pharmaceutical companies and delayed drug development projects. The continuation of or increase of these trends could have a negative effect on our business.

Additionally, numerous governments and managed care organizations have undertaken efforts to control growing healthcare costs through legislation, regulation and voluntary agreements with medical care providers and pharmaceutical companies. If future regulatory cost containment efforts limit the profits that can be derived on new drugs, our clients might reduce their research and development spending, which could reduce our business.

Government regulation could adversely affect our profitability.