

COVALENT GROUP INC  
Form 10-K  
March 30, 2005

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-K**

---

(Mark One)

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

For the fiscal year ended December 31, 2004.

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)

Edgar Filing: COVALENT GROUP INC - Form 10-K

---

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**56-1668867**  
(I.R.S. Employer Identification No.)

**One Glenhardie Corporate Center, 1275 Drummers Lane,**

**Suite 100, Wayne, Pennsylvania**  
(Address of principal executive offices)

**19087**  
(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 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  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 an accelerated filer (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the common stock held by non-affiliates as of June 30, 2004 was \$39,435,533.

As of March 1, 2005, there were 13,499,666 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement to be filed with the Securities and Exchange Commission relative to the Company's 2005 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

---

COVALENT GROUP, INC.

FORM 10-K ANNUAL REPORT

INDEX

	<u>Page</u>
PART I	
Item 1. <u>Business</u>	1
Item 2. <u>Properties</u>	17
Item 3. <u>Legal Proceedings</u>	17
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	17
PART II	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities</u>	18
Item 6. <u>Selected Financial Data</u>	19
Item 7. <u>Management's Discussion and Analysis of Results of Operations and Financial Condition</u>	19
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	27
Item 8. <u>Financial Statements and Supplementary Data</u>	28
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	28
Item 9A. <u>Controls and Procedures</u>	28
PART III	
Item 10. <u>Directors and Executive Officers of the Registrant</u>	29
Item 11. <u>Executive Compensation</u>	29
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	29
Item 13. <u>Certain Relationships and Related Transactions</u>	30
Item 14. <u>Principal Accountant Fees and Services</u>	30
PART IV	
Item 15. <u>Exhibit and Financial Statements Schedule</u>	31
<u>FINANCIAL STATEMENTS</u>	F-1

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 Guildford, Surrey, United Kingdom.

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 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.

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 is 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<sup>®</sup>, the angiotensin converting enzyme inhibitor Vasotec<sup>®</sup>, 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<sup>®</sup> resulted in a highly significant 31% reduction in adverse cardiovascular events. Directionally similar but smaller and non-significant treatment effects were observed with Vasotec<sup>®</sup>. Intravascular ultrasound imaging of coronary artery atherosclerotic plaque showed evidence of slowing of atherosclerosis progression only with Norvasc<sup>®</sup>. 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.

## Edgar Filing: COVALENT GROUP INC - Form 10-K

With our wholly-owned international subsidiary, Covalent Group, Ltd., we are able to meet many of the global drug development needs of our clients. We recently 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 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 more than doubled 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.

Recognizing the dynamic nature of the pharmaceutical and medical device development process, our size 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 7 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 23 years, 17 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, neurology/psychiatry, oncology, immunology, vaccines, infectious diseases, gastroenterology, dermatology, hepatology, women's 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. is not only building 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. Recently 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 position us to meet our clients' global clinical trial requirements.

Our bioterrorism vaccine program. During 2003, 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.

## **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.

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 clients' 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.

## Edgar Filing: COVALENT GROUP INC - Form 10-K

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.

#### 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<sup>®</sup> 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

Our 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, our biostatisticians represent clients in meetings with the FDA.

#### 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 2004, we provided services to 18 different clients covering 45 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 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% of our net revenues, respectively. In 2002, our three largest clients accounted for 86% of our net revenues, with the three largest representing 46%, 30%, and 10%, respectively. The decrease in the percentage of our client concentration during 2004 was principally due to a broadening of our client base.

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 10-20%, 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

## Edgar Filing: COVALENT GROUP INC - Form 10-K

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 2004, we obtained \$21.5



million of new business awards as compared to \$21.7 million in 2003, a 1% decrease. Our backlog was \$15 million at December 31, 2004, compared to \$13 million at December 31, 2003. We expect most of this backlog will be recognized in 2005.

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 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

## Edgar Filing: COVALENT GROUP INC - Form 10-K

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 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.

## Edgar Filing: COVALENT GROUP INC - Form 10-K

*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. Although the U.S. is a signatory to the ICH Guidelines, the FDA has not adopted all of these guidelines. 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.

### **Employees**

At December 31, 2004, we employed 85 full time personnel, of which 7 were based outside of the United States. Of our staff, 7 held Ph.D. or M.D. degrees and approximately 17 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 2004, 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

## Edgar Filing: COVALENT GROUP INC - Form 10-K

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;

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, 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. For the year ended December 31, 2002, net revenues from our three largest clients amounted to 86% of our net revenues, with the three largest clients representing 46%, 30%, and 10% of net revenues, respectively. We expect that a relatively small number of clients will continue to represent a significant percentage of our net revenue. 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. Although we have an employment agreement with Dr. Borow, this does not mean Dr. Borow will remain with us. 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 effect on our business operations, results of operations and financial condition.

## Edgar Filing: COVALENT GROUP INC - Form 10-K

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. 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 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 and results of operations.

**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 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, 2004, our backlog was \$15 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 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. Changes in regulation, such as relaxation in regulatory requirements or 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 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.**

## Edgar Filing: COVALENT GROUP INC - Form 10-K

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, 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 \$3,933,377 in retained earnings as of December 31, 2004 versus positive retained earnings of \$289,918 as of December 31, 2003 due to the net loss we reported for the year ended December 31, 2004. 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

## Edgar Filing: COVALENT GROUP INC - Form 10-K

current or future technologies, products or services, or render our technologies, 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 2004, approximately 10% 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.

**Future acquisitions could disrupt our ongoing business, distract our management and employees, increase our expenses and adversely affect our business.**

The majority of our growth is expected to be generated internally. In addition, current market conditions may provide us with the opportunity to partner with other quality institutions in the CRO market. As such, acquisitions that make financial sense, fill a strategic need, are of a manageable size, and complement our core competencies would be considered as a means to further supplement our internal growth. Although we may attempt to grow our business through acquisitions, we may not be able to identify acceptable businesses to acquire or be successful in negotiating mutually agreeable terms; and if we are successful in acquiring businesses, we may not be successful in integrating the acquired business with our existing operations and we may not realize the benefits anticipated from the acquisition of businesses. Although we have not previously used acquisitions as a means to expand our business, we may consider strategic acquisitions in the future. However, we may not be able to identify suitable acquisition opportunities or obtain any necessary financing on acceptable terms. Further, any future acquisitions could involve other risks, such as the assumption of additional expenses and liabilities, the dilution of earnings or dilution of our existing stockholders percentage of ownership, potential losses resulting from undiscovered liabilities of the acquired business not covered by indemnification we may obtain from the seller, and the diversion of management's attention from other business concerns.

If we were to close an acquisition, we would need to integrate the acquisition into our business operations. In doing so, we may face difficulties in coordinating and assimilating geographically separated 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 an acquisition. In addition, our ability to integrate an acquisition could be affected by factors beyond our control, including regulatory developments, general economic conditions, and increased competition. The integration of an 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.

An acquisition of a foreign business may involve still more risks, including not being able to successfully assimilate differences in foreign business practices and overcoming language barriers.

## Edgar Filing: COVALENT GROUP INC - Form 10-K

The occurrence of one or more of the above, or other factors, may adversely affect our ability to achieve the benefits anticipated from an acquisition. As a result, our financial condition or results of operations may be materially and adversely affected and we may not be able to grow our business in the manner we desire.

### **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 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 would be adversely affected.

**We are currently not in compliance with the NASDAQ's audit committee requirement as set forth in Marketplace Rule 4350.**

On March 14, 2005, the Company was notified by the staff of the NASDAQ stock market that due to the resignation of an independent director the Company no longer complies with NASDAQ's audit committee requirements as set forth in Marketplace Rule 4350. Consistent with Marketplace Rule 4350(d)(4), the Company will be provided a cure period until the earlier of the Company's next annual shareholders' meeting or March 5, 2006 in order to regain compliance. In the event the Company does not regain compliance within this period, the NASDAQ stock market will provide written notification to the Company that its securities will be delisted. If our shares of common stock were delisted, the liquidity and market value of our common stock would be adversely affected.

**ITEM 2. PROPERTIES**

As of December 31, 2004, we leased approximately 34,026 square feet of administrative and corporate offices from an independent landlord in Wayne, Pennsylvania, under a lease expiring in December 2010. The rent in 2004 was \$87,800 per month.

We lease approximately 1,350 square feet of office space from an independent landlord for our international operations in the Surrey Research Park, Guilford, Surrey, United Kingdom. The lease expires in November 2005 with rent of 2,947 GBP per month (or approximately 5,400 USD per month based on an exchange rate of 1.84 USD per 1.00 GBP).

**ITEM 3. LEGAL PROCEEDINGS**

The Company is involved in litigation and other legal matters which have arisen in the normal course of business. Although the ultimate results of these matters are not currently determinable, management does not expect that they will have a material adverse effect on the Company's consolidated financial position, results of operations or cash flows.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of security holders in the fourth quarter of 2004.

## PART II

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock is quoted in the NASDAQ Small Cap Market under the symbol CVGR. The following table indicates the high and low bid sale prices per share for each quarter over the last two fiscal years.

Quarter Ended	2004		2003	
	High Bid	Low Bid	High Bid	Low Bid
March 31	\$ 4.15	2.49	\$ 2.85	\$ 1.75
June 30	4.31	3.06	2.85	1.86
September 30	4.19	2.20	3.05	2.10
December 31	3.09	2.05	2.79	2.11

As of March 1, 2005, there were more than 619 holders of record of our common stock, however, we believe that there are approximately 3,200 additional shareholders in street name who beneficially own our common stock in various brokerage accounts.

We have never declared a cash dividend on our common stock and do not anticipate paying cash dividends in the foreseeable future.

For information concerning our Equity Compensation Plans, see Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

On July 31, 2003, Dr. Borow, our President and Chief Executive Officer, exercised an employee stock option to acquire 500,000 shares of our common stock. The option had a grant date of August 6, 1998, an expiration date of August 5, 2003 and an exercise price of \$0.6875. As payment for the shares issued and related withholding taxes, we received from Dr. Borow 140,432 Covalent common shares that were owned by him. The shares received are included as treasury stock in our Consolidated Balance Sheet at December 31, 2004 and 2003.

**ITEM 6. SELECTED FINANCIAL DATA**

The following table represents selected historical consolidated financial data. The statement of operations data for the years ended December 31, 2004, 2003 and 2002 and balance sheet data at December 31, 2003 and 2004 are derived from our audited consolidated financial statements included elsewhere in this report. The statement of operations data for the years ended December 31, 2001 and 2000 and the balance sheet data at December 31, 2002, 2001, and 2000, are derived from audited consolidated financial statements not included in this report. The historical results are not necessarily indicative of the operating results to be expected in the future. The selected data should be read together with Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and notes to the financial statements.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share data)				
Net revenue	\$ 13,590	\$ 20,836	\$ 24,677	\$ 18,353	\$ 12,027
Operating expenses (1)	19,061	21,946	20,607	14,804	10,088
Income (Loss) from operations	(5,471)	(1,110)	4,070	3,549	1,939
Other income (expense)	3	4	(11)	(56)	31
Income (Loss) before income taxes	(5,468)	(1,106)	4,060	3,493	1,970
Income tax provision (benefit)	(1,245)	(544)	1,605	1,458	834
Cumulative effect of change in accounting for revenue recognition, net of tax					136
Net income (loss)	\$ (4,223)	\$ (562)	\$ 2,454	\$ 2,035	\$ 1,000
Net income (loss) per common share:					
Basic	\$ (0.32)	\$ (0.04)	\$ 0.19	\$ 0.16	\$ 0.08
Diluted	\$ (0.32)	\$ (0.04)	\$ 0.19	\$ 0.16	\$ 0.08
Weighted average common and common equivalent shares outstanding					
Basic	13,239	12,747	12,591	12,420	12,168
Diluted	13,239	12,747	13,199	12,963	12,932
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 3,166	\$ 2,070	\$ 2,121	\$ 3,455	\$ 87
Working capital (2)	7,111	10,511	10,772	7,898	5,203
Total assets	12,823	20,385	20,836	15,113	9,311
Long term debt	63	87	3	62	75
Total liabilities	5,014	9,043	9,108	6,223	3,071
Shareholders' equity	7,809	11,342	11,728	8,889	6,240

(1) Excludes the impact of reimbursement for out-of-pocket expenses.

(2) Working capital is calculated as current assets minus current liabilities.

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION****Overview**

## Edgar Filing: COVALENT GROUP INC - Form 10-K

We are a clinical research organization 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 Guildford, Surrey, United Kingdom.

The following discussion should be read in conjunction with the Company's consolidated financial statements and notes thereto.

Net revenue is derived principally from the design, management and monitoring of clinical research studies. Clinical research service contracts generally have terms ranging from several months to several years. A portion of the contract fee is generally payable upon execution of the contract, with the balance payable in installments over the life of the contract. Several of our older contracts contain payment schedules that are weighted towards the later stages of the contract. The majority of our net revenue is recognized from fixed-price contracts on a proportional performance basis. To measure the performance, we compare actual direct costs incurred to estimated total contract direct costs, which we believe is the best indicator of the performance of the contract obligations as the costs relate to the labor hours incurred to perform the service.

Contracts generally may be terminated by clients immediately or with short notice. Clinical trials may be terminated or delayed for several reasons including, among others, unexpected results or adverse patient reactions to the drug, inadequate patient enrollment or investigator recruitment, manufacturing problems resulting in shortages of the drug, client budget constraints or decisions by the client to de-emphasize or terminate a particular trial or development efforts on a particular drug. Depending on the size of the trial in question, a client's decision to terminate or delay a trial in which we participate could have a material and adverse effect on our backlog, future revenue and results from operations. In 2004, we experienced contract cancellations as discussed in Item 1, Business.

### **Critical Accounting Policies and Estimates**

Our consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the periods presented. On an ongoing basis, management evaluates its judgments and estimates. Management bases its judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. Management considers the following policies to be most critical in understanding the more complex judgments that are involved in preparing our consolidated financial statements and the uncertainties that could affect our results of operations and financial condition.

#### Revenue Recognition

The majority of our net revenue is recognized from fixed-price contracts on a proportional performance basis. To measure the performance, we compare actual direct costs incurred to estimated total contract direct costs, which is the best indicator of the performance of the contract obligations as the costs relate to the labor hours incurred to perform the service. Total direct costs are incurred for each contract and compared to estimated total direct costs for each contract to determine the percentage of the contract that is completed. This percentage is multiplied by the estimated total contract value to determine the amount of net revenue recognized. A formal project review process takes place quarterly although most projects are evaluated on an ongoing basis. Management reviews the estimated total direct costs on each contract to determine if estimated amounts are correct, and estimates are adjusted as needed. If we determine that a loss will result from the performance of a fixed-price contract, the entire amount of the estimated loss is charged against income in the period in which such determination is made. Because of the inherent uncertainties in estimating direct costs required to complete a project, particularly complex, multi-year studies, it is possible that the estimates used will change and could result in a material change to our estimates. Original estimates might also be changed due to changes in the scope of work. We attempt to negotiate contract amendments with the client to cover these 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. During 2003

## Edgar Filing: COVALENT GROUP INC - Form 10-K

we performed services and incurred expense related to several changes in scope for a large clinical development program for which the related contract amendments were not signed until March 2004. We recognized the costs for such services during 2003, however, we recognized the related revenues for these services in the first

quarter 2004. For terminated studies, 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.

Costs and estimated earnings in excess of related billings on uncompleted contracts represents net revenue recognized to date that is currently unbillable to the client pursuant to contractual terms. In general, amounts become billable upon the achievement of milestones or in accordance with predetermined payment schedules set forth in the contracts with our clients. Several of our older contracts contain payment schedules that are weighted towards the later stages of the contract. Billings in excess of related costs and estimated earnings on uncompleted contracts represent amounts billed in excess of net revenue recognized at the balance sheet date.

#### Reimbursable Out-of-Pocket Expenses

On behalf of our clients, we pay fees to investigators and other out-of-pocket costs for which we are reimbursed at cost, without mark-up or profit. In connection with the required implementation on January 1, 2002, of Financial Accounting Standards Board Emerging Issues Task Force Rule No. 01-14 ( EITF 01-14 ), Income Statement Characterization of Reimbursements Received for Out-of-Pocket Expenses Incurred , out-of-pocket costs are included in Operating Expenses, while the reimbursements received are reported separately as Reimbursement Revenue in the Consolidated Statements of Operations.

As is customary in the industry, we exclude from revenue and expense in the Consolidated Statement of Operations fees paid to investigators and the associated reimbursement since we act as agent on behalf of our clients with regard to investigators. These investigator fees are not reflected in our Net Revenue, Reimbursement Revenue, Reimbursement Out-of-Pocket Expenses, and/or Direct Expenses. The amounts of these investigator fees were \$5.1 million, \$10.5 million, and \$8.1 million for the years ended December 31, 2004, 2003, and 2002 respectively.

#### Concentration of Credit Risk

Our accounts receivable and costs and estimated earnings in excess of related billings on uncompleted contracts are concentrated with a small number of companies within the pharmaceutical, biotechnology and medical device industries. The significant majority of this exposure is to large, well established firms. Credit losses have historically been minimal. As of December 31, 2004, the total of accounts receivable and costs and estimated earnings in excess of related billings on uncompleted contracts was \$6.9 million. Of this amount, the exposure to our three largest clients was 55% of the total, with the three largest clients representing 34%, 11%, and 10% of total exposure, respectively. As of December 31, 2003, the total of accounts receivable and costs and estimated earnings in excess of related billings on uncompleted contracts was \$14.5 million. Of this amount, the exposure to our three largest clients was 72% of the total, with the three largest clients representing 37%, 30%, and 5% of total exposure, respectively.

#### Operating Expenses

Direct expenses include amounts incurred during the period that are directly related to the management or completion of a clinical trial or related project and generally include direct labor and related benefit charges, other direct costs and certain allocated expenses. Direct costs as a percentage of net revenues tend to fluctuate from one period to another as a result of changes in the mix of services provided and the various studies conducted during any time period. Selling, general and administrative expenses include the salaries, wages and benefits of all administrative, finance and business development personnel, and all other support expenses not directly related to specific contracts.

Stock-Based Compensation

The company has adopted equity incentive plans that provide for the granting of stock options to employees, directors, advisors and consultants. We account for grants of options to employees and directors under these plans applying the intrinsic value method provided for in Accounting Principles Board ( APB ) Opinion No. 25 Accounting for Stock Issued to Employees and related interpretations. No stock-based compensation expense is reflected in net income as all options granted under the plan had an exercise price equal to the market value of the

underlying common stock on the date of the grant. In addition to APB Opinion No. 25, we provide the disclosures required by Statement of Financial Accounting Standards ( SFAS ) No. 123 Accounting for Stock-Based Compensation and by SFAS No. 148 Accounting for Stock-Based Compensation Transition and Disclosure.

#### Tax Valuation Allowance

The Company estimates its tax liability based on current tax laws in the statutory jurisdictions in which it operates. Because the Company conducts business on a global basis, its effective tax rate has and will continue to depend upon the geographic distribution of its pre-tax earnings (losses) among jurisdictions with varying tax rates. These estimates include judgments about deferred tax assets and liabilities resulting from temporary differences between assets and liabilities recognized for financial reporting purposes and such amounts recognized for tax purposes. The Company has assessed the realization of deferred tax assets and a valuation allowance has been established based on an assessment that it is more likely than not that realization cannot be assured. The ultimate realization of this tax benefit is dependent upon the generation of sufficient operating income in the respective tax jurisdictions.

#### **Results of Operations**

The following table sets forth amounts for certain items in our consolidated statements of operations expressed as a percentage of net revenue. The following table excludes revenue and costs related to reimbursable out-of-pocket expenses because they are not generated by the services we provide, do not yield any gross profit to us, and do not have any impact on our net income. We believe this information is useful to our investors because it presents the net revenue and expenses that are directly attributable to the services we provide to our clients and provides a more accurate picture of our operating results and margins.

#### Percentage of Net Revenue, Excluding Reimbursable Out-of-Pocket Expenses

	<u>Year Ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Net revenue	100.0%	100.0%	100.0%
Operating Expenses			
Direct	98.3%	74.0%	60.0%
Selling, general and administrative	36.4%	27.1%	20.9%
Depreciation	5.6%	4.2%	2.6%
Income (Loss) from Operations	(40.3)%	(5.3)%	16.5%
Net Income (Loss)	(31.1)%	(2.7)%	9.9%

**Year Ended December 31, 2004 Compared With Year Ended December 31, 2003**

Net revenue for 2004 decreased 35% to \$13.6 million as compared to \$20.8 million for 2003. The decrease in net revenue was a result of a lower than anticipated level of, and delay in obtaining, new business awards as well as the fact that several projects were winding down as they entered the later stages of their development schedules. Also reducing net revenue were increases in the estimate of the cost to complete for several projects. New business awards and changes of scope for 2004 were approximately \$21.5 million as compared to approximately \$21.7 million for 2003, an decrease of 1%. If we are not able to increase our level of new business production, our business, financial condition and results of operations would be materially and adversely affected. We have announced \$2.7 million in new contracts for the current calendar year. For the year ended December 31, 2004, net revenue from our three largest clients amounted to 57% of our net revenue, with the three largest clients representing 23%, 19%, and 15% of net revenue, respectively. For the year ended December 31, 2003, net revenue from our three largest clients amounted to 69% of our net revenue, with the three largest clients representing 41%, 21%, and 7% of net revenue, respectively.

Reimbursement revenue consisted of reimbursable out-of-pocket expenses incurred on behalf of our clients. Reimbursements are made at cost, without mark-up or profit, and therefore have no impact on net income.

Direct expenses included compensation and other expenses directly related to conducting clinical studies. These costs decreased by \$2.0 million to \$13.4 million for the year ended December 31, 2004 from \$15.4 million for the year ended December 31, 2003. The decrease in direct expenses resulted principally from a reduction in the level of clinical trial studies conducted by the Company during 2004. Direct expenses as a percentage of net revenue were 98% for the year ended December 31, 2004 as compared to 74% for the year ended December 31, 2003. The increase in the ratio was principally due to the lower level of net revenue reported during 2004 against an existing base of fixed direct expenses.

Selling, general, and administrative expenses included the salaries, wages and benefits of all administrative, financial and business development personnel and all other support expenses not directly related to specific contracts. Selling, general and administrative expenses for the year ended December 31, 2004 were \$4.9 million, or 36% of net revenue, as compared to \$5.7 million, or 27% of net revenue, for the year ended December 31, 2003. The decrease of \$708 thousand primarily reflected a reduction in staffing levels. The increase as a percentage of net revenue generally reflects the impact of increased rent expense against a lower level of net revenue.

Depreciation and amortization expense decreased to \$759 thousand for the year ended December 31, 2004 from \$878 thousand for the year ended December 31, 2003, primarily as a result of a reduction in fixed asset additions during 2004.

On August 30, 2004, the Company announced that it had initiated a workforce rationalization and efficiency program to reduce its workforce and cost of operations. The program was completed in the third quarter for a one time cost of approximately \$151 thousand which was incurred in the third quarter. The annualized benefit of the restructuring is approximately \$1.1 million.

Loss from operations increased by \$4.4 million to \$5.5 million, primarily for the reasons noted in the preceding paragraphs.

Net interest income for the year ended December 31, 2004 was \$3 thousand compared to net interest income of \$4 thousand for the year ended December 31, 2003, largely the result of having more cash to invest.

## Edgar Filing: COVALENT GROUP INC - Form 10-K

The effective income tax rate (benefit) for the year ended December 31, 2004 and 2003 was (22.8)% and (49.2)%, respectively. The Company's effective tax rate in 2004 was negatively affected by the increased loss from operations and a valuation allowance against excess net operating losses that the Company was unable to carryback against prior years. The Company recorded a valuation allowance of \$704,357 for certain net income tax operating loss carryforwards.

The net loss for the year ended December 31, 2004 increased to \$(4.2) million, or \$(.32) per diluted share, as compared to \$(562) thousand, or \$(.04) per diluted share for the year ended December 31, 2003, primarily for the reasons noted above.

#### **Year Ended December 31, 2003 Compared With Year Ended December 31, 2002**

Net revenue for 2003 decreased 16% to \$20.8 million as compared to \$24.7 million for 2002. The decrease in net revenue was a result of a lower than anticipated level of, and delay in obtaining, new business awards as well as the fact that several projects were winding down as they entered the later stages of their development schedules. Also reducing net revenue were increases in the estimate of the cost to complete for several projects. New business awards and changes of scope for 2003 were approximately \$21.7 million as compared to approximately \$18.6 million for 2002, an increase of 17%. For the year ended December 31, 2003, net revenue from our three largest clients amounted to 69% of our net revenue, with the three largest clients representing 41%, 21%, and 7% of net revenue, respectively. For the year ended December 31, 2002, net revenue from our three largest clients amounted to 86% of our net revenue, with the three largest clients representing 46%, 30%, and 10% of net revenue, respectively.

Reimbursement revenue consisted of reimbursable out-of-pocket expenses incurred on behalf of our clients. Reimbursements are made at cost, without mark-up or profit, and therefore have no impact on net income.

Direct expenses included compensation and other expenses directly related to conducting clinical studies. These costs increased by \$600 thousand to \$15.4 million for the year ended December 31, 2003 from \$14.8 million for the year ended December 31, 2002. The increase in direct expenses resulted principally from higher personnel costs to handle project requirements. Direct expenses as a percentage of net revenue were 74% for the year ended December 31, 2003 as compared to 60% for the year ended December 31, 2002. The increase in the ratio was principally due to the lower level of net revenue reported during 2003 against an existing base of fixed direct expenses.

Selling, general, and administrative expenses included the salaries, wages and benefits of all administrative, financial and business development personnel and all other support expenses not directly related to specific contracts. Selling, general and administrative expenses for the year ended December 31, 2003 were \$5.7 million, or 27% of net revenue, as compared to \$5.1 million, or 21% of net revenue, for the year ended December 31, 2002. The increase of \$600 thousand primarily reflected higher rent expense. The increase as a percentage of net revenue generally reflects the impact of increased rent expense against a lower level of net revenue.

Depreciation and amortization expense increased to \$878 thousand for the year ended December 31, 2003 from \$643 thousand for the year ended December 31, 2002, primarily as a result of having a full year of depreciation expense for leasehold improvements added during late 2002.

Income from operations decreased by \$5.2 million, to a loss from operations of \$1.1 million, primarily for the reasons noted in the preceding paragraphs.

Net interest income for the year ended December 31, 2003 was \$4 thousand compared to net interest expense of \$11 thousand for the year ended December 31, 2002, largely the result of having more cash to invest.



## Edgar Filing: COVALENT GROUP INC - Form 10-K

The effective income tax rate (benefit) for the year ended December 31, 2003 and 2002 was (49)% and 40%, respectively. The 2003 credit rate reflects a loss from operations in the U.S. and positive earnings from outside the United States that still benefit from the utilization of a tax loss carryforward.

The net income (loss) for the year ended December 31, 2003 decreased to \$(562) thousand, or \$(.04) per diluted share, as compared to \$2.5 million, or \$0.19 per diluted share for the year ended December 31, 2002, primarily for the reasons noted above.

---

## Liquidity and Capital Resources

Our primary cash needs are for the payment of salaries and fringe benefits, hiring and recruiting expenses, business development costs, acquisition-related costs, capital expenditures, and facilities related expenses. Our principal source of cash is from contracts with clients. If we are unable to generate new contracts with existing and new clients and/or if the level of contract cancellations increases, revenues and cash flow will be adversely affected. Absent a material adverse change in the level of the Company's new business bookings or contract cancellations, we believe that our existing capital resources together with cash flow from operations will be sufficient to meet our foreseeable cash needs for the next twelve months. However, if we significantly expand our business through acquisitions and/or continue to incur a loss from operations we may need to raise additional funds through the sale of debt or equity securities in order to keep operating our business.

Our contracts usually require a portion of the contract amount to be paid at the time the contract is initiated. Additional payments are generally made upon completion of negotiated performance milestones, or on a regularly scheduled basis, throughout the life of the contract. Several of our older contracts contain payment schedules that are weighted towards the later stages of the contract. Accordingly, cash receipts do not necessarily correspond to costs incurred and revenue recognized. For terminated studies, 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.

Net revenue is recognized on a proportional performance basis. We typically receive a low volume of large-dollar receipts. As a result, the number of days net revenue outstanding in accounts receivable, costs and estimated earnings in excess of related billings, customer advances, and billings in excess of related costs will fluctuate due to the timing and size of billings and cash receipts. At December 31, 2004, the net days revenue outstanding was 192 days compared to 188 days at December 31, 2003. Compared to December 31, 2003, accounts receivable decreased \$499 thousand to \$5.2 million at December 31, 2004, primarily due to the timing of billings and progress payments for clinical trials. Of the accounts receivable balance at December 31, 2004, 4% of the total was over 60 days past invoice date.

Compared to December 31, 2003, costs and estimated earnings in excess of related billings on uncompleted contracts decreased \$7.1 million to \$1.7 million at December 31, 2004. The decrease primarily represents the achievement of certain billing milestones or payment schedules contained in the contracts with our clients. The balance at December 31, 2004 primarily consisted of two clinical trials, which individually constituted 64%, and 14% of the balance. These amounts are expected to be billed during 2005 as billing milestones are met. The increase in the liability account billings in excess of related costs and estimated earnings on uncompleted contracts of \$589 thousand to \$1.8 million as of December 31, 2004 from \$1.2 million as of December 31, 2003, resulted from continued progress on several contracts with billing schedules weighted toward the earlier phases of the study. The \$1.9 million decrease in customer advances to \$1.1 million as of December 31, 2004 from \$3.0 million as of December 31, 2003 resulted primarily from the net utilization of customer advances for investigator payments.

Our net cash provided by operating activities was \$704 thousand for the year ended December 31, 2004, compared with net cash provided by operating activities of \$428 thousand for the year ended December 31, 2003. The primary factors underlying this change was the decrease in our costs and estimated earnings in excess of related billings on uncompleted contracts relative to the end of the prior year and a significant increase in cash collections of receivables. Net cash used by investing activities, consisting principally of purchases of property, equipment and leasehold improvements, was \$275 thousand for the year ended December 31, 2004, compared with net cash used by investing activities of \$581 thousand for the year ended December 31, 2003. Purchases and leasehold improvements for the year ended December 31, 2004 included leasehold improvements, software and hardware, including host servers and computers for our corporate office and field-based personnel. Net cash provided by financing activities was \$621 thousand for the year ended December 31, 2004, compared with net cash provided by financing activities of \$3 thousand for the year ended December 31, 2003. The primary difference related to proceeds from the exercise of stock options. As a result of these cash flows, our cash and cash equivalents balance at December 31, 2004 was \$3.2 million as compared to \$2.1 million at December 31, 2003, an increase of \$1.1 million.

We previously maintained a demand line of credit with a bank under which maximum borrowings were the lesser of \$2.5 million or 75% of eligible accounts receivable, as defined in the loan agreement, and interest was charged at the



LIBOR Market Index Rate plus 2.65%. This line of credit expired on August 15, 2004. The Company is currently in discussions with a bank regarding a new credit facility to replace the expired one.

The Company has incurred losses in recent years. However, we believe we will be able to return to being a profitable business as a result of anticipated new business awards combined with a leaner cost structure, increased backlog and a more favorable mix of existing contracts. Management believes that cash on hand and cash from operations will be sufficient to meet the Company's obligations for the foreseeable future. In the event that we are not able to develop new business or existing contracts are terminated, there is a potential risk that the Company will not be able to meet future cash obligations. There can be no assurance that anticipated new business will be obtained and if such business is not obtained our financial results and cash flow could be adversely and materially affected.

### Off Balance Sheet Financing Arrangements

As of December 31, 2004, we did not have any off-balance sheet financing arrangements or any equity ownership interests in any variable interest entity or other minority owned ventures.

### Contractual Obligations and Commitments

For 2004, we entered into no new capital lease obligations as compared to \$123 in new capital lease obligations in 2003. These leases were recorded as assets and in general were for peripheral office equipment. We are committed under a number of non-cancelable operating leases, primarily related to office space and other office equipment.

Below is a summary of our future payment commitments by year under contractual obligations as of December 31, 2004. Actual amounts paid under these agreements could be higher or lower than the amounts shown below as a result of changes in volume and other variables:

	2005	2006	2007	2008	2009	Thereafter	Total
Obligations under capital leases	\$ 23,709	\$ 26,314	\$ 29,204	\$ 7,791	\$	\$	\$ 87,018
Operating leases	960,171	921,018	937,259	952,728	969,741	986,754	5,727,671
Employment agreement	325,000	81,250					406,250
Service agreements	1,418,609	109,840	65,120	55,432	33,479	99,319	1,781,799
<b>Total</b>	<b>\$ 2,727,489</b>	<b>\$ 1,138,422</b>	<b>\$ 1,031,583</b>	<b>\$ 1,015,951</b>	<b>\$ 1,003,220</b>	<b>\$ 1,086,073</b>	<b>\$ 8,002,738</b>

In 2005, we anticipate capital expenditures of approximately \$150,000 - \$250,000 for leasehold improvements, software applications, workstations, personal computer equipment and related assets. A significant portion of our service agreement commitments, which are primarily comprised of investigator payments, are expected to be reimbursed under agreements with clients.

### Recently Issued Accounting Standards

## Edgar Filing: COVALENT GROUP INC - Form 10-K

In January 2003, the FASB issued Financial Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities an Interpretation of ARB No. 51." FIN 46 addresses consolidation by business enterprises of variable interest entities. In December 2003, the FASB then issued FIN 46(R), "Consolidation of Variable Interest Entities an Interpretation of ARB No. 51," which replaced FIN 46. Application of FIN 46(R) was required in financial statements of public entities that have interests in variable interest entities or potential variable interest entities commonly referred to as special-purpose entities for periods ending after December 15, 2003. Application by public entities for all other types of entities are required in financial statements for periods ending after March 15, 2004. The Company had adopted both FIN 46 and FIN 46(R), and the adoption had no impact on the Company's financial position or results of operations.

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003, except as stated below and for hedging relationships designated after June 30, 2003. The provisions of SFAS No. 149 that relate to Statement 133 Implementation Issues that have been effective for fiscal quarters that began prior to June 15, 2003, should continue to be applied in accordance with their respective effective dates. The Company has not entered into any derivative transactions and therefore the adoption of this standard has not had a material impact on our financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that an issuer classify a financial instrument that is within its scope, which may have previously been reported as equity, as a liability (or an asset in some circumstances). This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. Adoption of SFAS No. 150 has not had a material impact on our financial statements. The FASB is addressing certain implementation issues associated with the application of SFAS No. 150 including those related to mandatorily redeemable financial instruments representing noncontrolling interesting subsidiaries included in consolidated financial statements. The Company will monitor the actions of the FASB and assess the impact, if any, that these actions may have on its financial statements.

In December 2004, the FASB issued SFAS 123(R), "Share-Based Payment" SFAS No. 123(R) revises SFAS 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. SFAS 123(R) will require compensation costs related to share-based payment transactions to be recognized in the financial statements. The amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. This statement is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. The Company is currently evaluating the impact from this standard on its results of operations and financial position.

#### **ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK***

##### **Market Risk**

The fair values of cash and cash equivalents, restricted cash, accounts receivable, costs and estimated earnings in excess of related billings on uncompleted contracts, accounts payable, accrued expenses and billings in excess of related costs and estimated earnings on uncompleted contracts were not materially different than their carrying amounts as reported at December 31, 2004 and December 31, 2003.

As of December 31, 2004, the Company was not a counterparty to any forward foreign exchange contracts or any other transaction involving a derivative financial instrument.

##### **Foreign Currency Exchange Risk**

The Company is exposed to foreign currency exchange risk through its international operations. For the year ended December 31, 2004, approximately 10% of our net revenue was derived from contracts denominated in 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. Contracts entered into in the U.S. are denominated in U.S. Dollars. Contracts entered into by our international subsidiary are generally denominated in pounds sterling or Euros. To date, we have not engaged in any derivative or contractual hedging activities related to our foreign exchange exposures. We believe that these exposures are limited by virtue of their size relative to our overall operations as well as the partial natural hedge afforded by our local currency expenditures to service these local currency contracts.

Assets and liabilities of the Company's international operations are translated into U.S. Dollars at exchange rates in effect on the balance sheet date and equity accounts are translated at historical exchange rates. Revenue and expense items are translated at average exchange rates in effect during the quarter. Gains or losses from translating foreign currency financial statements are recorded in other comprehensive income. The

## Edgar Filing: COVALENT GROUP INC - Form 10-K

cumulative translation adjustment included in other comprehensive income for the years ended December 31, 2004, December 31, 2003 and December 31, 2002 was \$45 thousand, \$99 thousand, and \$18 thousand, respectively.

We believe that the effects of inflation generally have not had a material adverse impact on our operations or financial condition.

---

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Our financial statements listed below are contained herein beginning at page F-1:

(a) Financial Statements

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Statements of Operations</u>	F-3
<u>Consolidated Balance Sheets</u>	F-4
<u>Consolidated Statements of Stockholders' Equity</u>	F-5
<u>Consolidated Statements of Cash Flows</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES**

Our management, including our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2004. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in this annual report on Form 10-K has been appropriately recorded, processed, summarized and reported. Based on that evaluation, our principal executive and principal financial officers have concluded that our disclosure controls and procedures are effective at the reasonable assurance level. Our management, including our principal executive and principal financial officers, has evaluated any changes in our internal control over financial reporting that occurred during the year ended December 31, 2004, and has concluded that there was no change that occurred during the year ended December 31, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The Company conducts periodic evaluations of its controls to enhance, where necessary, its procedures and controls. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.



**PART III**

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF REGISTRANT**

Information concerning Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act, is incorporated herein by reference to the similarly titled section in our definitive proxy materials for our 2005 Annual Meeting of Stockholders.

The Company has adopted a Code of Business Conduct and Ethics that applies to all of its directors, officers and employees. Additionally, it has adopted a Financial Code of Conduct for the Chief Executive Officer and the Chief Financial Officer and any persons who provide similar functions. Both documents are available for review on the Company's website at [www.covalentgroup.com](http://www.covalentgroup.com), under the Corporate Governance section. The Company intends to satisfy the applicable disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of its Codes of Conduct on its website, except as otherwise required by applicable Nasdaq requirements.

**ITEM 11. EXECUTIVE COMPENSATION**

Information concerning Executive Compensation is incorporated herein by reference to the similarly titled section in our definitive proxy materials for our 2005 Annual Meeting of Stockholders.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Information concerning Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters is incorporated herein by reference to the similarly titled section in our definitive proxy materials for our 2005 Annual Meeting of Stockholders.

The following table details information regarding the Company's existing equity compensation plans as of December 31, 2004:

**Equity Compensation Plan Information**

<b>Plan Category</b>	<b>(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights</b>	<b>(b) Weighted- average exercise price of outstanding options, warrants and rights</b>	<b>(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</b>
Equity compensation plans approved by security holders	1,481,192	3.27	1,110,603

Edgar Filing: COVALENT GROUP INC - Form 10-K

Equity compensation plans not approved by security holders

Total	1,481,192	3.27	1,110,603
-------	-----------	------	-----------

**ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS***

Information concerning Certain Relationships and Related Transactions is incorporated herein by reference to the similarly titled section in our definitive proxy materials for our 2005 Annual Meeting of Stockholders.

**ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES***

Information concerning Principal Accountant Fees and Services is incorporated herein by reference to the similarly titled section in our definitive proxy materials for our 2005 Annual Meeting of Stockholders.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) Financial Statement Schedule.

(b) Exhibits

- 3.1 Certificate of Incorporation of Covalent Group, Inc., a Delaware corporation, filed with the Secretary of State of the State of Delaware on April 16, 2002. <sup>(1)</sup>
- 3.2 Bylaws of Covalent Group, Inc., a Delaware corporation. <sup>(1)</sup>
- 10.1 Covalent Group, Inc. 2002 Equity Incentive Plan. <sup>(2)\*</sup>
- 10.2 Amended and Restated Covalent Group, Inc. 1996 Stock Incentive Plan. <sup>(3)\*</sup>
- 10.3 1995 Stock Option Plan. <sup>(4)\*</sup>
- 10.4 Lease between Dean Witter Realty Income Partnership II and Covalent Group, Inc. dated November 14, 1996. <sup>(4)</sup>
- 10.5 Fourth Amendment to Lease between FV Office Partners, L.P. (successor to Dean Witter Realty Income Partnership II) and Covalent Group, Inc. dated November 27, 2001. <sup>(5)</sup>
- 10.6 Fifth Amendment to Lease between FV Office Partners, L.P. and Covalent Group, Inc. dated December 13, 2002. <sup>(6)</sup>
- 10.7 Loan Agreement with Wachovia Bank, National Association dated June 17, 2003. <sup>(7)</sup>
- 10.8 Employment Agreement between Covalent Group, Inc. and Kenneth M. Borow, M.D. <sup>(6)\*</sup>
- 10.9 Form of Indemnification Agreement between Covalent Group, Inc., a Delaware Corporation, and its officers and directors. <sup>(8)</sup>
- 10.10 Amended and Restated Employment Agreement between Covalent Group, Inc. and Brian Dickson, M.D. <sup>(9)\*</sup>
- 10.11 Letter Agreement between Covalent Group, Inc. and Lawrence R. Hoffman<sup>(10)</sup>
- 10.10 Compensation Arrangements for Directors and Executive Officers<sup>(11)</sup>
- 21 Subsidiaries of the Registrant.
- 23 Consent of Deloitte & Touche LLP.
- 31.1 Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Principal Accounting Officer required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

---

(1) Filed as an Exhibit on Form 8-K (No. 0-21145) filed with the Securities & Exchange Commission on July 2, 2002 and incorporated herein by reference.

Edgar Filing: COVALENT GROUP INC - Form 10-K

- (2) Incorporated by reference to Appendix E of the Proxy Statement for the 2002 Annual Meeting of Stockholders.
- (3) Incorporated by reference to Annex A of the Proxy Statement for the 2000 Annual Meeting of Stockholders.

## Edgar Filing: COVALENT GROUP INC - Form 10-K

---

- (4) Filed as an Exhibit to our Annual Report on Form 10-KSB (No. 0-21145) filed with the Securities and Exchange Commission on March 30, 1998 and incorporated herein by reference.
- (5) Filed as an Exhibit to our Annual Report on Form 10-KSB (No. 0-21145) filed with the Securities and Exchange Commission on April 1, 2002 and incorporated herein by reference.
- (6) Filed as an Exhibit to our Annual Report on Form 10-KSB (No. 0-21145) filed with the Securities and Exchange Commission on March 31, 2003 and incorporated herein by reference.
- (7) Filed as an Exhibit to our Quarterly Report on Form 10-Q (No. 0-21145) filed with the Securities & Exchange Commission on August 13, 2003 and incorporated herein by reference.
- (8) Filed as an Exhibit to our Quarterly Report on Form 10-QSB (No. 0-21145) filed with the Securities & Exchange Commission on August 13, 2002 and incorporated herein by reference.
- (9) Filed as an Exhibit to our Quarterly Report on Form 10-Q (No. 0-21145) filed with the Securities & Exchange Commission on November 13, 2003 and incorporated herein by reference.
- (10) Filed as an Exhibit to our Quarterly Report on Form 10-Q (no. 0-21145) filed with the Securities & Exchange Commission on November 15, 2004 and Incorporated herein by reference.

COVALENT GROUP, INC.

CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004, 2003 and 2002

INDEX

	<u>Page</u>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Statement of Operations</u>	F-3
<u>Consolidated Balance Sheets</u>	F-4
<u>Consolidated Statement of Stockholders' Equity</u>	F-5
<u>Consolidated Statement of Cash Flows</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

F-1

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of:

Covalent Group, Inc.

Wayne, Pennsylvania

We have audited the accompanying consolidated balance sheets of Covalent Group, Inc. and subsidiaries (the Company) as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedules based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Covalent Group, Inc. and subsidiaries as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedules, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

Philadelphia, Pennsylvania

March 25, 2005



## Covalent Group, Inc.

## Consolidated Statements of Operations

	Year Ended December 31,		
	2004	2003	2002
Net revenue	\$ 13,589,614	\$ 20,835,742	\$ 24,677,061
Reimbursement revenue	5,387,731	5,793,459	4,510,425
<b>Total Revenue</b>	<b>18,977,345</b>	<b>26,629,201</b>	<b>29,187,486</b>
<b>Operating Expenses</b>			
Direct	13,360,367	15,417,144	14,817,692
Reimbursement out-of-pocket expenses	5,387,731	5,793,459	4,510,425
Selling, general and administrative	4,942,316	5,650,693	5,146,286
Depreciation and amortization	758,779	877,623	642,833
<b>Total Operating Expenses</b>	<b>24,449,193</b>	<b>27,738,919</b>	<b>25,117,236</b>
<b>Income (Loss) from Operations</b>	<b>(5,471,848)</b>	<b>(1,109,718)</b>	<b>4,070,250</b>
Interest Income	13,625	16,545	10,935
Interest Expense	(10,425)	(12,962)	(21,536)
<b>Net Interest Income (Expense)</b>	<b>3,200</b>	<b>3,583</b>	<b>(10,601)</b>
<b>Income (Loss) before Income Taxes</b>	<b>(5,468,648)</b>	<b>(1,106,135)</b>	<b>4,059,649</b>
<b>Income Tax Provision (Benefit)</b>	<b>(1,245,353)</b>	<b>(544,032)</b>	<b>1,605,335</b>
<b>Net Income (Loss)</b>	<b>\$ (4,223,295)</b>	<b>\$ (562,103)</b>	<b>\$ 2,454,314</b>
<b>Net Income (Loss) per Common Share</b>			
<b>Basic</b>	<b>\$ (0.32)</b>	<b>\$ (0.04)</b>	<b>\$ 0.19</b>
<b>Diluted</b>	<b>\$ (0.32)</b>	<b>\$ (0.04)</b>	<b>\$ 0.19</b>
<b>Weighted Average Common and Common Equivalent Shares Outstanding</b>			
<b>Basic</b>	<b>13,238,778</b>	<b>12,746,973</b>	<b>12,591,229</b>
<b>Diluted</b>	<b>13,238,778</b>	<b>12,746,973</b>	<b>13,199,483</b>

See accompanying notes to the consolidated financial statements.

## Covalent Group, Inc.

## Consolidated Balance Sheets

	December 31,	
	2004	2003
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 3,165,986	\$ 2,069,687
Restricted cash	145,612	604,185
Accounts receivable, less allowance of \$40,000 and \$0 for 2004 and 2003, respectively	5,209,950	5,709,326
Prepaid expenses and other	158,287	166,322
Prepaid taxes	1,132,315	1,267,501
Costs and estimated earnings in excess of related billings on uncompleted contracts	1,667,947	8,740,964
<b>Total Current Assets</b>	<b>11,480,097</b>	<b>18,557,985</b>
<b>Property and Equipment, Net</b>	<b>1,321,139</b>	<b>1,805,331</b>
<b>Other Assets</b>	<b>21,665</b>	<b>21,665</b>
<b>Total Assets</b>	<b>\$ 12,822,901</b>	<b>\$ 20,384,981</b>
<b>Liabilities and Stockholders Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 1,101,788	\$ 3,545,039
Accrued expenses	392,385	263,664
Obligations under capital leases	23,709	24,268
Billings in excess of related costs and estimated earnings on uncompleted contracts	1,770,275	1,181,426
Customer advances	1,080,469	3,032,758
<b>Total Current Liabilities</b>	<b>4,368,626</b>	<b>8,047,155</b>
<b>Long Term Liabilities</b>		
Obligations under capital leases	63,309	87,018
Other liabilities	581,710	698,050
Deferred income tax		211,040
<b>Total Long Term Liabilities</b>	<b>645,019</b>	<b>996,108</b>
<b>Total Liabilities</b>	<b>5,013,645</b>	<b>9,043,263</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders Equity</b>		
Common stock, \$.001 par value 25,000,000 shares authorized, 13,495,534 and 13,235,483 shares issued and outstanding respectively	13,496	13,235
Additional paid-in capital	12,017,822	11,372,674
Retained earnings (deficit)	(3,933,377)	289,918
Accumulated other comprehensive income	170,289	124,865
<b>Less:</b>	<b>8,268,230</b>	<b>11,800,692</b>

Edgar Filing: COVALENT GROUP INC - Form 10-K

Treasury stock, at cost, 152,932 shares	(458,974)	(458,974)
<b>Total Stockholders Equity</b>	<u>7,809,256</u>	<u>11,341,718</u>
<b>Total Liabilities and Stockholders Equity</b>	<u>\$ 12,822,901</u>	<u>\$ 20,384,981</u>

See accompanying notes to the consolidated financial statements.

F-4

## Covalent Group, Inc.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Number of Common Shares	Par Value	Additional Paid-In Capital	Retained Earnings (Accum. Deficit)	Accum. Other Comprehensive Income	Treasury Stock at Cost	Total Stockholders Equity
Balance at December 31, 2001	12,502,713	\$ 12,503	\$ 10,521,132	\$ (1,602,293)	\$ 8,383	\$ (50,316)	\$ 8,889,409
Net income				2,454,314			2,454,314
Other comprehensive income:							
Foreign currency translation adjustment					17,961		17,961
Total comprehensive income							2,472,275
Issuance of common shares - exercise of stock options	161,870	162	366,627				366,789
Balance December 31, 2002	12,664,583	\$ 12,665	\$ 10,887,759	\$ 852,021	\$ 26,344	\$ (50,316)	\$ 11,728,473
Net loss				(562,103)			(562,103)
Other comprehensive income:							
Foreign currency translation adjustment					98,521		98,521
Total comprehensive income							(463,582)
Issuance of common shares - exercise of stock options	570,900	570	484,915			(408,658)	76,827
Balance December 31, 2003	13,235,483	\$ 13,235	\$ 11,372,674	\$ 289,918	\$ 124,865	\$ (458,974)	\$ 11,341,718
Net loss				(4,223,295)			(4,223,295)
Other comprehensive income:							
Foreign currency translation adjustment					45,424		45,424
Total comprehensive income							(4,177,871)
Issuance of common shares - exercise of stock options	260,051	261	645,148				645,409
Balance December 31, 2004	13,495,534	\$ 13,496	\$ 12,017,822	\$ (3,933,377)	\$ 170,289	\$ (458,974)	\$ 7,809,256

See accompanying notes to the consolidated financial statements.

## Covalent Group, Inc.

## Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2004	2003	2002
<b>Operating Activities:</b>			
Net income (loss)	\$ (4,223,295)	\$ (562,103)	\$ 2,454,314
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:			
Depreciation and amortization	758,779	877,623	642,833
Changes in assets and liabilities:			
Restricted cash	458,573	(184,394)	232,256
Accounts receivable	499,376	1,877,249	(5,493,721)
Prepaid expenses and other	8,035	214,082	(83,202)
Prepaid Taxes	135,186	(1,267,501)	
Costs and estimated earnings in excess of related billings on uncompleted contracts	7,073,017	283,890	(1,706,912)
Other assets		600	15,805
Accounts payable	(2,443,251)	789,519	1,173,272
Accrued expenses	128,721	(140,071)	(157,865)
Other Liabilities	(116,340)		
Income taxes payable		(111,646)	(517,252)
Deferred taxes	(211,040)	(133,185)	100,000
Billings in excess of related costs and estimated earnings on uncompleted contracts	588,849	(636,271)	1,622,575
Customer advances	(1,952,289)	(580,098)	730,496
<b>Net Cash Provided by (Used) In Operating Activities</b>	<b>704,321</b>	<b>427,694</b>	<b>(987,401)</b>
<b>Investing Activities:</b>			
Purchases of property and equipment	(274,587)	(580,755)	(663,785)
<b>Net Cash Used In Investing Activities</b>	<b>(274,587)</b>	<b>(580,755)</b>	<b>(663,785)</b>
<b>Financing Activities:</b>			
Net repayments and borrowings under capital leases	(24,268)	(74,039)	(66,668)
Proceeds from exercise of stock options	645,409	76,827	366,789
<b>Net Cash Provided By Financing Activities</b>	<b>621,141</b>	<b>2,788</b>	<b>300,121</b>
<b>Effect of Exchange Rate Changes on Cash and Cash Equivalents</b>	<b>45,424</b>	<b>98,521</b>	<b>17,961</b>
<b>Net Increase (Decrease) In Cash and Cash Equivalents</b>	<b>1,096,299</b>	<b>(51,752)</b>	<b>(1,333,104)</b>
<b>Cash and Cash Equivalents, Beginning of Period</b>	<b>2,069,687</b>	<b>2,121,439</b>	<b>3,454,543</b>
<b>Cash and Cash Equivalents, End of Period</b>	<b>\$ 3,165,986</b>	<b>\$ 2,069,687</b>	<b>\$ 2,121,439</b>

See accompanying notes to the consolidated financial statements.



Covalent Group, Inc.

Notes to Consolidated Financial Statements

1. DESCRIPTION OF BUSINESS:

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

We are a clinical research organization 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 based in Wayne, Pennsylvania and our International operations are in Guildford, Surrey, United Kingdom.

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.

In November 2000, we established Covalent Group, Ltd., a wholly-owned subsidiary in the United Kingdom, to support existing contracts on clinical trials and expand our presence internationally. We were incorporated in August 1989 in Nevada and in June 2002, the Company changed its state of incorporation to Delaware.

The Company has incurred losses in recent years. However, we believe we will be able to return to being a profitable business as a result of anticipated new business awards combined with a leaner cost structure, increased backlog and a more favorable mix of existing contracts. Management believes that cash on hand and cash from operations will be sufficient to meet the Company's obligations for the foreseeable future. In the event that we are not able to develop new business or existing contracts are terminated, there is a potential risk that the Company will not be able to meet future cash obligations. There can be no assurance that anticipated new business will be obtained and if such business is not obtained our financial results and cash flow could be adversely and materially affected.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (generally accepted accounting principles) require management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Consolidation

The consolidated financial statements for 2004, 2003 and 2002 include our accounts and the accounts of our wholly-owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation.

Cash and Cash Equivalents

We consider all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents.

Restricted Cash

We received advance payments from one of our clients as part of a long-term contract, which includes a separate restricted cash account to be utilized for payment of investigator fees. As of December 31, 2004 and 2003, this restricted cash amount was \$146 thousand and \$604 thousand, respectively. This amount is also included in customer advances in the accompanying balance sheets.



### Revenue Recognition

The majority of our net revenue is recognized from fixed-price contracts on a proportional performance basis. To measure the performance, we compare actual direct costs incurred to estimated total contract direct costs, which is the best indicator of the performance of the contract obligations as the costs relate to the labor hours incurred to perform the service. Total direct costs are incurred for each contract and compared to estimated total direct costs for each contract to determine the percentage of the contract that is completed. This percentage is multiplied by the estimated total contract value to determine the amount of net revenue recognized. A formal project review process takes place quarterly although most projects are evaluated on an ongoing basis. Management reviews the estimated total direct costs on each contract to determine if estimated amounts are correct, and estimates are adjusted as needed. If we determine that a loss will result from the performance of a fixed-price contract, the entire amount of the estimated loss is charged against income in the period in which such determination is made. Because of the inherent uncertainties in estimating direct costs required to complete a project, particularly complex, multi-year studies, it is possible that the estimates used will change and could result in a material change to our estimates. Original estimates might also be changed due to changes in the scope of work. We attempt to negotiate contract amendments with the client to cover these 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. For terminated studies, 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.

Costs and estimated earnings in excess of related billings on uncompleted contracts represents net revenue recognized to date that is currently unbillable to the client pursuant to contractual terms. In general, amounts become billable upon the achievement of milestones or in accordance with predetermined payment schedules set forth in the contracts with our clients. Billings in excess of related costs and estimated earnings on uncompleted contracts represent amounts billed in excess of net revenue recognized at the balance sheet date.

### Reimbursable Out-of-Pocket Expenses

On behalf of our clients, we pay fees to investigators and other out-of-pocket costs for which we are reimbursed at cost, without mark-up or profit. Effective January 1, 2002, in connection with the required implementation of Financial Accounting Standards Board ( FASB ) Emerging Issues Task Force Rule No. 01-14 ( EITF 01-14 ), Income Statement Characterization of Reimbursements Received for Out-of-Pocket Expenses Incurred , out-of-pocket costs are included in Operating Expenses, while the reimbursements received are reported separately as Reimbursement Revenue in the Consolidated Statements of Operations.

As is customary in the industry, we exclude from revenue and expense in the Consolidated Statement of Operations fees paid to investigators and the associated reimbursement since we act as agent on behalf of our clients with regard to investigators. These investigator fees are not reflected in our Net Revenue, Reimbursement Revenue, Reimbursement Out-of-Pocket Expenses, and/or Direct Expenses. The amounts of these investigator fees were \$5.1 million, \$10.5 million, and \$8.1 million for the years ended December 31, 2004, 2003, and 2002 respectively.

### Accounts Receivable

Accounts receivable and costs and estimated earnings in excess of related billings on completed contracts represent amounts due from our clients who are concentrated primarily in the pharmaceutical, biotechnology and medical device industries. Included in accounts receivable are amounts due from clients in connection with unbilled out-of-pocket pass-through costs in the amount of \$150 thousand as of December 31, 2004 and \$1.3 million as of December 31, 2003.

Concentration of Credit Risk

Our accounts receivable and costs and estimated earnings in excess of related billings on uncompleted contracts are concentrated with a small number of companies within the pharmaceutical, biotechnology and medical device industries. The significant majority of this exposure is to large, well established firms. Credit

F-8

losses have historically been minimal. As of December 31, 2004, the total of accounts receivable and costs and estimated earnings in excess of related billings on uncompleted contracts was \$6.9 million. Of this amount, the exposure to our three largest clients was 55% of the total, with the three largest clients representing 34%, 11%, and 10% of total exposure, respectively. As of December 31, 2003, the total of accounts receivable and costs and estimated earnings in excess of related billings on uncompleted contracts was \$14.5 million. Of this amount, the exposure to our three largest clients was 72% of the total, with the three largest clients representing 37%, 30%, and 5% of total exposure, respectively.

#### Financial Instruments

The fair value of cash and cash equivalents, restricted cash, accounts receivable, costs and estimated earnings in excess of related billings on uncompleted contracts, accounts payable, accrued expenses and billings in excess of related costs and estimated earnings on uncompleted contracts were not materially different than their carrying amounts as reported at December 31, 2004 and December 31, 2003.

As of December 31, 2004, the Company was not a counterparty to any forward foreign exchange contracts or any other transaction involving a derivative financial instrument.

#### Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets, which range from 3 to 8 years for equipment and furniture and fixtures and the remaining lease term for leasehold improvements and assets under capital lease. Depreciation and amortization for the years ended December 31, 2004 and 2003 was \$759 thousand and \$878 thousand, respectively. Expenditures for maintenance and repairs are charged to expense as incurred. When assets are sold, retired, or fully depreciated the cost and accumulated depreciation are removed from the accounts, and any gain or loss on the sale of property and equipment is included in operations.

#### Operating Expenses

Direct expenses include amounts incurred during the period that are directly related to the management or completion of a clinical trial or related project and generally include direct labor and related benefit charges, other direct costs and certain allocated expenses. Direct costs as a percentage of net revenues tend to fluctuate from one period to another, as a result of changes in the mix of services provided and the various studies conducted during any time period. Selling, general and administrative expenses include the salaries, wages and benefits of all administrative, finance and business development personnel, and all other support expenses not directly related to specific contracts.

#### Stock-Based Compensation

The Company has adopted equity incentive plans that provide for the granting of stock options to employees, directors, advisors and consultants. We account for grants of options to employees and directors under these plans applying the intrinsic value method provided for in Accounting Principles Board ( APB ) Opinion No. 25 Accounting for Stock Issued to Employees and related interpretations. No stock-based compensation expense is reflected in net income as all options granted under the plan had an exercise price equal to the market value of the underlying common stock on the date of the grant. In addition to APB Opinion No. 25, we provide the disclosures required by Statement of Financial

Edgar Filing: COVALENT GROUP INC - Form 10-K

Accounting Standards ( SFAS ) No. 123 Accounting for Stock-Based Compensation and by SFAS No. 148 Accounting for Stock-Based Compensation Transition and Disclosure. See Note 10.

F-9

## Edgar Filing: COVALENT GROUP INC - Form 10-K

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123, Accounting for Stock-Based Compensation to stock-based employee compensation:

	Year Ended December 31,		
	2004	2003	2002
Net Income (Loss) - as reported	\$ (4,223,295)	\$ (562,103)	\$ 2,454,314
Deduct: Pro forma stock-based compensation expense determined under the fair value method, net of related tax effects	(306,769)	(477,056)	(860,285)
<b>Pro forma Net Income (Loss)</b>	<b>\$ (4,530,064)</b>	<b>\$ (1,039,159)</b>	<b>\$ 1,594,029</b>
<b>Net Income (Loss) Per Share</b>			
Basic - as reported	\$ (0.32)	\$ (0.04)	\$ 0.19
Basic - pro forma	\$ (0.34)	\$ (0.08)	\$ 0.13
Diluted - as reported	\$ (0.32)	\$ (0.04)	\$ 0.19
Diluted - pro forma	\$ (0.34)	\$ (0.08)	\$ 0.12

### Foreign Currency Translations

Assets and liabilities of the Company's international operations are translated into U.S. dollars at exchange rates in effect on the balance sheet date and equity accounts are translated at historical exchange rates. Revenue and expense items are translated at average exchange rates in effect during the year. Gains or losses from translating foreign currency financial statements are recorded in other comprehensive income. The cumulative translation adjustment included in other comprehensive income for the years ended December 31, 2004, December 31, 2003 and December 31, 2002 was \$45 thousand, \$99 thousand, and \$18 thousand, respectively.

### Income Taxes

The Company accounts for income taxes in accordance with the provisions of Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes. SFAS No. 109 requires recognition of deferred tax liabilities and assets for the future expected tax consequences of events that have been included in the financial statements or tax returns. Under this method deferred tax liabilities and assets are determined based on the difference between the financial statement tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. At December 31, 2004, the Company recorded a full valuation allowance against its net deferred tax assets and net operating loss carry-forwards given that it is more likely than not that the deferred tax asset will not be realized.

### Earnings (Loss) Per Share

Earnings (loss) per share is calculated in accordance with SFAS No. 128, Earnings Per Share. Basic earnings (loss) per share is computed by dividing net income (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed by



dividing net income (loss) by the weighted average number of common shares plus the dilutive effect of warrants and outstanding stock options under the Company's equity incentive plans. For 2004, diluted net loss per common share is the same as basic net loss per common share, since the effects of potentially dilutive securities are antidilutive.

#### Supplemental Cash Flow Information

Cash paid for income taxes net of refunds for the years ended December 31, 2004, 2003, and 2002 was \$0, \$1.0 million, and \$2.0 million, respectively. Cash paid for interest for the years ended December 31, 2004, 2003, and 2002 was \$10 thousand, \$13 thousand, and \$22 thousand, respectively. We entered into capital leases with obligations totaling \$0 thousand, \$123, and \$0 thousand during the years ended December 31, 2004, 2003, and 2002, respectively.

The acquisition of property and equipment through lease incentives totaled \$0 for year ended December 31, 2004. During 2003 and 2002 respectively, acquisition of property and equipment through lease incentives totaled \$814 thousand and \$0.

On July 31, 2003, Dr. Borow, President and Chief Executive Officer of Covalent Group, Inc., exercised an employee stock option to acquire 500,000 shares of Covalent common stock. The option had a grant date of August 6, 1998, an expiration date of August 5, 2003 and an exercise price of \$0.6875. As payment for the shares issued and related withholding taxes, Covalent Group, Inc. received from Dr. Borow 140,432 Covalent common shares that were owned by him. The shares received by the Company are included as treasury stock in our Consolidated Balance Sheet at December 31, 2004 and 2003.

#### Reclassifications

Certain prior year balances have been reclassified to conform to the current year presentation.

#### Recently Issued Accounting Standards

In January 2003, the FASB issued Financial Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities an Interpretation of ARB No. 51. FIN 46 addresses consolidation by business enterprises of variable interest entities. In December 2003, the FASB then issued FIN 46(R), Consolidation of Variable Interest Entities an Interpretation of ARB No. 51, which replaced FIN 46. Application of FIN 46(R) was required in financial statements of public entities that have interests in variable interest entities or potential variable interest entities commonly referred to as special-purpose entities for periods ending after December 15, 2003. Application by public entities for all other types of entities are required in financial statements for periods ending after March 15, 2004. The Company had adopted both FIN 46 and FIN 46(R), and the adoption had no impact on the Company's financial position or results of operations.

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003, except as stated below and for hedging relationships designated after June 30, 2003. The provisions of SFAS No. 149 that relate to Statement 133 Implementation Issues that have been effective for fiscal quarters that began prior to June 15, 2003, should continue to be applied in accordance with their respective effective dates.

## Edgar Filing: COVALENT GROUP INC - Form 10-K

The Company has not entered into any derivative transactions and therefore the adoption of this standard has not had a material impact on our financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that an issuer classify a financial instrument that is within its scope, which may have previously been reported as equity, as a liability (or an asset in some circumstances). This statement is effective for financial

F-11



instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. Adoption of SFAS No. 150 has not had a material impact on our financial statements. The FASB is addressing certain implementation issues associated with the application of SFAS No. 150 including those related to mandatorily redeemable financial instruments representing noncontrolling interests in subsidiaries included in consolidated financial statements. The Company will monitor the actions of the FASB and assess the impact, if any, that these actions may have on its financial statements.

In December 2004, the FASB issued SFAS 123(R), *Share-Based Payment*. SFAS No. 123(R) revises SFAS 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. SFAS 123(R) will require compensation costs related to share-based payment transactions to be recognized in the financial statements. The amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. This statement is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. The Company is currently evaluating the impact from this standard on its results of operations and financial position.

3. PROPERTY & EQUIPMENT:

	December 31,	
	2004	2003
Property & equipment consists of the following:		
Equipment	\$ 700,790	\$ 2,935,501
Furniture & fixtures	321,120	549,305
Leasehold improvements	1,016,581	1,168,441
Equipment under capital lease	316,265	316,265
	<u>2,354,756</u>	<u>4,969,512</u>
Accumulated depreciation	(1,033,617)	(3,164,181)
	<u>2,354,756</u>	<u>4,969,512</u>
Property and equipment, net	<u>\$ 1,321,139</u>	<u>\$ 1,805,331</u>

The Company removed from the accounts, at the end of 2004, approximately \$2,891,837 of property and equipment which was fully depreciated at the time of removal. The balance sheet and income statement impact of this removal on the net amount of property and equipment is zero for the year ended December 31, 2004. The removal of this property and equipment was a result of the Company determining that there was no future economic value of the property and equipment.

4. PREPAID EXPENSES AND OTHER:

Prepaid expenses and other includes loans to non-executive officer employees at December 31, 2004 and 2003 of approximately \$0 thousand and \$3 thousand, respectively.

5. INCOME TAXES:

The components of the income tax (benefit) provision are as follows:

	Year Ended December 31,		
	2004	2003	2002
Current:			
Federal	\$ (1,034,313)	\$ (406,859)	\$ 1,260,625
State		(3,988)	244,710
	<u>(1,034,313)</u>	<u>(410,847)</u>	<u>1,505,335</u>
Deferred:			
Federal	(192,730)	(96,103)	83,744
State	(18,310)	(37,082)	16,256

Edgar Filing: COVALENT GROUP INC - Form 10-K

	(211,040)	(133,185)	100,000
	<u>\$ (1,245,353)</u>	<u>\$ (544,032)</u>	<u>\$ 1,605,335</u>

The federal statutory income tax rate is reconciled to the effective income tax rate as follows:

	<u>Year Ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Federal statutory rate	(34.0)%	(34.0)%	34.0%
State income taxes, net of federal benefit		(3.0)%	4.2%
Adjustment to prior year accrual		(12.0)%	
Increase in valuation allowance	11.2%		
Other		(.02)%	1.2%
	<u>(22.8)%</u>	<u>(49.2)%</u>	<u>39.4%</u>

Edgar Filing: COVALENT GROUP INC - Form 10-K

The components of the net current and long-term deferred tax assets and liabilities, measured under SFAS No. 109, are as follows:

	Year Ended December 31,	
	2003	2002
Deferred Tax Asset		
Long Term contract revenue	\$	\$ 82,467
Investment valuation		96,679
Net Operating Losses	61,029	
Other		68,857
	<u>61,029</u>	<u>248,003</u>
Deferred tax liabilities		
Depreciation	(79,339)	(144,902)
Accrual	(192,730)	(447,326)
Other		
	<u>(272,069)</u>	<u>(592,228)</u>
Net deferred tax liability	<u>\$ (211,040)</u>	<u>\$ (344,225)</u>

As of December 31, 2004, the Company had federal and state net operating loss carryforwards of approximately \$1,083,000 and \$5,615,000, respectively. These net operating loss and credit carryforwards have begun to expire and will continue to expire through 2024.

	2004
Deferred tax assets:	
Net Operating loss carryforward	\$ 705,109
Depreciation	(15,936)
Accrual	15,184
Total deferred tax assets	<u>704,357</u>
Valuation allowance	704,357
Net deferred tax assets	<u>\$</u>

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amount used for income tax purposes. Based on the Company's net loss before income taxes during 2004, the Company would have recorded a larger tax benefit. However, due to the Company's recent loss history, and uncertainty regarding the realization of deferred tax assets, deferred tax assets have been fully reserved as of December 31, 2004.

6. LINE OF CREDIT:

## Edgar Filing: COVALENT GROUP INC - Form 10-K

We previously maintained a demand line of credit with a bank under which maximum borrowings were the lesser of \$2.5 million or 75% of eligible accounts receivable, as defined in the loan agreement, and interest was charged at the LIBOR Market Index Rate plus 2.65%. This line of credit expired on August 15, 2004. The Company is currently in discussions with a bank regarding a new credit facility to replace the expired one.

F-14

7. EARNINGS (LOSS) PER SHARE:

Earnings (loss) per share is calculated in accordance with SFAS No. 128, Earnings Per Share. Basic earnings (loss) per share is computed by dividing net income (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares plus the dilutive effect of outstanding stock options under the Company's equity incentive plans. For 2004 and 2003, diluted net loss per common share is the same as basic net loss per share, since the effects of potentially dilutive securities are anti-dilutive. Stock options outstanding that are not included in the table below because of their anti-dilutive effect for the year ended December 31, 2004 were 814,150, for the year ended December 31, 2003 were 1,351,946 and for the year ended December 31, 2002 were 913,400.

F-15

The net income and weighted average common and common equivalent shares outstanding for purposes of calculating net income per common share were computed as follows:

	Year Ended December 31,		
	2004	2003	2002
Net Income (Loss)	\$ (4,223,295)	\$ (562,103)	\$ 2,454,314
Weighted average number of common shares outstanding used in computing basic earnings per share	13,238,778	12,746,973	12,591,229
Dilutive effect of stock options outstanding			608,254
Weighted average shares used in computing diluted earnings per share	13,238,778	12,746,973	13,199,483
Basic earnings (loss) per share	\$ (0.32)	\$ (0.04)	\$ 0.19
Diluted earnings (loss) per share	\$ (0.32)	\$ (0.04)	\$ 0.19

#### 8. STOCKHOLDERS EQUITY:

##### Treasury Stock

We have 152,932 common shares in treasury. The shares are valued using the cost method of accounting for treasury stock.

#### 9. EXERCISE OF EMPLOYEE STOCK OPTION

On July 31, 2003, Dr. Borow, President and Chief Executive Officer of Covalent Group, Inc., exercised an employee stock option to acquire 500,000 shares of Covalent common stock. The option had a grant date of August 6, 1998, an expiration date of August 5, 2003 and an exercise price of \$0.6875. As payment for the shares issued and related withholding taxes, Covalent Group, Inc. received from Dr. Borow 140,432 Covalent common shares that were owned by him. The shares received by the Company are included as treasury stock in our Consolidated Balance Sheet at December 31, 2004 and 2003.

#### 10. STOCK-BASED COMPENSATION:

We have adopted equity incentive plans that provide for the granting of stock options to employees, directors, advisors and consultants. We account for grants of options to employees and directors under these plans applying the intrinsic value method provided for in Accounting Principles Board ( APB ) Opinion No. 25 Accounting for Stock Issued to Employees and related interpretations. No stock-based compensation expense is reflected in net income as all options granted under the plan had an exercise price equal to the market value of the underlying common stock on the date of the grant. In addition to APB Opinion No. 25, we provide the disclosures required by SFAS No. 123 Accounting for Stock-Based Compensation and by SFAS No. 148 Accounting for Stock-Based Compensation Transition and Disclosure. See Note 2 for disclosure of Pro Forma Net Income and Net Income Per Share.

## Edgar Filing: COVALENT GROUP INC - Form 10-K

For purposes of determining the pro forma amounts in Note 2, the fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,		
	2004	2003	2002
Risk-free interest rate	2.85% - 3.91%	2.11% - 3.54%	2.61% - 4.74%
Expected dividend yield			
Expected life	5 years	5 years	5 years
Expected volatility	56%	49%	58%

F-16



Based upon the above assumptions, the weighted average fair value of the stock options granted for the years ended December 31, 2004, 2003, and 2002 was \$1.56, \$1.01, and \$1.82 respectively. As of December 31, 2004, the weighted average remaining contractual life of stock options outstanding was 1.7 years. Because additional option grants are expected to be made each year, the above pro forma disclosures are not representative of pro forma effects on reported net income for future years.

#### 2002 Equity Incentive Plan

In March 2002, the Board of Directors approved the 2002 Equity Incentive Plan, which was approved by the shareholders in June 2002. Upon adoption, a total of 1,000,000 shares were available for grant under this plan. The plan provides for the granting of incentive and non-qualified stock options for the purchase of shares of common stock to directors, officers, employees, advisors and consultants, as defined under the provisions of the plan.

#### 1996 Equity Incentive Plan

The Company's 1996 Stock Incentive Plan and 1995 Stock Option Plan provide for the granting of incentive and non-qualified stock options for the purchase of shares of common stock to directors, officers, employees and consultants, as defined under the provisions of the plans. The 1996 Stock Incentive Plan was amended in 2000 to increase the number of common shares available for grant from 2,500,000 to 3,000,000. The stock incentive plan provides for the granting of incentive and non-qualified stock options for the purchase of shares of common stock to directors, employees and non-employee consultants, as defined under the provisions of the plan.

Edgar Filing: COVALENT GROUP INC - Form 10-K

Aggregate stock option activities for all plans for the years ended December 31, 2004, 2003, and 2002 were as follows:

	Number of Shares	Range of Exercise Prices per Share	Weighted Average Exercise Price per Share
Options outstanding at December 31, 2001	2,428,100	\$ 0.69 - 4.47	\$ 2.56
Granted	394,175	2.05 - 4.49	3.37
Exercised	(161,870)	1.25 - 4.38	2.25
Canceled	(256,133)	0.69 - 4.38	2.93
Options outstanding at December 31, 2002	2,404,272	\$ 0.69 - 4.49	\$ 2.68
Granted	354,000	2.05 - 2.59	2.20
Exercised	(570,900)	0.69 - 2.19	0.85
Canceled	(438,376)	1.94 - 4.47	2.78
Options outstanding at December 31, 2003	1,748,996	\$ 1.80 - 4.49	\$ 3.15
Granted	274,450	2.23 - 3.93	3.04
Exercised	(260,051)	1.94 - 2.86	2.49
Canceled	(282,203)	1.80 - 4.39	3.03
Options outstanding at December 31, 2004	1,481,192	\$ 1.80 - 4.49	\$ 3.27
Exercisable options outstanding at:			
December 31, 2002	1,403,920	\$ 0.69 - 4.49	\$ 2.33
December 31, 2003	984,225	\$ 1.80 - 4.49	\$ 3.36
December 31, 2004	1,014,711	\$ 1.80 - 4.49	\$ 3.45

The following table summarizes information regarding stock options outstanding at December 31, 2004:

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding At December 31, 2004	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price per Share	No. Exercisable December 31, 2004	Weighted Average Exercise Price
\$1.80	4,000	1.2	\$ 1.80	4,000	\$ 1.80
1.94	103,640	1.2	1.94	82,360	1.94
2.05-2.54	183,868	3.4	2.34	46,541	2.27
2.57-2.90	359,534	2.4	2.79	213,710	2.85
2.99-3.93	252,650	3.1	3.44	94,600	3.30
4.00-4.49	577,500	0.1	4.03	573,500	4.03
	1,481,192	1.7	\$ 3.27	1,014,711	\$ 3.45

As of December 31, 2004, there were 1,110,603 stock options available for grant under our stock option plans.

11. EMPLOYEE BENEFIT PLAN:

The Company sponsors a 401(k) retirement savings plan that is available to substantially all its U.S. based full-time employees who elect to participate. Effective January 1, 2003, the Company began providing a matching contribution equal to 50% on the first 2% of the participant's compensation (excluding bonus payments). In 2004 and 2003 company matching contributions were \$39 thousand and \$71 thousand, respectively. Matching contributions are determined each payroll period. The matching contribution is credited to the participant using a graded vesting schedule with six or more years of service required to become fully vested. The method for crediting vesting service is the plan year.

12. SEGMENT DISCLOSURES:

The Company has adopted the provisions of SFAS No. 131, Disclosures About Segments of an Enterprise and Related Information which establishes standards for reporting business segment information. The Company operates in one segment predominantly in the clinical research industry providing a broad range of clinical research services on a global basis to the pharmaceutical, biotechnology and medical device industries.

The following table summarizes the distribution of net revenue and contracts with significant clients:

	Year Ended December 31,					
	2004		2003		2002	
	Percentage of Revenues	Number of Contracts	Percentage of Revenues	Number of Contracts	Percentage of Revenues	Number of Contracts
Client A	23%	3	41%	12	46%	14
Client B	19	5	21	3	30	4
Client C	15	2	7	1	10	3
Top Three Clients	57%	10	69%	16	86%	21

Client A, B and C in the table above represent the three largest clients for each year, but do not necessarily represent the same client for each year shown.

The significant clients above represented 2% and 83%, respectively, of the balance of cost and estimated earnings in excess of related billings on uncompleted contracts at December 31, 2004 and 2003.

The following table summarizes the distribution of net revenues from external clients by geographical area:

	Year Ended December 31,		
	2004	2003	2002
U.S.	\$ 12,264,999	\$ 19,678,729	\$ 23,826,702
Europe	1,324,615	1,157,013	850,359
<b>Total</b>	<b>\$ 13,589,614</b>	<b>\$ 20,835,742</b>	<b>\$ 24,677,061</b>

13. CAPITAL AND OPERATING LEASE COMMITMENTS:

We entered into no new capital lease obligations during 2004. Leased equipment accounted for as a capital lease at December 31, 2004 totaled \$123,000 with associated accumulated amortization of \$43,050.

Edgar Filing: COVALENT GROUP INC - Form 10-K

Future minimum lease payments on capital lease obligations at December 31, 2004 are as follows:

For the year ending December 31:	
2005	\$ 31,704
2006	31,704
2007	31,704
2008	7,926
<b>Total</b>	<b>\$ 103,038</b>
Less amount representing interest	(16,020)
<b>Present value of capital lease payments</b>	<b>\$ 87,018</b>

We are committed under a number of non-cancelable operating leases, primarily related to office space and other office equipment. Total lease expense was \$922 thousand for the year ended December 31, 2004, \$987 thousand for the year ended December 31, 2003, and \$695 thousand for the year ended December 31, 2002.

Future minimum lease payments on operating lease obligations at December 31, 2004, are as follows:

	2005	2006	2007	2008	2009	Thereafter	Total
Operating leases	\$ 960,171	\$ 921,018	\$ 937,259	\$ 952,728	\$ 969,741	\$ 986,754	\$ 5,727,671

14. OTHER LIABILITIES

As of January 1, 2003, the Company increased by approximately 12,700 to 34,000 the amount of square feet under lease in the same building. The term of the lease was also extended to 2010 and monthly lease payments increased from \$50 thousand to \$72 thousand. As an incentive for the Company to acquire the additional space, the lessor granted the Company \$814 thousand in lease incentives that were used to pay for architectural fees, renovations and improvement costs for the new space. The lease incentives were capitalized as if the Company incurred the costs to make the improvements and are included in Property and Equipment. These assets and the related liability are amortized over the remaining life of the lease at a rate of approximately \$116 thousand per year as an additional amortization expense and a reduction in rent expense, respectively. The accounting for these lease incentives has no impact on net income, stockholders' equity or cash flow.

15. QUARTERLY FINANCIAL DATA (UNAUDITED):

	2004	For the Quarter Ended			
		March 31	June 30	September 30	December 31
Net Revenues		\$ 5,282,585	\$ 3,778,774	\$ 1,876,406	\$ 2,651,849

Edgar Filing: COVALENT GROUP INC - Form 10-K

Income (Loss) From Operations	29,665	(1,951,200)	(2,148,791)	(1,401,522)
Net Income (Loss)	27,105	(1,446,730)	(1,443,314)	(1,360,356)
Net Income (Loss) Per Common Share				
Basic	\$	\$ (0.11)	\$ (0.11)	\$ (0.10)
Diluted	\$	\$ (0.11)	\$ (0.11)	\$ (0.10)

2003

Net Revenue	\$ 6,387,062	\$ 5,732,295	\$ 3,876,593	\$ 4,839,792
Income (Loss) From Operations	806,995	110,492	(987,516)	(1,039,689)
Net Income (Loss)	482,093	70,899	(392,284)	(722,811)
Net Income (Loss) Per Common Share				
Basic	\$ 0.04	\$ 0.01	\$ (0.03)	\$ (0.06)
Diluted	\$ 0.04	\$ 0.01	\$ (0.03)	\$ (0.06)

F-20

16. COMMITMENTS AND CONTINGENCIES:

We have entered into an employment agreement with one of our officers that calls for specified minimum annual compensation of \$325,000 per year over a three-year period and includes provisions for continuation of salary upon termination as defined in the agreement.

The Company is involved in litigation and other legal matters which have arisen in the normal course of business. Although the ultimate results of these matters are not currently determinable, management does not expect that they will have a material adverse effect on the Company's consolidated financial position, results of operations or cash flows.

The contract research organization industry is subject to legislation and regulations that are revised or amended on an on-going basis. The impact of complying with such legislation and regulations could materially affect our business.

As discussed in Item. 7, and as set forth in the table below, the Company is obligated under outsourcing agreements related to certain aspects of its support functions, which are reflected as purchase obligations in the table below. Actual amounts paid under these outsourcing agreements could be higher or lower than the amounts shown below as a result of changes in volume and other variables.

<u>Contractual Obligations</u>	<u>Payments due by period</u>				
	<u>Total</u>	<u>&lt;1 Year</u>	<u>1-3 Years</u>	<u>3-5 Years</u>	<u>&gt;5 years</u>
Purchase Obligations	\$ 1,781,799	\$ 1,418,609	\$ 174,960	\$ 88,911	\$ 99,319

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**COVALENT GROUP, INC.**

Dated: March 30, 2005

By: */s/* **KENNETH M. BOROW, M.D.**  
**Kenneth M. Borow, M.D.**  
**President, Chief Executive Officer and Director**

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Dated: March 30, 2005

By: */s/* **KENNETH M. BOROW, M.D.**  
**Kenneth M. Borow, M.D.**  
**President, Chief Executive Officer and Director**

Dated: March 30, 2005

By: */s/* **LAWRENCE R. HOFFMAN**  
**Lawrence R. Hoffman**  
**Executive Vice President and Chief Financial Officer**

Dated: March 30, 2005

By: */s/* **SCOTT M. JENKINS**  
**Scott M. Jenkins**  
**Director**

Dated: March 30, 2005

By: */s/* **EARL M. COLLIER, JR.**  
**Earl M. Collier, Jr.**  
**Director**



Covalent Group, Inc.

Financial Statement Schedule

## Schedule II

## COVALENT GROUP, INC.

## VALUATION AND QUALIFYING ACCOUNTS

(IN THOUSANDS)

<u>DESCRIPTION</u>	<u>BALANCE AT BEGINNING OF PERIOD</u>	<u>ADDITIONS CHARGED TO COSTS AND EXPENSES</u>	<u>DEDUCTIONS</u>	<u>BALANCE AT END OF PERIOD</u>
<b>YEAR ENDED DECEMBER 31, 2004</b>				
Allowance for doubtful accounts	\$	\$ 301	\$ 261	\$ 40
<b>YEAR ENDED DECEMBER 31, 2003</b>				
Allowance for doubtful accounts	\$ 11	\$	\$ 11	\$
<b>YEAR ENDED DECEMBER 31, 2002</b>				
Allowance for doubtful accounts	\$ 6	\$ 5	\$	\$ 11

EXHIBIT INDEX

<b>Exhibit</b>	<b>Description</b>
21	Subsidiaries of the Registrant.
23	Consent of Deloitte & Touche LLP.
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.