COVALENT GROUP INC
Form 10-K
March 29, 2006
Table of Contents

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 December 31, 2005.

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from _____ to _____

Commission file number: 0-21145

COVALENT GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware	**56-1668867**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
One Glenhardie Corporate Center, 1275 Drummers Lane, Suite 100, Wayne, Pennsylvania	**19087**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: 610-975-9533

Securities registered under Section 12(b) of the Exchange Act: None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, $.001 Par Value

(Title of Class)

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

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

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

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

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

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer x

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

As of June 30, 2005, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $25,567,682 based on the closing sale price as reported on the National Association of Securities Dealers Automated Quotation System Market System.

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Class	**Outstanding at March 1, 2006**
Common Stock, $.001 par value per share	13,501,333 shares

DOCUMENTS INCORPORATED BY REFERENCE

Document
NONE

Table of Contents

COVALENT GROUP, INC.

FORM 10-K ANNUAL REPORT

INDEX

Table of Contents

In this discussion, the terms Company, we, us and our refer to Covalent Group, Inc. and our consolidated subsidiaries, except where it is made clear otherwise.

FORWARD LOOKING STATEMENTS

When used in this Report on Form 10-K and in other public statements, both oral and written, by the Company and Company officers, the words estimate, project, expect, intend, believe, anticipate and similar expressions are intended to identify forward-looking statements regarding and trends that may affect our future operating results and financial position. Such statements are subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Such factors include, among others: (i) our success in attracting new business and retaining existing clients and projects; (ii) the size, duration and timing of clinical trials; (iii) the termination, delay or cancellation of clinical trials; (iv) the timing difference between our receipt of contract milestone or scheduled payments and our incurring costs to manage these trials; (v) outsourcing trends in the pharmaceutical, biotechnology and medical device industries; (vi) the ability to maintain profit margins in a competitive marketplace; (vii) our ability to attract and retain qualified personnel; (viii) the sensitivity of our business to general economic conditions; and (ix) other economic, competitive, governmental and technological factors affecting our operations, markets, products, services and prices. We undertake no obligation to publicly release the result of any revision of these forward-looking statements to reflect events or circumstances after the date they are made or to reflect the occurrence of unanticipated events. Please refer to the section entitled Risk Factors that Might Affect our Business or Stock Price beginning on page 9 for a more complete discussion of factors which could cause our actual results and financial position to change.

PART I

ITEM 1. *BUSINESS*
General

In this discussion, the terms Company, we, us and our refer to Covalent Group, Inc. and our consolidated subsidiaries, except where it is made clear otherwise.

We are a clinical research organization (CRO) which is a leader in the design and management of complex clinical trials for the pharmaceutical, biotechnology and medical device industries. Our mission is to provide our clients with high quality, full-service support for their clinical trials. We offer therapeutic expertise, experienced team management and advanced technologies. Our headquarters is in Wayne, Pennsylvania and our International operations are based in London, England.

Our clients consist of many of the largest companies in the pharmaceutical, biotechnology and medical device industries. From protocol design and clinical program development, to proven patient recruitment, to managing the regulatory approval process, we have the resources to directly implement or manage Phase I through Phase IV clinical trials and to deliver clinical programs on time and within budget. We have clinical trial experience across a wide variety of therapeutic areas, such as cardiovascular, endocrinology/metabolism, diabetes, neurology, oncology, immunology, vaccines, infectious diseases, gastroenterology, dermatology, hepatology, womens health and respiratory medicine. We have the capacity and expertise to conduct clinical trials on a global basis.

We were initially incorporated in August 1998 in Nevada. In June 2002, we changed our state of incorporation to Delaware.

Industry Overview

The CRO industry provides independent clinical trial and product development services for the pharmaceutical, biotechnology and medical device industries. Companies in these industries often outsource product development services to CROs in order to manage the drug development process more efficiently and cost-effectively. Outsourcing also enables these companies to access expertise and experience beyond their organizations. Historically, many companies in the pharmaceutical, biotechnology and medical device industries have performed the majority of their product development internally. Outsourcing drug development activities to CROs provides these companies with a variable cost alternative to the fixed costs associated with internal drug development. Companies no longer need to staff for peak periods and can benefit from a CRO s technical resources, therapeutic expertise, and the global infrastructure required to conduct clinical trials on a worldwide basis.

At the present time, we believe that the percentage of services required for product development that are being outsourced is increasing and will continue to increase in the future because of numerous factors, including: cost containment pressures; attempts to overcome limitations on internal capacity; a desire to improve the timeline for evaluating and developing new drugs and/or devices; the desire to increase the percentage

of development costs that are variable as compared to fixed costs; the need to perform research relating to new drugs in multiple countries simultaneously; the response to increasingly

Table of Contents

stringent government regulations in various countries; and the desire to use external expertise to supplement internal design and development capabilities.

As the investment required to develop new drugs continues to increase, an opportunity is created to help speed the drug development process or make this process more efficient.

Our Strategy

Our strategy is to be a leader in the design and management of complex clinical trials by providing our clients with exceptional performance ensuring that they achieve their goals on-time, on-budget and with superlative quality. Our competitive advantage is based upon our ability to deliver a knowledge-based and intellectually rich level of service that provides our clients with a well-conceived protocol design and operational plan intended to maximize their return on investment. We believe that many of the reported regulatory delays or rejections for prospective drugs can be directly attributed to underlying issues in protocol design and development. Our Company is led by experienced executives with significant prior success in the drug development and regulatory approval process. Unlike larger, more conventional CROs, we provide a value-added approach to the design and management of clinical trials. We believe that our leadership in the design of complex clinical trials, our application of innovative technologies, our therapeutic expertise and our commitment to quality offer clients a means to more quickly and cost-effectively develop products through the clinical trial process.

A significant aspect of our strategy is to expand our geographic presence and add to our clinical development capabilities in existing new therapeutic areas or service offerings. In March 2006, we announced the signing of a Combination Agreement with Remedium OY (Remedium), a privately owned, full service CRO based in Espoo, Finland with offices in 8 countries throughout Scandinavia, Central Europe and Eastern Europe. Under the terms of the Agreement, we expect to pay approximately $20 million for all of the outstanding shares and common stock equivalents of Remedium. The consideration for the transaction is expected to be in the form of Company shares in the amount of $16 million and $4 million in cash, subject to certain purchase price adjustments. The closing of the transaction is expected to occur at the end of the second quarter of 2006 subject to certain contingencies including, but not limited to, the approval of our shareholders and a scheduled new fundraising for at least $4 million to help finance the transaction. In connection with the transaction, we plan to change our name to Encorium BioSolutions, Inc. and apply for a new ticker symbol in connection with our name change.

Once the Remedium transaction closes, we intend to manage all our current and future European and Asian clinical studies from Remedium s facility in Espoo, Finland. We intend to continue to manage our North American and South American clinical trial studies from our Wayne, Pennsylvania facility. Our worldwide headquarters will remain in Wayne, Pennsylvania.

A significant way to demonstrate our capabilities and attract new business is to showcase our prior success in managing complex clinical trials. In 2003, we experienced great success with the REVERSAL study. We were an instrumental part of the team that designed, wrote, and conducted the trial for Pfizer. The results of this landmark study, which showed for the first time that aggressive pharmacological therapy could stabilize or even regress coronary artery disease, were presented at the American Heart Association Scientific Sessions in November 2003 and subsequently published as the lead article in the Journal of the American Medical Association. The REVERSAL results have appeared on the front page of the New York Times as well as in the Wall Street Journal, USA Today, and Time Magazine. The results were also featured on MSNBC and CNN. It was a major success story for the Company and is a concrete example of what we can do from both an intellectual and operational perspective. In January 2005, a follow-up article that presented additional data from the REVERSAL study appeared as a lead article in the New England Journal of Medicine.

In 2004, we substantially completed the CAMELOT/NORMALISE study, which was conducted in North America and Europe. Two thousand patients with coronary artery disease and well controlled blood pressure were randomized to standard-of-care therapy plus either the calcium channel blocker Norvasc®, the angiotensin converting enzyme inhibitor Vasotec®, or placebo. After two years of follow-up, patients treated with active drug had a decrease in systolic blood pressure of 5.5 mmHg and a decrease in diastolic blood pressure of 3.0 mmHg. Administration of Norvasc® resulted in a highly significant 31% reduction in adverse cardiovascular events. Directionally similar but smaller and non-significant treatment effects were observed with Vasotec®. Intravascular ultrasound imaging of coronary artery atherosclerotic plaque showed evidence of slowing of atherosclerosis progression only with Norvasc®. The results of the CAMELOT/NORMALISE study have raised clinically relevant questions about how low the target blood pressure should be in patients with coronary artery disease. This issue is currently under intense review by physician groups charged with establishing blood pressure treatment guidelines for patients with coronary artery disease.

With our wholly-owned international subsidiary, Covalent Group, Ltd., we are able to meet many of the global drug development needs of our clients. In 2003, we formed strategic partnerships with several highly experienced regional CROs to broaden our geographic reach. These regional CROs share our vision and values, and are known to produce quality

Table of Contents

deliverables. They are based in Moscow, Russia, Sofia, Bulgaria, Sao Paulo, Brazil and Sydney, Australia regions that were specifically targeted because we believe they have or will achieve strategic prominence over the next several years with respect to clinical trials. Overall, these partnerships have substantially increased the number of operational personnel that we can employ on global trials and allow us to better service the needs of the pharmaceutical and biotechnology industries. These strategic partnerships also complement our proposed acquisition of Remedium since they are based in locations in which Remedium does not conduct major operations.

Recognizing the dynamic nature of the pharmaceutical and medical device development process, our experience and capabilities enables us to adapt our services to fit our clients specific needs. The distinguishing features of our services include the following:

Experienced Management. We are an established company led by a senior management team who average greater than 20 years of clinical research experience from both the CRO and pharmaceutical/biotechnology industry perspective. Our company includes 4 individuals who hold a Ph.D. or M.D. degree. For example, our President and Chief Executive Officer, Dr. Kenneth M. Borow, is a Harvard-trained physician with nearly 30 years of medical, academic and clinical trials experience at Merck, University of Chicago School of Medicine, Brigham and Women s Hospital, Boston Children s Hospital, and Covalent. Our Senior Vice President, Global Operations, Alison O Neill has worked in the pharmaceutical industry for 24 years, 18 of these in clinical research for both pharmaceutical and CRO employers.

Credibility in the clinical research marketplace. We have a strong client base with a high rate of repeat business. We have gained the confidence of our clients as demonstrated by their entrusting us with broad responsibilities, including designing and implementing global clinical research programs for some of their most important products. We provide leadership in a wide variety of therapeutic areas including cardiovascular, endocrinology/metabolism, diabetes, nephrology, immunology, vaccines, infectious diseases, gastroenterology, dermatology, hepatology, womens health, and respiratory medicine.

Global capabilities. In 2000, Covalent Group, Ltd., our wholly-owned international subsidiary, commenced operations, providing us with a strategically important international presence. Covalent Group, Ltd. has an international client base with their own clinical trials, but also assists us in conducting clinical trials in Western Europe, Eastern Europe, Scandinavia and elsewhere for our clients. During 2003, we established proprietary strategic partnerships with several highly experienced regional CROs in order to strengthen and broaden our global offerings and our geographic reach. We have made a very determined effort to broaden and diversify our client list. This has resulted in an attractive mix of pharmaceutical and biotechnology companies and we will continue to focus on expanding our capabilities both in the United States and internationally. We believe that these capabilities better positions us to meet our clients global clinical trial requirements. Once the proposed Remedium acquisition is completed, the management of our European and Asian operations will be based at Remedium s offices in Espoo, Finland.

Our bioterrorism vaccine program. During 2003 and 2004, we began the process of conducting a global Counter-Bioterrorism program focused on the development of vaccines against biological agents with potential military and terrorism applications. This program offers clients an inter-disciplinary group of clinical development professionals with extensive experience working with vaccines, recombinant technology and immunotherapy products. During 2005, we continued to win additional business focusing on the development of counter-bioterrorism vaccines for a new client. In total, we managed four separate clinical trials in 2005 in this particular therapeutic area.

Our Services

We offer our clients on a global basis a broad range of clinical research and development services supporting Phase I through Phase IV clinical trials. Our services include study protocol design, clinical trials management, global data management services, biostatistics, medical and regulatory affairs, and quality assurance and compliance.

Study Protocol Design

We specialize in complex clinical trials with a particular focus on understanding conceptual issues and creating practical solutions. Much of the conceptual value-added work focuses on the design of an effective development program which includes individual clinical trial protocols. The study protocol is the critical document provided to the study investigators that defines the study and details the procedures which must be followed for the proper conduct of the trial. The protocol defines the medical issues the study seeks to examine and the statistical tests that will be conducted. The protocol also defines the frequency and type of laboratory and clinical measurements to be performed, tracked and analyzed. Also defined is the number of patients required to produce a statistically meaningful result, the period of time over which they must be tracked, and the frequency and dosage of drug administration.

3

Table of Contents

A properly designed protocol targets the correct primary efficacy variable (i.e. the key outcome being studied, such as a reduction in sitting diastolic or systolic blood pressure), is statistically sound, effectively incorporates strategic marketing and product positioning issues, and proactively conforms to regulatory guidelines. We believe that many of the reported regulatory delays or rejections for prospective drugs can be directly attributed to underlying issues in protocol design and study process. A significant value we provide to our clients is in designing the initial study protocol or in significantly enhancing the protocol s design.

Clinical Trials Management

We serve our clients needs by conducting clinical trials through a project team. A project manager leads and facilitates all aspects of the conduct of the clinical trial. Other members of our project team typically include representatives from clinical trials management, global data services, regulatory affairs, information services, quality assurance, medical writing and field monitoring. Within this project-oriented structure, we can manage every aspect of clinical trials conducted in Phases I through Phase IV of the drug development process. Many of our current projects involve Phase II, Phase III or Phase IIIb clinical trials, which are generally larger, longer and more complex than Phase I trials.

We have adopted global standard operating procedures intended to satisfy global regulatory requirements and serve as tools for controlling and enhancing the quality of our clinical trials. All of our standard operating procedures are designed and maintained in compliance with Good Clinical Practice (GCP) requirements and the International Conference on Harmonization (ICH) standards. The U.S. Food and Drug Administration (FDA) and the European union have adopted these standards. We compile, analyze, interpret and submit data generated during clinical trials in report form to our clients, as well as, at our client s request, directly to the FDA or other relevant regulatory agencies for purposes of obtaining regulatory approval.

Clinical trials represent one of the most expensive and time-consuming parts of the overall drug development process. The information generated during these trials is critical for gaining marketing approval from the FDA or other regulatory agencies. We assist our clients with one or more of the following steps:

Case Report Form Design. Once the study protocol has been finalized, the Case Report Form (CRF) must be developed. The CRF is the document for collecting the necessary clinical data as defined by the study protocol. The CRF for a single patient in a study may consist of 100 or more pages.

Investigator Recruitment. The success of a clinical trial is dependent upon finding experienced investigators who are capable of performing clinical trials in accordance with the highest ethical and scientific standards. During clinical trials, physicians (who are also referred to as investigators) at hospitals, clinics or other locations, supervise administration of the drug or study product to patients or normal subjects. We recruit investigators who contract directly with either us or our clients to participate in clinical trials. Our global investigator database includes thousands of physician-investigators specializing in a multitude of therapeutic areas.

Patient Enrollment. The investigators find and enroll patients suitable for the study. The speed at which trials can be completed is significantly affected by the rate at which patients are enrolled. Prior to participating in a clinical trial, patients are required to review information about the study medication and its possible side effects, and sign an informed consent form to record their knowledge and acceptance of potential side effects. Patients also undergo a medical examination by the investigator to determine whether they meet the requirements of the study protocol. Patients then receive the study medication and are examined by the investigator as specified by the study protocol.

Study Monitoring and Data Collection. As patients are examined and tests are conducted in accordance with the study protocol, data is recorded on CRFs. CRFs are reviewed or monitored by specially trained clinical research associates or field monitors. Field monitors visit study sites regularly to ensure that the CRFs are completed correctly and that the data specified in the protocol are obtained. The field monitors send completed CRFs to a data management group where they are reviewed for consistency and accuracy before the data are entered into a database. An alternative data flow process utilizes remote data entry technology and a fax based system that frequently enhances the timeliness of clinical data collection while achieving cost savings to the Sponsor. We are currently involved in studies using both types of data flow processes.

4

Table of Contents

Data Management Services

We have automated the data management process associated with clinical trial management through our use and customization of industry standard software known as clinical trials management systems. We license Oracle Clinical® and Datafax as our clinical trials management systems. The software assists us in the collection, validation and reporting of clinical results to our clients. Our data management professionals provide CRF review and tracking, data entry, integrated clinical/statistical reports, as well as writing manuscripts for publication.

Biostatistics

Typically, biostatisticians assist clients with all phases of drug development, including biostatistical consulting, database design, data analysis and statistical reporting. These professionals help develop and review protocols, design appropriate analysis plans and design report formats to address the objectives of the study protocol, as well as the client s individual objectives. Frequently, we represent clients in meetings with the FDA regarding biostatistical consulting.

Medical and Regulatory Affairs

Typically, before a drug, biologic, or medical device can be sold in a particular country, it must be approved by the regulatory agency in that country. We provide comprehensive regulatory product registration services for pharmaceutical, biotechnology products and medical devices in the United States and Europe. These services include regulatory strategy formulation, New Drug Application (NDA) and Biologic License Application document preparation and review, quality assurance and liaison with the FDA and other regulatory agencies.

Quality Assurance and Compliance

We conduct field inspections that include investigator audits, pre-submission protocol compliance audits and GCP audits. Our staff also provides training sessions to our personnel, as well as to study site employees. Finally, our Quality Assurance and Compliance group performs audits of study documents as well as data contained in our clinical trials databases.

Report Writing

The statistical analysis findings for data collected during the trial, together with other clinical data, can be included in a final study report to be included in a regulatory filing or as a final deliverable to the client.

Patient Registries

Patient Registries are becoming an essential, emerging tactic for all brand marketers and therapeutic categories. They provide an opportunity to rapidly populate databases with real-world, patient-derived information that can be analyzed and disseminated in multiple formats. This has become particularly important considering the recent issues that have come to the forefront regarding long-term patient safety associated with FDA approved and commercially marketed drugs. Data collection, analysis and reporting requirements for Registries are significantly less stringent than for traditional phase IIIb and IV studies. Their success is independent of investigator experience. Therefore, a Registry is an ideal tool for reaching out to the primary care population in a clinically meaningful and credible way. In addition, Registries facilitate and improve relationship building between biopharmaceutical companies and regional/local opinion leaders and high volume providers. They increase access to these important community based physicians while creating a credible, necessary, real-world decision database that provides multiple patient safety, commercialization, communication and education opportunities for stakeholders in the healthcare environment.

Clients and Marketing

We provide a broad range of clinical research and consulting services to the pharmaceutical, biotechnology and medical device industries. Our clients consist of many of the largest companies in the pharmaceutical, biotechnology and medical device industries. In 2005, we provided services to 23 different clients covering 41 separate studies or projects. We have in the past derived, and may in the future derive, a significant portion of our revenues from a core group of major clients. We are likely to continue to experience client concentration in future years. In 2005, our three largest clients accounted for 70 % of our net revenues, with the three largest representing 27%, 26% and 17% of our net revenues, respectively. In 2004, our three largest clients accounted for 57% of our net revenues, with the three largest representing 23%, 19% and 15% of our net revenues, respectively. In 2003, our three largest clients accounted for 69% of our net revenues, with the three largest representing 41%, 21%, and 7%, respectively. Our largest clients for any one year period may not represent the same customers as in a prior year period.

Table of Contents

We are generally awarded contracts based upon our response to requests for proposals received from pharmaceutical, biotechnology and medical device companies. Our business development and marketing strategy is based on expanding our relationships with our existing clients as well as gaining new clients. Our senior executives and project team leaders all share responsibility for maintaining and enhancing client relationships and business development activities. Our business development program is supported by a marketing and communications program that includes selective advertising in trade publications, management of the corporate web site, development of marketing materials, and related activities.

Contractual Arrangements

Most of our contracts with our clients are based on a fixed price with the option for additional variable components (i.e. change of scope). Therefore, we generally bear the risk of cost overruns, but we may also benefit if the costs are lower than we anticipated. Contracts may range from a few months to several years depending on the nature of the work performed. In general, for multi-year contracts, a portion of the contract fee, typically 10-15%, is paid at the time the trial is started, with the balance of the contract fee payable in installments over the trial duration. In some cases, the installments are tied to meeting specific performance milestones, while others have an agreed upon fixed payment plan independent of performance milestones. For example, installment payments for clinical trial projects may be related to investigator recruitment or patient enrollment. Several of our older contracts contain payment schedules that are weighted towards the later stages of the contract. As is typical in the CRO industry, when a client requests a change in the scope of a trial or in the services to be provided by us, we prepare a work order. An executed work order becomes an amendment to the original contract. Work orders resulting from changes of scope often produce additional revenue for us. We are at risk for any work performed outside the scope of the study or in advance of signing a new work order. We attempt to negotiate contract amendments with the client to cover any services provided outside the terms of the original contract. There can be no assurance that the client will agree to the proposed amendments, and we ultimately bear the risk of cost overruns.

Most of our contracts may be terminated by the client at any time with prior notice. Our contracts frequently entitle us to receive the costs of winding down the terminated project, as well as all fees earned by us up to the time of termination. Contracts may be terminated or delayed for several reasons, including unexpected results or adverse patient reactions to the drug, inadequate patient enrollment or investigator recruitment, manufacturing problems resulting in shortages of the drug, budget constraints of clients or decisions by the client to de-emphasize or terminate a particular trial, development efforts on a particular drug, or our failure to properly perform our obligations.

Backlog

Our backlog consists of anticipated net revenue from uncompleted projects which have been authorized by the client, through a written contract, verbal commitment or letter of intent. Many of our studies and projects are performed over an extended period of time, which may be several years. Amounts included in backlog have not yet been recognized as net revenue in our consolidated statements of operations. Once contracted work begins, net revenue is recognized over the life of the contract on a proportional performance basis. The recognition of net revenue reduces our backlog while the awarding of new business increases our backlog. In 2005, we obtained $19.1 million of new business awards as compared to $21.5 million in 2004, an 11% decrease. Our backlog was $22.7 million at December 31, 2005, compared to $15 million at December 31, 2004. We expect most of this backlog will be recognized in 2006 subject to the risk factors listed herein.

We believe that our backlog as of any date may not necessarily be a meaningful predictor of future results because backlog can be affected by a number of factors including the size and duration of contracts, many of which are performed over several years. Additionally, contracts may be subject to early termination by the client or delay for many reasons, as described above. Also, the scope of a contract can change during the course of a study. For these reasons, we might not be able to fully realize our entire backlog as net revenue.

Competition

The contract research organization industry is highly fragmented, consisting of several hundred small, limited-service providers and a limited number of mid-sized and large CROs with global capabilities.

Newer, smaller firms with specialty focuses, such as those aligned with a specific disease or therapeutic area, may compete against established CROs for clients. We primarily compete against full-service and limited service contract research organizations, mid-sized CROs, in-house research and development departments of pharmaceutical and biotechnology companies and, to a lesser extent, universities and teaching hospitals. CROs generally compete on the basis of a number of factors, including the following: expertise and experience in specific therapeutic areas; the ability to design sound protocols or enhance the design; reputation for on-time quality performance; scope of service offerings; price; ability to enroll patients and recruit investigators; data management capabilities; strengths in various geographic markets; technological expertise and

6

Table of Contents

efficient drug development processes; the ability to acquire, process, analyze and report data in a timely and accurate manner; the ability to manage large-scale clinical trials both domestically and internationally; and organizational size. Although there can be no assurance that we will continue to do so, we believe that we compete favorably in these areas.

Some of our largest competitors include Quintiles Transnational Corporation, Covance, Inc., Parexel International Corporation, Pharmaceutical Product Development, Inc., Icon Clinical Research and Kendle International, Inc. In general, the CRO industry is not capital-intensive and the financial costs of entry into the industry are relatively low. Newer, smaller entities with specialty focuses, such as those aligned to a specific disease or therapeutic area, may compete aggressively against us for clients. Furthermore, clients may also choose to limit the CROs with whom they are willing to work. Increased competition might lead to heightened price and other forms of competition that may adversely affect our operating results.

Government Regulation

The development and clinical research of new drugs is highly regulated by government agencies. The standards for the conduct of clinical research and development studies are embodied in governmental regulations and in guidelines such as the ICH s Guideline on GCP. The standards stipulate procedures designed to ensure the quality and integrity of data obtained from clinical testing and to protect the rights and safety of clinical subjects. The FDA and similar regulatory authorities require that test results submitted to such authorities be based on studies conducted in accordance with GCP and regulations providing protections for research participants.

Our obligations under GCP may include, but are not limited to, the following: assuring the selection of investigators who are qualified and have adequate staff and facilities to conduct the trial properly and safely; obtaining specific written commitments from the investigators; verifying that adequate informed consent of trial subjects has been obtained; monitoring clinical trials to ensure that the rights and well-being of trial subjects are protected and that the reported trial data are accurate, complete, and verifiable from source documents; ensuring that adverse drug reactions are medically evaluated and reported; verifying drug or device accountability; implementing quality assurance and quality control systems; instructing investigators and study staff to maintain proper records and reports; and permitting appropriate governmental authorities access to source documents for their review. We must also maintain reports for each study for specified periods for auditing by the study sponsor and by the FDA or similar regulatory authorities. Noncompliance with GCP can result in disqualification of the data collected during the clinical trial and we could be required to redo the trial under the terms of our contract at no further cost to our client, but at substantial cost to us. CROs are also typically contractually obligated to comply with GCP and other patient protection regulations. Failure to comply could expose the CRO to contractual liability to its clients.

Development of New Drugs

Before a new drug may be marketed, the drug must undergo extensive testing and regulatory review in order to determine that the drug is safe and effective. The following discussion focuses on the FDA approval process. Similar procedures must be followed for clinical trials in other countries as well as for the approval of biologics and medical devices. The following provides a broad summary of the stages of this development process:

Preclinical research (1 to 4 years). This phase includes in vitro (test tube) and animal studies to establish the relative toxicity of the drug over a wide range of doses and to detect any potential to cause any serious adverse effects. If results warrant continuing development of the drug, the sponsor of the drug will file for an Investigational New Drug Application, upon which the FDA may grant permission to begin human clinical trials.

Clinical Trials (4 to 6 years).

Phase I (6 months to 2 years). Phase I includes basic safety and pharmacology testing in approximately 20 to 80 human subjects, usually healthy volunteers. Phase I work also includes studies to determine metabolic and pharmacologic action of the drug in humans, if it is safe, how it is affected by other drugs, where it goes in the body, how long it remains active, and how it is broken down and eliminated from the body.

Phase II (1 to 2 years). Phase II trials test basic efficacy (effectiveness) and potential dosing ranges in approximately 100 to 200 patients afflicted with the specific disease or condition for which the study medication is intended for use. Phase II trials help to determine the best effective dose, determine frequency of dosing, establish that the study medication has at least some effect, and provide additional safety data. If the Phase II study yields satisfactory results and no hold is placed by the FDA on further studies, a Phase III study of the drug may begin.

Phase III (2 to 4 years). Phase III trials are larger, more complex and more expensive than earlier phase studies and involve properly powered efficacy and safety evaluations in hundreds to thousands of patients afflicted with

Table of Contents

a specific disease or condition. These patients receive their medical care during the clinical trials at investigational sites, typically hospitals, clinics, or private practice settings. The objective of the Phase III study is to collect enough data for a statistically valid test of safety and effectiveness as required by the FDA, and to provide a basis for the labeling of the drug. The studies may be placebo-controlled trials, in which the study medication under investigation is compared with a sugar pill, or active-comparator studies that test the safety and effectiveness of the study medication against one or more drugs with established safety and efficacy profiles in the same therapeutic category.

The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension, or termination of clinical trials if, among other things, an unreasonable risk is presented to patients or if the design of the trial is insufficient to meet its stated objective.

NDA Preparation and Submission. Upon the completion of the Phase III trials, the sponsor of the study medication assembles the statistically analyzed data from all phases of development into a single large submission: the NDA. An NDA may be submitted as a paper document (which may contain tens of thousands of pages) or in an electronic format.

FDA Review and Approval (approximately 12 months). The staff of the FDA will carefully scrutinize the data from all phases of development to confirm that the applicant has complied with regulations and that the drug is safe and effective for the specific use or indication under study. The FDA may refuse to accept the NDA for filing and substantive review if certain administrative and content criteria are not satisfied. After accepting the submission for review, the FDA may require additional testing or information before approval of an NDA. The FDA will deny approval of the NDA if applicable regulatory requirements are not ultimately satisfied.

Post-Marketing Surveillance and Phase IV Studies. Federal regulation requires the marketer of the drug to collect and periodically report to the FDA additional safety and efficacy data on the drug for as long as the drug is marketed (post-marketing surveillance). If the drug is marketed outside the United States, the reports must include data from all countries in which the drug is sold. Phase IV (post-FDA approval) studies may be undertaken after initial approval to find new uses for the drug (broadening the label), to test new dosage formulations, or to confirm selected non-clinical benefits (e.g. increased cost-effectiveness or improved quality of life). Product approval may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

In providing our clinical research services to our clients, we are obligated to comply with regulatory requirements governing the drug development process. We have established standard operating procedures that are designed to comply with regulations and guidelines appropriate to the region and the nation where the clinical trials will be conducted. We strive to perform all clinical research in accordance with the GCP and ICH guidelines and the requirements of the applicable country. From an international perspective, we have implemented common standard operating procedures across regions to assure consistency wherever appropriate to do so.

Intellectual Property

We have developed certain computer software and technically derived procedures that provide separate services and are intended to maximize the quality and effectiveness of our services. Our intellectual property rights are important to us. We also believe that factors such as technical expertise, knowledge, ability and experience of our professionals are important and provide significant benefits to our clients.

Potential Liability and Insurance

We contract with physicians who serve as investigators in conducting clinical trials to test new drugs on their patients. Such testing creates a risk of liability for personal injury to or death of the patients, resulting from adverse reactions to the drugs administered. In addition, although the Company does not believe it is legally accountable for the medical care rendered by third party investigators, it is possible that we could be subject to claims and expenses arising from any professional malpractice of the investigators with whom we contract with. We also may be held liable for errors and omissions in connection with the services we perform.

We believe that the risk of liability to patients in clinical trials is mitigated by various regulatory requirements, including the role of institutional review boards (IRBs) and the need to obtain each patient s informed consent. The FDA requires each human clinical trial to be reviewed and approved by the IRB at each study site. An IRB is an independent committee that includes both medical and non-medical personnel and is obligated to protect the interests of patients enrolled in the trial.

8

Table of Contents

After the trial begins, the IRB monitors the protocol and measures designed to protect patients, such as the requirement to obtain informed consent.

We attempt to reduce our risk through contractual indemnification provisions with clients and investigators, insurance maintained by clients, investigators and us, and various regulatory requirements, including the use of IRBs and the procurement of each patient s informed consent to participate in the study. However, the contractual indemnifications generally do not protect us against certain of our own actions such as negligence. In addition, the terms and scope of such indemnification vary from client to client and from trial to trial and the financial performance of these indemnities is not secured. Therefore, we bear the risk that the indemnity may not be sufficient or that the indemnifying party may not have the financial ability to fulfill its indemnification obligations. We maintain worldwide professional liability insurance. We believe that our professional liability insurance coverage is adequate. There can be no assurance, however, that we will be able to maintain such insurance coverage on terms acceptable to us, if at all. Our operating results and financial position could be materially and adversely affected if we were required to pay damages or bear the costs of defending any claim outside the scope of or in excess of a contractual indemnification provision or beyond the level of insurance coverage in the event that an indemnifying party does not fulfill its indemnification obligations.

Employees

At December 31, 2005, we employed 82 full time and 2 part time personnel, of which 9 were based outside of the United States. Of our staff, 4 held Ph.D. or M.D. degrees and approximately 14 held masters or other post graduate degrees. None of our employees are subject to a collective bargaining agreement. We believe that our relations with our employees are good. In addition, during 2005, we supplemented our employee base with contractors on an as-needed basis.

Risk Factors that Might Affect our Business or Stock Price

Failure to develop new business in our intensely competitive industry will cause our revenues to decline.

The market for contract research services is highly competitive. We primarily compete against in-house departments of pharmaceutical, biotechnology and medical device companies and other contract research organizations. Competitors in our industry range from small, limited-service providers to full service, global contract research organizations. Many of our competitors have an established global presence, including Quintiles Transnational Corp., Covance, Inc., Parexel International Corporation, Pharmaceutical Product Development, Inc., Icon Clinical Research, and Kendle International, Inc. These competitors have substantially greater financial and other resources than we do. Significant factors in determining whether we will be able to compete successfully include: our consultative and clinical trials design capabilities; our reputation for on-time quality performance; our expertise and experience in specific therapeutic areas; the scope of our service offerings; our ability to recruit investigators and study subjects in a timely manner; our strength in various geographic markets; the price of our services; our ability to acquire, process, analyze and report data in a time-saving and accurate manner; our global data services capabilities; our ability to manage large-scale clinical trials both domestically and internationally; and our size.

If our services are not competitive based on these or other factors and we are unable to develop an adequate level of new business, our business, backlog position, financial condition and results of operations will be materially and adversely affected. In addition, we may compete for fewer clients arising out of consolidation within the pharmaceutical industry and the growing tendency of drug companies to outsource to a smaller number of preferred contract research organizations.

Our services may from time to time experience periods of increased price competition that could have a material adverse effect on our profitability and revenues. Additionally, the CRO industry is not highly capital-intensive, and the financial costs of entry into the industry are relatively low. Therefore, as a general matter, the industry has few barriers to entry. Newer, smaller entities with specialty focuses, such as those aligned to a specific disease or therapeutic area, may compete aggressively against us for clients.

We depend on a small number of industries and 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 by 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;

Table of Contents

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.

Three of our clients account for a significant percentage of our revenues. For the year ended December 31, 2005, net revenues from our three largest clients amounted to 70% of our net revenues, with the three largest clients representing 27%, 26% and 17% of net revenues, respectively. For the year ended December 31, 2004, net revenues from our three largest clients amounted to 57% of our net revenues, with the three largest clients representing 23%, 19%, and 15% of net revenues, respectively. For the year ended December 31, 2003, net revenues from our three largest clients amounted to 69% of our net revenues, with the three largest clients representing 41%, 21%, and 7% of net revenues, respectively. We expect that a relatively small number of clients will continue to represent a significant percentage of our net revenue although our largest clients from year to year vary. Our contracts with these clients generally can be terminated on short notice. The loss of business from any one of these significant clients or our failure to continue to obtain new business would have a material and adverse effect on our business and revenues.

Loss of key personnel, or failure to attract and retain additional personnel, may cause the success and growth of our business to suffer.

Our future success depends on the personal efforts and abilities of the principal members of our senior management and scientific team to provide strategic direction, develop business, provide service to our clients, manage our operations and finances, and maintain a cohesive and stable environment. The loss of their services might significantly delay or prevent the achievement of business development and strategic objectives. As a provider of complex clinical trial support services, our success depends on our ability to retain key employees and to attract additional qualified employees. Competition for qualified personnel is intense and we cannot assure you that we will be able to retain existing personnel or attract and retain additional highly qualified employees in the future. Specifically, we are substantially dependent upon the efforts of Kenneth M. Borow, M.D., our President and Chief Executive Officer and Alison O Neill, our Senior Vice President, Global Operations. We have an employment agreement with Dr. Borow which expires on March 31, 2006. We currently do not have an employment agreement with Ms. O Neill. The loss of services of any of our key executives would have a material and adverse affect on our business operations, results of operations and financial position.

Competition for our key executives and skilled personnel, particularly those with a medical degree, a Ph.D. or equivalent degrees, is intense. We compete with contract research organizations, pharmaceutical and biotechnology companies, and academic and research institutions with far greater financial resources to recruit skilled personnel. Our inability to attract and retain qualified executives and scientific staff could have a material and adverse affect on our business plan, results of operations and financial condition. There can be no assurance that we will be able to continue to attract and retain qualified executives and scientific staff in the future.

The fixed price nature of the Company s contracts could have a negative impact on our operating results.

The majority of our contracts are at fixed prices. As a result, we bear the risk of cost overruns. If we fail to adequately price our contracts, fail to effectively estimate the cost to complete contracts, or if we experience significant cost overruns, our operating results and financial condition could be materially and adversely affected. In 2003 and 2004, we had to commit unanticipated resources to complete projects, resulting in higher costs and lower operating margins on those projects. During 2005, we experienced no significant cost overruns on our fixed price contracts. The Company attempts to negotiate contract amendments with the sponsor to cover services provided outside the terms of the contract. However, there can be no guarantee that the sponsor will agree to proposed amendments, and the Company ultimately bears the risk of cost overruns. We might experience similar situations in the future, which would have a material and adverse impact on our operating results and financial condition.

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

As described in our discussion of contractual arrangements in the description of our business, our contracts generally may be terminated or reduced in scope either immediately or upon 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; merger or potential merger related activities; the client s 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

Table of Contents

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 adversely affected.

In addition, companies may proceed with fewer clinical trials or conduct them without assistance of contract research organizations 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 the 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.

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. Many 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 drug or biologics development programs could result in potential liability to us.

We also contract with physicians to serve as investigators in conducting clinical trials. Such testing creates risk of liability for personal injury to or death of volunteers, particularly to volunteers with life-threatening illnesses, resulting from adverse reactions to the drugs administered during testing. It is possible third parties could claim that we should be held liable for losses arising from any professional malpractice of the investigators with whom we contract or in the event of personal injury to or death of persons participating in clinical trials. We do not believe we are legally accountable for the medical care rendered by third party investigators, and we would vigorously defend any such claims. However, such claims may still be brought against us requiring us to incur legal defense costs, and it is possible we could be found liable for these types of losses.

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 affect 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.

Failure to comply with existing regulations could harm our reputation and our operating results.

Any failure on our part to comply with applicable regulations could result in the termination of on-going clinical research or the disqualification of data for submission to regulatory authorities. For example, if we were to fail to verify that patient participants were fully informed and have fully consented to a particular clinical trial, the data collected from that trial could be disqualified. If this were to happen, we could be contractually required to repeat the trial at no further cost to our client, but at a substantial cost to us. The issuance of a notice from the FDA based upon a finding of a material violation by us of GCP requirements could result in contractual liability to our clients and/or the termination of ongoing studies which could

11

Table of Contents

materially and adversely affect our results of operations. Furthermore, our reputation and prospects for future work could be materially and adversely diminished.

Our backlog may not be indicative of future results.

As of December 31, 2005, our backlog was $22.7 million. The backlog represents anticipated net 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 revenue at the rate originally expected. Accordingly, historical indications of the relationship of backlog to revenues may not be indicative of future results.

If we are unable to successfully develop and market new services in the U.S. 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. For example, we have invested in the creation and administrative set-up of our wholly-owned international subsidiary, Covalent Group, Ltd. which has sustained operating losses to date. We may need to make additional investments in this subsidiary in the future in order for it to achieve our objectives. The profitability of this subsidiary depends, in part, on client acceptance and use of its services. There can be no assurance that this subsidiary will be profitable in the future or that any revenue resulting from it will be sufficient to recover our investment in the subsidiary. If our international subsidiary does not develop as anticipated, our business, financial condition and results of operations may be materially and adversely affected.

Changes in governmental regulation could reduce the need for the services we provide, which would negatively affect our future business opportunities.

In recent years the United States Congress and state legislatures have considered various types of health care reform in order to control growing health care costs. The United States Congress and state legislatures may again address health care reform in the future. We are unable to predict what legislative proposals will be adopted in the future, if any. Similar reform movements have occurred in Europe and Asia.

Implementation of health care reform legislation that results in additional costs to develop new drugs could limit the profits that can be made by our clients from the development of new products. This could adversely affect our clients research and development expenditures, which could in turn decrease the business opportunities available to us both in the United States and elsewhere in the world. In addition, new laws or regulations may create a risk of liability, increase our costs or limit our service offerings. We cannot predict the likelihood of any of these events.

Governmental agencies throughout the world, but particularly in the U.S., strictly regulate the drug development and approval process. Our business involves helping pharmaceutical, biotechnology and medical device companies navigate the regulatory drug approval process. Any changes in drug approval regulatory requirements such as the introduction of simplified drug approval procedures or an increase in regulatory requirements that we have difficulty satisfying, could eliminate or substantially reduce the need for our services. These and other changes in regulation could have an impact on the business opportunities available to us. As a result, our business, results of operations and financial condition could be materially and adversely affected.

Proposed and future laws and regulations, including the confidentiality of patient information, might increase the cost of our business, increase our risks of liability or limit our service offerings.

Federal or state authorities might adopt healthcare legislation or regulations that are more burdensome than existing regulations. These changes in regulation could increase our expenses or limit our ability to offer some of our products or services. For example, the confidentiality of patient specific information and the circumstances under which it may be released for inclusion in our databases or used in other aspects of our business are subject to substantial government regulation. Additional legislation governing the possession, use and dissemination of medical record information and other personal health information has been proposed at both the state and national levels. Proposed federal regulations governing patient specific health information might require us to implement new security measures that require substantial expenditures or limit our ability to offer some of our products and services. These regulations might also increase our costs by creating

12

Table of Contents

new privacy requirements and mandating additional privacy procedures for our business, thereby materially and adversely affecting our results of operations and financial condition.

Our operating results have fluctuated between quarters and years and may continue to fluctuate in the future.

Our quarterly and annual operating results have varied, and will continue to vary as a result of a variety of factors, many of which are beyond our control. Factors that may cause these variations include: the commencement, postponement, completion or cancellation of large contracts; the progress of on-going projects; changes in the mix of services offered; our ability to successfully negotiate contract amendments in a timely manner; and the timing and amount of start-up costs incurred in connection with the introduction of new products, services or subsidiaries.

A significant percentage of our operating costs are fixed. The timing of the completion, delay or loss of contracts, or the progress of client projects, can cause our operating results to vary substantially between reporting periods. We had an accumulated deficit of $5,418,116 and $3,933,377 as of December 31, 2005 and 2004, respectively, versus positive retained earnings of $289,918 for the year ended December 31, 2003. We believe that operating results for any particular quarter are not necessarily a meaningful indication of future results. While fluctuations in our quarterly or annual operating results could negatively impact the market price of our common stock, these fluctuations may not be related to our future overall operating performance.

Our operations may be interrupted by the occurrence of a natural disaster or other catastrophic event.

We depend upon our clients, study sites and our facilities, as well as the ability to readily travel among these, for the continued operation of our business. We also depend upon the continuous, effective, reliable and secure operation of our computer hardware, software, networks, telecommunications networks, Internet servers and related infrastructure. We have contingency plans in effect for natural disasters or other catastrophic events. However, catastrophic events, including terrorist attacks, could still disrupt our operations, those of our clients or study sites, or our ability to travel among these locations, which would also affect us. Although we carry business interruption insurance, we might suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies. Any natural disaster or catastrophic event affecting our facilities could have a material and adverse affect on our business and results of operations.

We may have exposure to substantial personal injury claims and may not have adequate insurance to cover such claims.

Our business primarily involves the testing of experimental drugs and biologics or other regulated FDA products on consenting human volunteers pursuant to a study protocol. These tests create a risk of liability for personal injury to or death of volunteers resulting from negative reactions to the drugs administered or from improper care provided by third party investigators, particularly to volunteers with life-threatening illnesses. In connection with many clinical trials, we contract with physicians to serve as investigators in conducting clinical trials to test new drugs on human volunteers. We do not believe that we are legally accountable for the medical care rendered by third party investigators, and we seek to limit our liability with our clients, third party investigators and others. Although our contracts with clients generally include indemnity provisions and we have loss insurance, our financial condition and results of operations could be materially and adversely affected if we had to pay damages or incur defense costs in connection with a claim that is outside the scope of an indemnity or insurance coverage. Additionally, our financial condition could be adversely affected if our liability exceeds the amount of our insurance.

We believe that our risks are generally reduced by the following: contracts with our clients and, where applicable, investigators containing provisions entitling us to be indemnified by them; insurance maintained by our clients, investigators, where applicable, and by us; and various regulatory requirements we must follow in connection with our business.

Contractual indemnifications generally do not protect us against liability arising from certain of our own actions, such as negligence. Our financial condition and results of operations could be materially and adversely affected if we were required to pay damages or bear the cost of defending any claim which is not covered by a contractual indemnification provision, in the event that a party who must indemnify us does not fulfill its indemnification obligations or which is beyond the level of our insurance coverage. In addition, we may not be able to continue to maintain adequate insurance coverage on terms acceptable to us.

Our success depends on our ability to keep pace with rapid technological changes that could make our products and services less competitive or obsolete.

The clinical research aspects of the pharmaceutical, biotechnology and medical device industries 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,

13

Table of Contents

products or services less competitive or obsolete. For example, if our proprietary technology systems were to become less competitive or obsolete, our ability to develop new business and our operating results would be adversely affected. If competitors introduce superior technologies, products or services and we cannot make enhancements to our technologies, products and services necessary for us to remain competitive, our competitive position, and in turn our business, results of operations and financial condition, would be materially and adversely affected.

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

In 2005, approximately 7% of our net revenues were derived from contracts denominated in currencies other than U.S. dollars. 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 anticipate that net revenues from international operations may grow in the future and represent a greater percentage of total net 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.

The Remedium acquisition could disrupt our ongoing business, distract our management and employees, increase our expenses and adversely affect our business.

In March 2006, we announced the planned acquisition of Remedium OY, a privately held CRO based in Espoo, Finland. If we close the Remedium acquisition as expected, we would need to integrate the acquisition into our business operations. In doing so, we may face difficulties in coordinating and assimilating geographically separate units or organizations and integrating, motivating and retaining personnel with diverse business backgrounds. Further, we may not be able to successfully implement appropriate operational, financial and management systems and controls to achieve the anticipated benefits from the acquisition. In addition, our ability to integrate the Remedium acquisition could be affected by factors beyond our control, including regulatory developments, general economic conditions, and increased competition. The integration of the Remedium acquisition may also result in disruption to our existing business and the loss of existing key personnel and clients, or the loss of the acquired business key personnel or clients.

The occurrence of one or more of the above, or other factors, may adversely affect our ability to achieve the benefits anticipated from the Remedium acquisition. As a result, our financial condition and results of operations may be materially and adversely affected since the Remedium acquisition may not achieve the revenue growth and profitability expected.

Our stock price may be volatile and could experience substantial declines.

The market price of our common stock has experienced historical volatility and might continue to experience volatility in the future in response to quarter-to-quarter variations in: operating results; changes in backlog and new business results; the issuance of analysts reports; market conditions in the industry; prospects of health care reform; changes in governmental regulations; and changes in general conditions in the economy or the financial markets.

The general equity markets have also experienced significant fluctuations in value. This volatility and the market variability has affected the market prices of securities issued by many companies, often for reasons unrelated to their operating performance, and may adversely affect the price of our common stock.

We have never declared a cash dividend on our common stock and do not anticipate paying cash dividends in the foreseeable future. Instead, we intend to retain future earnings for reinvestment in our business.

Failure to satisfy NASDAQ SmallCap Market maintenance criteria could negatively impact the liquidity and market price of our common stock.

Our common stock began trading on the NASDAQ SmallCap Market in December 1997. There are several requirements for continued listing on the NASDAQ SmallCap Market including, but not limited to, a minimum stock price of $1.00 per share and either (a) $2.5 million or more in stockholders equity, (b) market capitalization of $35.0 million or more, or (c) net income in the last fiscal year, or two of the last three fiscal years, of $500,000 or more.

If our common stock price closes below $1.00 per share for 30 consecutive days, we may receive notification from NASDAQ that our common stock will be delisted from the NASDAQ SmallCap Market unless the stock closes at or above $1.00 per share for at least ten consecutive days during the 180-day period following such notification. In the future, our common stock

Table of Contents

price or tangible net worth may fall below the NASDAQ SmallCap Market listing requirements, or we may not comply with other listing requirements, with the result being that our common stock might be delisted. If our common stock is delisted, we may list our common stock for trading over-the-counter. Delisting from the NASDAQ SmallCap Market could adversely affect the liquidity and price of our common stock and it could have a long-term impact on our ability to raise future capital through a sale of our common stock. In addition, it could make it more difficult for investors to obtain quotations or trade our stock.

Our common stock may not continue to qualify for exemption from the penny stock restrictions, which may make it more difficult for you to sell your shares.

The SEC has adopted regulations which define a penny stock to be any equity security that has a market price of less than $5.00 per share, or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, these rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule relating to the penny stock market. Disclosure is also required to be made about current quotations for the securities and about commissions payable to both the broker-dealer and the registered representative. Finally, broker-dealers must send monthly statements to purchasers of penny stocks disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. These penny stock restrictions will not apply to our shares of common stock as long as: (1) they continue to be listed on the NASDAQ SmallCap Market; (2) certain price and volume information is publicly available about our shares on a current and continuing basis; and (3) we meet certain minimum net tangible assets or average revenue criteria. Our common stock may not continue to qualify for an exemption from the penny stock restrictions. If our shares of common stock were subject to the rules on penny stocks, the liquidity of our common stock wo