Averion International Corp. Form 10KSB March 31, 2008

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 10-KSB

(Mark One)

X ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2007

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

For the transition period from to

Commission file number 000-50095

# AVERION INTERNATIONAL CORP.

(Name of Small Business Issuer in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

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

225 Turnpike Road

Southborough, Massachusetts (Address of Principal Executive Offices)

closing price of such

( NASD ) on March 17, 2008 was \$12,430,538

01772 (Zip Code)

Issuer s telephone number (508) 597-6000
Securities registered under Section 12(b) of the Exchange Act: <b>None</b>
Securities registered under Section 12(g) of the Exchange Act:
Common Stock, par value \$0.001  (Title of Class)
Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. O
Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 o No x
Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. O
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x
Revenues for the issuer s fiscal year ended December 31, 2007 were \$34,852,000.
The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price of such stock on the Over-the-Counter Bulletin Board (OTCBB) administered by the National Association of Securities Dealers

State the number of shares outstanding of each of the issuer s classes of common equity as of the latest practicable date: 625,632,455 shares of common stock, \$0.001 par value, issued and outstanding as of March 17, 2008.

Transitional Small Business Disclosure Format (Check one): Yes o No x

# FORM 10-KSB

# **INDEX**

<u>PART I</u>	3
ITEM 1. Description of Business	3
ITEM 2. Description of Property	19
ITEM 3. Legal Proceedings	19
ITEM 4. Submission of Matters to a Vote of Security Holders	19
PART II	20
ITEM 5. Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities	20
ITEM 6. Management s Discussion and Analysis or Plan of Operation	22
ITEM 7. Financial Statements	33
ITEM 8. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	37
ITEM 8A. Controls and Procedures	37
ITEM 8B. Other Information	39
PART III	39
ITEM 9. Directors, Executive Officers, Promoters, Control Persons and Corporate Governance; Compliance With Section 16(a) of the	39
Exchange Act	
ITEM 10. Executive Compensation	45
ITEM 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	50
ITEM 12. Certain Relationships and Related Transactions, and Director Independence	52
ITEM 13. Exhibits	55
ITEM 14. Principal Accountant Fees and Services	61
<u>Signatures</u>	62
1	

In this report, the terms Averion, Company, we, us, and our refer to Averion International Corp. and our consolidated subsidiaries, except where it is made clear otherwise.

#### FORWARD LOOKING STATEMENTS

This document contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act ) and Section 21E of the Exchange Act of 1934, as amended (the Exchange Act ). Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, will, may, estimate, and other similar expressions. In addition, any statements that refer to projections or other characterizations of future events or circumstances are forward-looking statements.

We wish to caution readers that these forward-looking statements are only predictions and that our business is subject to significant risks. The factors discussed herein, and other important factors, in some cases have affected, and in the future could affect, our actual results and could cause our future operating results and financial position, to differ materially from those expressed in any forward-looking statements made by us or on our behalf. Such risks and uncertainties include, without limitation:

- our ability to complete acquisitions and integrate acquired companies;
- our ability to attract and retain key personnel;
- general economic and business conditions;
- our success in attracting new business and retaining existing clients and projects;
- outsourcing trends in the pharmaceutical, biotechnology and medical device industries;
- the size, timing, duration and outcome of clinical trials;
- the impact of technological developments and competition;
- the potential of awarded contracts to be terminated early due to lack of safety or efficacy;

• the potential of awarded studies to be delayed due to product development or the FDA;
<ul> <li>our expectations and estimates concerning future financial performance and financing plans;</li> </ul>
• our ability to service our outstanding debt;
our ability to raise capital to finance our growth; and
• the impact of current, pending or future legislation and regulation on the pharmaceutical industry and other risks detailed from time to time in our filings with the Securities and Exchange Commission (SEC.)
You should read this report with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this report by these cautionary statements.
2

#### PART I

ITEM 1. DESCRIPTION OF BUSINESS
Overview
General
We are an international clinical research organization ( CRO ) focused on providing our clients with global clinical research services and solutions throughout the drug development lifecycle. We serve a variety of clients in the pharmaceutical, biotechnology and medical device industries.
Our core competencies are in strategic consulting, product agency registration support, trial design, site selection, project management, medical and site monitoring, data management, biostatistical analysis and reporting, pharmacovigilance, medical writing, and full clinical trial management and consulting services throughout the clinical trials lifecycle. We have the resources to directly implement or manage Phase I through Phase IV clinical trials and have clinical trial experience and expertise across a wide variety of therapeutic areas, including the following core focus areas: Oncology, Cardiovascular and Medical Devices.
The Company s corporate headquarters is located in Southborough, MA. We also have additional U.S. offices in New York, Maryland, and California. Outside of the United States, we have offices in Switzerland, France, the Netherlands, the United Kingdom, Poland, Russia, Israel, Germany, Austria, and Ukraine. We have additional operations in the Czech Republic, Slovakia, and Hungary.
Industry Overview

The CRO industry is highly fragmented and consists of several hundred small, limited-service providers and approximately a dozen mid-sized and large CROs with global capabilities. The industry continues to experience consolidation and, in recent years, a group of large, full-service competitors has emerged. This trend of industry consolidation appears to have created greater competition among the larger companies for clients and acquisition candidates. Continued consolidation within the CRO industry is expected to be driven by sponsor demand for full-service, deep therapeutic specialization and global reach; accelerated needs for operating infrastructure and IT systems; favorable CRO valuations; and an increased level of investor interest in the CRO sector.

The CRO industry will continue to be impacted by life sciences company outsourcing trends including, without limitation, a shift in outsourcing higher percentages of work by drug developers; a shift in the geographic allocation of outsourced work away from North America and into Europe, Asia and the rest of the world; and a growing amount of outsourced Phase IIb through Phase IIIb work. A CRO s capability, relationships, experience and pricing are expected to be the most important drivers of new business awards.

Strategy
Acquisitions
We have pursued a strategy of seeking other complimentary businesses to acquire so that we can expand our geographic presence and CRO capabilities. We believe the expansion of our business through the acquisition of established CROs enables us to provide a multitude of services sooner and more effectively than if we were to build such services organically.

Averion International Corp. was originally organized under the name Clinical Trials Assistance Corporation ( Clinical Trials ) by the filing of Articles of Incorporation with the Secretary of State of the State of Nevada on April 22, 2002. On June 14, 2004, Clinical Trials acquired IT&E International Corporation, which was engaged in the life sciences staffing services business, and amended its Articles of Incorporation to change the corporate name from Clinical Trials to IT&E International Group.

3

In November 2005, we acquired substantially all the assets of Millennix, Inc. (Millennix), a CRO based in the State of New York that provided comprehensive clinical research services for Phase I through Phase IV clinical trials in oncology (see Note 7 to our Consolidated Financial Statements). On March 2, 2006, with the written consent of holders of the majority of our shares of common stock, we reincorporated into Delaware and filed a Certificate of Incorporation to change our corporate name to IT&E International Group, Inc.

On July 31, 2006, we expanded our CRO operation through the acquisition of Averion Inc. (formerly, Boston Biostatistics, Inc), a CRO located in the Commonwealth of Massachusetts, which provided comprehensive clinical research services for Phase I through Phase IV clinical trials, with a focus on oncology, dermatology, nephrology, critical care and medical devices (see Note 6 to our Consolidated Financial Statements). The acquisition of Averion Inc. enabled us to diversify our portfolio of clinical trial support services and expertise and deepen our relationship with existing clients. In August of 2006, we expanded our CRO business into Europe with the formation of Averion Europe GmBH, which allowed us to assist our clients that wish to run clinical trials and gain access to patients internationally. On September 21, 2006, we filed an amendment to our Certificate of Incorporation to change our corporate name to Averion International Corp. Our common stock symbol was changed from ITER.OB to AVRO.OB in conjunction with the name change.

On October 3, 2007, we sold our former staffing services operating segment to members of management of that operating segment (see Note 4 to our Consolidated Financial Statements). The divestiture of our staffing services business segment enables us to focus on our core CRO business.

On October 31, 2007, we acquired Hesperion AG (Hesperion), an international CRO based in Switzerland (see Note 3 to our Consolidated Financial Statements). The acquisition of Hesperion significantly strengthened our presence in Europe and significantly improved our capabilities to compete for and to manage complex larger global clinical trials for our clients.

Global Reach

Although our immediate focus will be on the continued integration of Hesperion, as and when appropriate, we intend to continue to pursue our growth strategy to further improve our market position within the CRO industry. We expect future growth will focus on expanding, both organically and through acquisition, our global reach, particularly in Europe, Asia and Latin America. We currently have offices in 11 countries and operations through regionally-based employees in 3 additional countries.

Therapeutic Focus

We will continue to leverage our experience and expertise in our key therapeutics areas, namely Oncology, Cardiovascular, and Medical Devices. We believe clients will increasingly seek depth of expertise in their product s specific therapeutic area when awarding business to a CRO.

Expansion of our Client Base

As a result of the Hesperion acquisition, our client base expanded due to the complementary nature of Averion and Hesperion client rosters. In addition, we expect the acquisition will enhance our ability to compete for larger, Phase II/III global trials which will assist us in further expanding our client-base.

#### **Clinical Research Services**

We provide a broad range of clinical research solutions to the pharmaceutical, biotechnology and medical device industries. Through our clinical research services, we provide:

- strategic planning to assist clients in formulating and negotiating the most efficient product development programs leading to maximized chances for regulatory approval;
- high-quality, professional clinical research services to our pharmaceutical, biotechnology, medical device and academic sponsor clients in focused, complex and challenging clinical development areas;

4

• methods for using changing patterns of health care delivery systems to maximize access to clinical studies by providers and patients and effectively manage drug development programs within both traditional and managed care settings;
• a professional relationship with investigative sites, sponsor clients and employees which respects their respective contributions, skills and achievements; and
<ul> <li>medical monitoring and pharmacovigilance services with specialty expertise in targeted therapy areas and data coding algorithms focused on drug safety events, trends and reporting.</li> </ul>
In addition, we are able to manage the subtleties and special requirements of all phases of clinical research, such as:
• Phase I first-time-in-man or safety studies which require meticulous safety reporting and rapid communication between sponsor and sites;
• Phase II clinical studies which emphasize the most ideal patient populations, most relevant study endpoints, best dosing strategy, and optimum follow-up interval;
• Phase III clinical studies which require accelerated investigator and patient accrual, patient retention and timely reporting of study status through centralized project management reporting tools; and
• Phase IV clinical studies which include on-going safety studies, publication support, third party databases, disease management protocols, and patient education/intervention strategies.
The information and data derived from these trials is critical for obtaining marketing approval from the Food and Drug Administration (FDA), the European Agency for the Evaluation of Medicinal Products (EMEA), and other comparable regulatory agencies.
Our employees have supported numerous regulatory submissions, applications, and registrations in both the United States and Europe. A more detailed description of our clinical research services follows.

Our biostatisticians focus on the delivery of study design consulting and statistical analyses for clients engaged in complex clinical studies for regulatory approval or health care management. Our biostatisticians execute the data analysis plan, producing report ready analysis tables, data listings and figures for interpretation and inclusion in a Sponsor s study report or regulatory submission for product approval.

Clinical Project Management

Our Clinical Project Managers (CPM) ultimately oversee the implementation and execution of a sponsor s clinical trials. The CPM is the core member of the project team acting as the main contact for the sponsor, internal team members and vendors. The CPM is responsible for study oversight, day-to-day project flow, assessment and allocation of resources and timelines, budget management and study communication. They ensure that the project team understands the study-specific needs of a project and that study-specific training is provided for team members. The CPM manages risks, challenges and changes that occur throughout the life of a clinical trial and ensures the client is apprised of all trial dynamics.

Clinical Site Monitoring

We provide comprehensive site monitoring activities including protocol compliance, accurate data capture, and GCP/ICH compliance at investigative sites in the US, Canada, Europe and the rest of world. Our monitors act as a liaison between the sites and the study team. Monitors are typically assigned to specific sites to ensure an appropriate level of support and the establishment of firm relationships with their sites. All monitoring activities are conducted under GCP/ICH Guidelines and follow FDA regulations. Monitoring visits are conducted at pre-determined intervals and/or as study needs dictate. Our monitors work closely with their assigned sites to ensure that the sites receive the training necessary to conduct their studies properly.

Data Management
Our data management group provides Case Report Form ( CRF ) development, creation of data collection guidelines, database specifications, and logic checks design at the start of the study. Data managers perform patient/CRF tracking, entry, and verification, as well as medical coding throughout the duration of the study. As a study progresses, data managers have continued involvement in the evaluation, analysis, and report review to provide insight and enhance deliverable quality. We utilize paper-based, fax-based, and EDC-based systems, or a combination of these, to accommodate sponsor or project-specific requirements.
Data Monitoring and Clinical Endpoint Committees
We facilitate Data Monitoring Committee ( DMC ) and Clinical Endpoint Committee ( CEC ) member recruitment, DMC Charter development, DMC/CEC meetings and logistics coordination, and communication with the members. We also ensure the independence of the DMC/CEC. The goal of a DMC and/or CEC is to ensure the safety of each study subject. While not all studies require a DMC, those that carry a high risk of adverse health outcomes frequently utilize DMCs for recommendations of study continuation, modification or termination at different pre-determined intervals.
Medical Monitoring
Our medical monitors work closely with the sponsor and each internal project group throughout the course of a study and/or a product s phase of development. Our medical monitors assist sponsors with: product development strategies, sponsor representation with regulatory agencies, study and protocol design, coding review, regulatory evaluation of Serious Adverse Events (SAEs), review of safety or efficacy data points, review of statistical analysis plans and literature evaluation.
Medical Writing
Our medical writers write clinical study reports, protocols, investigator brochures, non-clinical study summaries, briefing documents, informed consent documents, annual reports, integrated summaries of safety and efficacy (ISS/ISEs), abstracts/presentations and white papers/journal articles regarding the drugs, biologics, and medical devices that our clients research.
Pharmacovigilance
We offer comprehensive global pharmacovigilance solutions for clinical safety, post-market surveillance and risk management or risk minimization plans. We develop pharmacovigilance management plans that describe in detail the safety processes unique to each client s program. We also provide full database and hosting services that encompass the collection and management of safety data, from our safety surveillance system.

Quality	Assurance	and	Auditing
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We provide quality assurance services to support sponsors throughout the clinical research and development process. There are many types of audits that can occur prior to and during a clinical study that can contribute to the regulatory submission of a program. Averion s global clinical quality assurance team combines expertise with knowledge to ensure that the appropriate quality systems are in place for each client s clinical study.

Site Selection/Patient Recruitment Services

Selecting investigative sites and recruiting patients is a critical factor in meeting a clinical trial stimeline. We work closely with sponsors to understand their preferences for site selection and make recommendations based on our experience working with clinical sites. We maintain an investigator database to support these services. We also assist in the development of patient recruitment plans to support clinical sites in patient recruitment efforts.

Program Planning/Clinical Trial Design

Averion assists sponsors in examining product development strategies including screening new product concepts, evaluating pre-clinical and clinical data, determining product need, identifying regulatory hurdles, and researching current market competition. Clinical trial design begins with research on the clinical setting of the product including therapeutic principles, timelines, resources and regulatory guidance documents such as product history, background literature, competing

product labeling and summary bases for approval. We use our expertise and research to develop defined clinical trial project plans for monitoring, safety reporting, data management, analyses, and quality assurance.
Regulatory Planning and Consulting
We guide our clients through the entire regulatory process, from regulatory strategy consulting to the preparation of clinical trial authorizations, to the development of regulatory submissions/marketing authorizations and to client representation at regulatory authorities.
Strategic Research Planning
We help our clients develop the strategic plans that transition new developments in the laboratory into clinical trials with minimal time delays. By using in-house staff experience and having access to specialized services and therapeutic area thought leaders, we strategize, plan and execute first-in-man trials in order to gain a competitive edge for our sponsors and facilitate swift go/no go decisions.
Innovative Technologies
We have a dedicated group focused on providing comprehensive technology solutions for clinical trial and corporate management. We provide these solutions:
• through the assessment, qualification and management of third party technology vendors that we have formed partnerships with;
• through the evaluation, purchase and implementation of off the shelf industry specific technology products that are managed in-house; or
• through the in-house design and development of proprietary web based applications that our applications developers build, validate and customize around our internal processes.
All of these approaches support our commitment to deliver automated and efficient process management to our staff and clients. Included in our technology portfolio are both proprietary and commercially available systems such as CTMS, IVRS, safety systems, EDC, scanning and imaging systems, document management systems, web portals and a metrics suite containing reports for tracking study, staff and process efficiencies

Examples of some of these systems include:

Clinical Trial Management Systems (CTMS) and Portals

The H-System is a secure, web-based, custom-built and fully validated CTMS, designed to facilitate efficient clinical trial management by ensuring quality and consistency in project management across the company. Through a secure, password protected, web based portal, this system will ensure that all up-to-date, relevant study information is centralized and accessible on-line to all relevant parties including the sponsor and the project team. The H-System is used for both regional and global trials, with features that are specific to the region or to the entire trial. This information can be easily tracked through a robust reporting feature that provides on-demand client access to real-time data.

The Averion Information Management System (AIMS) is a secure, 24/7 web portal that offers a suite of organizational and group communication tools for information exchange within a clinical program. The portal, which is customized for each client or study, allows document and file upload and download through tiered, authenticated user groups. Security, audit, and version control functions are facilitated by access to document URLs. Communication forums, contact lists, study directories, links, calendar reminders, participation tracking and core data accessibility are additional dynamic features of AIMS. This secure portal is a critical path solution to the ongoing demand for speed, accuracy and accessibility of up to date, real time information needed in the management of clinical trials.

Data Management Systems and Remote Data Browsing (RDB)

We use Clintrial , an industry leading Oracle®-based clinical database management system for paper-based trials. We have a fully validated and CFR 21 part 11 compliant installation of Clintrial . We also have significant expertise in handling Electronic Data Capture (EDC) trials, an approach to clinical trial management that is ever increasing across the

industry. Averion is equally comfortable working with EDC and paper-based trials and will help clients evaluate when a trial is best done in EDC, paper or a hybrid data capture model.

Remote Data Browsing (RDB) is a supplement to the AIMS technology, providing a gateway for sponsors to track the progress of their study by viewing and running study reports in real-time and without the need to request such reports from the CRO. This secure, user-authenticated technology allows both clients and project teams to work more effectively in managing and tracking the clinical trial.

Interactive Voice Response System (IVRS)

Averion offers its clients multiple options for implementing an IVRS. We have and continue to work with several third party IVRS providers when requested by our clients as well as our internally developed and validated in-house IVRS.

Our internally developed IVRS is a competitive, cost-effective and automated way for sites to enroll and/or randomize their patients, order and receive shipment confirmations of drug inventory and collect patient reported outcome data (PRO). The system is sophisticated enough to ensure that upon randomization, the appropriate stratification logistics and institutional balancing are adhered to as outlined in the study protocol and that the appropriate fax and/or email confirmations are sent. Additionally, the IVRS has an alert feature that calls and notifies the patient when they fall outside of any window of adherence for providing data as specified by the study protocol.

Metrics Suite

Because we have a multitude of applications and systems built from different platforms, some of which do not interface or communicate easily with each other, we have developed our own internal central data warehouse to integrate data sources. The benefit of having a centralized data repository is that we can report data from all systems collectively without having to manage the data in a fragmented, restrictive environment. This ensures that data from multiple sources can be linked allowing metrics reports to pull information across multiple platforms into one report. The result is a metrics suite that contains a growing library of over 200 reports which are accessible to all employees via their desktops to assist in managing their study, staff, or department. These metrics provide information to help measure and track study status, staff performance and process turnaround and benchmarking.

Safety Surveillance Systems

We use ARISg , a software product purchased from Aris Global, for comprehensive adverse event tracking and reporting. It allows users to record details related to adverse events caused by drugs, biologics, medical devices or vaccines and tracks all aspects of adverse events by cycling cases through a workflow using an approval concept. The system can be easily configured around a clinical trial s specific logistics by establishing rules that conform to a sponsor s business needs. It assures secure and restricted access to the safety data by the sponsor or project team with a comprehensive audit trail facility and generates regulatory, safety and management reports for analysis. The system allows for the collection, tracking, analysis and reporting of adverse event data generated by our pharmacovigilance personnel.

#### **Contractual Arrangements**

Many of our contracts with our clients are either fixed price or fee-for-service. In cases where the contracts are fixed price, we generally bear the cost of overruns, but we benefit if the costs are lower than we anticipated. Contracts may range in duration from a few months to several years or longer depending on the nature of the work performed. In some cases, a portion of the contract fee is paid at the time the contract is executed with the balance of the contract fee payable either monthly or in installments upon the achievement of milestones over the study duration.

Our contracts generally may be terminated or reduced in scope either immediately or upon short notice. These contracts typically require payment to us of expenses to wind down a study, fees earned to date and, in some cases, a termination fee.

#### **Backlog**

Our backlog consists of anticipated net service revenue from uncompleted projects which have been authorized by the client through a written contract 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 service revenue in our consolidated statements of operations. Once contracted work begins, net service revenue is recognized over the life of the contract on a fee for service or percentage completion basis. The recognition of net service revenue reduces our backlog while the awarding of new business increases our backlog. Our backlog was approximately \$74.7 million at December 31, 2007.

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 delayed or cancelled during the course of a study. For these reasons, we might not be able to fully realize our entire backlog as net service revenue.

#### Competition

In addition to competing with a number of global, full-service CROs, we also compete with some small to medium-sized CROs, in-house research and development departments of pharmaceutical and biotechnology companies, as well as universities and teaching hospitals. The industry has few barriers to entry. Newer, smaller entities with specialty focuses, such as those aligned to a specific disease or therapeutic area compete aggressively against larger companies for clients. Increased competition may lead to price and other forms of competition that may adversely affect our operating results.

We compete on the basis of a number of factors, including reputation for on-time quality performance, expertise in specific therapeutic areas, reputation with regulatory agencies, scope of service offerings, price, technological expertise and systems, and ability to manage clinical trials both domestically and internationally.

#### Dependence on One or a Few Major Customers

Our industry continues to be dependent on the research and development efforts of pharmaceutical, biotechnology, and medical device companies as major clients. A relatively small number of clients represent, and we expect will continue to represent, a significant percentage of our net service revenue. For the period ended December 31, 2007, approximately 25% of our total net service revenues were from two (2) clients, representing 13% and 12% of total net service revenues, respectively. Similarly, a relatively small number of clients represent, and we expect will continue to represent, a significant percentage of our backlog. For the period ended December 31, 2007, approximately 27% of our total backlog was from two (2) clients, representing approximately 13.5% of backlog each. The contracts with our clients generally can be terminated on short notice. The loss of business from any significant client or our failure to continue to obtain new business would have a material and adverse effect on our business and revenues.

#### **Government Regulation**

The clinical investigation of new drugs, biologics, and medical devices is highly regulated by government agencies. Consequently, the services we provide for our clients must comply with relevant laws and regulations, and we believe we are, and have been, compliant with such laws and regulations.

Clinical research services provided by Averion in the United States are subject to ongoing FDA regulation. Prior to commencing human clinical trials in the United States, a company developing a new drug must file an Investigational New Drug application ( IND ) with the FDA. For medical devices, an Investigational Device Exemption ( IDE ) needs to be filed. The IND must include information about animal toxicity and distribution studies, manufacturing and control data, stability data and a detailed plan, or study protocol, for the proposed clinical trial of the drug or biologic in humans. If the FDA does not object within 30 days after the IND is filed, human clinical trials may begin. A similar process applies for the IDE. The study protocol will also be reviewed and approved by the institutional review board ( IRB ) in each institution in which a study is conducted, and the IRB may impose additional requirements on the way in which the study is conducted in its institution.

Human trials usually start on a small scale to assess safety and then expand to larger trials to test efficacy along with safety in the target population. The trials are generally conducted in three phases, which sometimes overlap, although the FDA may require a fourth phase as a condition of approval. After the successful completion of the first three clinical phases, a company requests approval for marketing its product by submitting a new drug application, or NDA. The NDA is a comprehensive, multi-volume filing that includes, among other things, the results of all pre-clinical and clinical studies, information about how the product will be manufactured and tested, additional stability data and proposed labeling. The FDA is review can last from six months to many years, with the average review lasting 18 months. Once the NDA is approved, the product may be marketed in the United States subject to any conditions imposed by the FDA. The Centers for Medicare & Medicaid Services (CMS) must approve the product for the client to get reimbursed from third party payers. There is no guarantee that an FDA approved product will be approved for reimbursement by CMS or other reimbursement agencies.

We must conform to the Good Clinical Practice (GCP) and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) regulatory requirements that are designed to ensure the quality and integrity of the clinical studies used to support the submission. To help ensure compliance with these regulations, we have an established quality assurance function to monitor ongoing compliance by auditing test data and conducting regular inspections of testing procedures and facilities. The FDA and many other regulatory agencies require that study results submitted to such agencies be based on studies conducted in accordance with GCP.

Effective as of May 1, 2004, the European Union ( EU ) established the Clinical Trials Directive (the Directive ) in an attempt to harmonize the regulatory requirements for the conduct of clinical trials throughout the member states of the EU. The Directive requires sponsors of clinical trials to submit formal applications to national ethics committees and regulatory authorities prior to the initiation of clinical trials in any of the 27 member states of the EU. Clinical trials in the EU are expected to be carried out in compliance with GCP requirements. The international regulatory approval process involves risks and potential delays similar to those associated with the United States FDA approval process.

#### **Employees**

At December 31, 2007, we had at total of 406 employees. Approximately, 45% of our employees are located in the United States and 55% are located throughout the rest of the world, primarily in Europe. Additionally, we utilize the services of outside consultants who work as independent contractors to supplement our employee base on an as needed basis. At December 31, 2007, we utilized the services of approximately 45 outside consultants. None of our employees are subject to a collective bargaining agreement. We believe that our relations with our employees are good.

10

#### RISK FACTORS

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

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

#### RISKS RELATED TO OUR BUSINESS

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

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

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

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

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

Our contracts generally may be terminated or reduced in scope either immediately or upon short notice. Clients may terminate or delay their contracts for a variety of reasons, including, but not limited to, the failure of products to satisfy safety requirements, unexpected or undesired clinical results relating to safety, merger or potential merger-related activities, client budget constraints, the client s decision to terminate the development of a particular product or to end a particular study, insufficient patient enrollment in a study, insufficient investigator recruitment, manufacturing problems resulting in shortages of the product, or our failure to perform our obligations under the contract. This risk of loss or delay of contracts potentially has greater effect as we pursue larger outsourcing arrangements with global pharmaceutical companies. Also, over

the past several years we have observed that clients may be more willing to delay, cancel or reduce contracts more rapidly than in the past. If this trend continues, it could become more difficult for us to balance our resources with demands for our services and our financial results could be materially and adversely affected.

In addition, companies may proceed with fewer clinical trials or conduct them without assistance of 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 a terminated project, as well as all fees earned by us up to the time of termination. The loss, reduction in scope, or delay of a significant contract, or the loss or delay of multiple contracts, could materially and adversely affect our business, results of operations and financial condition. To counter this potential downside, we maintain an aggressive posture in soliciting and generating new opportunities.

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

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

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

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

We are significantly influenced by our directors and executive officers.

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

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

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

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

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

- our clients reduce their research and development expenditures or reduce the rate of growth in their research and development expenditures;
- consolidation in the pharmaceutical, biotechnology or medical device industries leads to a smaller client base for us;

- one or more significant studies are terminated as a result of the failure of the product to satisfy safety requirements, unexpected or undesired clinical results, or other reasons; or
- our clients businesses experience financial problems or are affected by a general economic downturn.

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

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

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

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

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

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

Our quarterly and annual operating results have varied and will continue to vary in the future as a result of a variety of factors. We incurred net operating losses of \$2,196,000 and \$4,663,000 for the years ended December 31, 2007 and 2006, respectively. Factors that can cause these variations in our operating results include:

- the level of new business authorizations in a particular quarter or year;
- the timing of the initiation, progress, or cancellation of significant projects;
- the mix of services offered in a particular quarter or year;
- the timing of the opening of new offices;
- the costs and the related financial impact of acquisitions;

•	the timing of internal expansion;
•	the timing and amount of costs associated with integrating acquisitions;
•	the amount of effort necessary to integrate operations;
• the	the timing and amount of startup costs incurred in hiring and training staff on new projects or in connection with introduction of new products, services or subsidiaries; and
•	the incurrence of debt and certain costs associated with such debt.
Man	y of these factors, such as the initiation of new projects between quarters or years, are beyond our control.
loss oper	gnificant portion of our operating costs relate to personnel. As a result, the effect on our revenues of the timing of the completion, delay or of contracts, or the progress of client projects, could cause our operating results to vary substantially between reporting periods. If our ating results do not match the expectations of securities analysts and investors as a result of these factors, the trading price of our common k will likely decrease.
Our	backlog may not be indicative of future results.
proj	December 31, 2007, our backlog was approximately \$74.7 million. Backlog consists of anticipated net service revenue from uncompleted ects which have been authorized by the client through a written contract or letter of intent. We cannot be certain that the backlog we have rted will be
	13

indicative of our future results. A number of factors may affect our backlog, including: the ability of clients to reduce or expand the size and duration of the projects (some are performed over several years); the termination or delay of projects; and a change in the scope of work during the course of a project.
Also, if clients delay projects, the projects will remain in backlog, but will not generate net service revenue at the rate originally expected. Accordingly, historical indications of the relationship of backlog to net service revenues may not be indicative of future results.
Restrictive debt covenants in our senior secured notes issued in October and November 2007 limit our operating flexibility, and all amounts outstanding under our senior secured notes may become immediately payable if we default under the senior secured notes or related documents.
To finance our recent acquisition of Hesperion, we entered into a Securities Purchase Agreement (the Debt SPA) pursuant to which we issued senior secured notes (the Senior Secured Notes) in the aggregate principal amount of Twenty Six Million Dollars (\$26,000,000) (collectively, the Senior Debt). Our Senior Debt limits our ability to finance operations, service debt or engage in other business activities that may be in our interest. Specifically, the Senior Debt restricts or limits our ability to, among other things:
• make payments, including dividends or other distributions, on our capital stock;
• incur additional indebtedness;
• sell, lease, license or dispose of any of our assets;
• make loans or investments;
• repurchase or redeem any shares of our capital stock;
• conduct future equity or debt financings; or

issue or sell securities of our subsidiaries.

Our failure to comply with the obligations under our Senior Debt may result in an event of default, which, if not cured or waived, may permit acceleration of the indebtedness under the Senior Secured Notes. In addition, we have agreed to certain financial covenants as set forth in the Senior Secured Notes. If we breach any of the financial covenants set forth in the Senior Secured Notes, we will be required to make certain payments to the holders of the Senior Secured Notes. We cannot be certain that we will have sufficient funds available to pay any accelerated indebtedness or payments due upon breach of financial covenants or that we will have the ability to refinance accelerated indebtedness on terms favorable to us.

Increased leverage may harm our results of operations and financial condition.

In addition to the outstanding Senior Secured Notes, as of December 31, 2007, we had additional notes outstanding in the aggregate principal amount of \$10.2 million. As a result, our total consolidated debt as of December 31, 2007 was approximately \$36.2 million and represents approximately 29% of our total capitalization as of that date. Our consolidated debt above includes the Senior Secured Notes at their stated amount of \$26 million and has not been reduced for the unamortized discount of \$10.6 million at December 31, 2007.

Our level of indebtedness could have important consequences, because:

- it could affect our ability to satisfy our debt and capital lease obligations;
- a substantial portion of our cash flows from operations will be dedicated to interest and principal payments on our debt, thereby reducing our ability to fund operations, working capital, capital expenditures, expansion, acquisitions, or general corporate or other purposes;
- it may impair our ability to obtain additional financing in the future;

14

• it may limit our flexibility in planning for, or reacting to, changes in our business and industry;
• it may place us at a competitive disadvantage compared to competitors that have less indebtedness; and
• it may make us more vulnerable to downturns in our business, our industry or the economy in general.
Our ability to make payments of principal and interest on our indebtedness depends upon our future performance, which will be subject to our success in obtaining new business, general economic conditions, and financial, business and other factors affecting our operations, many of which are beyond our control. We cannot give assurances that our business will generate sufficient cash flow from operations to enable us to pay our indebtedness or to fund our other needs. If we are not able to generate sufficient cash flow from operations in the future to service our indebtedness, we may be required, among other things, to:
seek additional financing in the debt or equity markets;
• refinance or restructure all or a portion of our indebtedness, including the Senior Secured Notes;
• sell assets; and/or
• reduce or delay planned expenditures on research and development and/or commercialization activities.
Any such financing, refinancing or sale of assets might not be available on economically favorable terms or at all. In addition, we cannot give assurances that any of the above actions would provide sufficient funds to enable us to service our debt.
If we do not adequately protect the confidential information of clients and other third parties in our possession, our business may suffer.
In the course of providing our services to the pharmaceutical, biotechnology and medical device industries, we may have access to proprietary and confidential information belonging to our clients. As a result, we must take steps to protect the confidential information of clients and other parties in our possession. We have entered into confidentiality and non-disclosure agreements with many of our clients, employees, contractors, and other parties with whom we conduct business, in order to limit access to and disclosure of proprietary and confidential information in our possession. Any unauthorized or inappropriate disclosure or use of such information could harm our business and reputation and could result in a claim against us for substantial damages.

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

One of the factors on which we compete is the ability to recruit independent investigators who can identify volunteers for the clinical studies we manage on behalf of our clients. These clinical trials rely upon the ready accessibility and willing participation of volunteer subjects. These subjects generally include volunteers from the communities in which the studies are conducted, which to date have provided an adequate pool of potential subjects for research studies. Some of our contracts include specific milestone payments directly tied to the recruitment of study subjects. The trials we manage and our operating results could be materially and adversely affected if we are unable to attract suitable and willing volunteers on a consistent basis.

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

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

We offer many of our services on a worldwide basis and we are therefore subject to risks associated with doing business internationally. We expect that net service revenues from international operations will increase in the future and represent a

greater percentage of total net service revenues. As a result, our future results could be negatively affected by a variety of factors, including changes in a specific country spolitical or economic conditions, potential negative consequences from changes in tax laws, difficulty in staffing and managing widespread operations, and unfavorable labor regulations applicable to our international operations.

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

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

#### RISKS RELATED TO OUR INDUSTRY

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

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

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

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

Industry trends and economic factors that affect our clients in the pharmaceutical, biotechnology and medical device industries also affect our business. Our revenues depend greatly on the expenditures made by the pharmaceutical, biotechnology and medical device industries in research and development. The practice of many companies in these industries has been to hire outside organizations like us to conduct clinical research

projects. This practice has grown significantly in the last decade, and we have benefited from this trend. However, if this trend were to change and companies in these industries were to reduce the number of research and development projects they outsource, our business could be materially and adversely affected. For example, mergers and other factors in the pharmaceutical industry appear to have historically 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.

Government regulation could adversely affect our pro-	ofitability.
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The industry standards for the conduct of clinical research and development studies are embodied in the regulations for Good Clinical Practice (GCP). The FDA and other regulatory authorities require that results of clinical trials that are submitted to such authorities be based on studies conducted in accordance with GCP. These regulations require that we, among other things, comply with the following specific requirements:

- obtain specific written commitments from the investigators;
- verify that appropriate patient informed consent is obtained;
- monitor the validity and accuracy of data;
- instruct investigators and studies staff to maintain records and reports; and
- permit appropriate governmental authorities access to data for their review.

We must also maintain reports for each study for specified periods for auditing by the study sponsor and by the FDA. We may be liable to our clients for any failure to conduct their studies properly according to the agreed upon protocol and contract. If we fail to conduct a study properly in accordance with the agreed upon procedures, we may have to repeat the study at our expense, reimburse the client for the cost of the study and pay additional damages. Further, if we fail to meet government specifications with regards to record-keeping and protocol development, it could result in a major delay for our client to obtain FDA approval for their pharmaceutical product, and even negate a multi-million dollar client study, requiring the study to be repeated. Compliance with government regulations to develop a proper study protocol and record-keeping methodologies, places a major burden on us. Failure to do so can result in loss of clients, liability to us from these clients, and loss of business.

In foreign countries, including European countries, we are also subject to government regulation, which could delay or prevent our ability to sell our services in those jurisdictions.

In order for us to market our services in Europe and some other international jurisdictions, we and our agents must obtain required regulatory registrations or approvals. We must also comply with extensive regulations regarding safety, efficacy and quality in those jurisdictions. We may not be able to obtain the required regulatory registrations or approvals, or we may be required to incur significant costs in obtaining or maintaining any regulatory registrations or approvals we receive. Delays in obtaining any registrations or approvals required to market our services, failure to receive these registrations or approvals, or future loss of previously obtained registrations or approvals would limit our ability to sell our services internationally.

#### RISKS RELATED TO AN INVESTMENT IN OUR SECURITIES

Failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price.

Our management is required to evaluate periodically the design and effectiveness of our disclosure controls and procedures and related internal controls over financial reporting. Any failure to maintain effective disclosure controls and procedures or internal controls over financial reporting could have a material adverse effect on our business, operating results and stock price.

Issuance of stock to fund our operations may dilute your investment and reduce your equity interest.

We may need to raise capital in the future or to issue additional equity securities in connection with one or more acquisitions. Any equity financing may have significant dilutive effect to stockholders and a material decrease in our stockholders—equity interest in us. We may be required to raise capital, at a time and in and amount, which are uncertain, especially under the current capital market conditions, and on undesirable terms. New sources of capital may not be available to us when we need it or may be available only on terms we would find unacceptable. If such capital is not available on satisfactory terms or is not available at all, we may be unable to continue to fully develop our business, and our operations and financial condition may be materially and adversely affected. In addition, debt financing, if obtained, could increase our expenses and would be required to be repaid regardless of operating results. Equity financing, if obtained, could result in

substantial dilution to our existing stockholders. At its sole discretion, our Board of Directors (the Board) may issue additional securities without seeking stockholder approval, and we do not know when we will need additional capital or, if we do, whether it will be available to us.

The actual or anticipated resale by the selling stockholders of shares of our common stock may cause the market price of our common stock to decline.

The public float of our common stock is small in comparison to our total shares outstanding on a fully diluted basis, which will likely result in a very thin public market for the trading of our shares if such a market develops. Limited trading in our stock will also result in a high degree of volatility in our stock price. Sales of a substantial number of shares of our common stock in the public markets, or the perception that these sales may occur, could cause the market price of our common stock to decline and could materially impair our ability to raise capital through the sale of additional equity securities or to enter into strategic acquisitions with third parties.

Moreover, actual or anticipated downward pressure on the market price of our common stock due to actual or anticipated resales of our common stock could cause some institutions or individuals to engage in short sales of our common stock, which may itself cause the market price of our common stock to decline.

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.

The application of the penny stock rules could adversely affect the market price of our common stock and increase your transaction costs to sell those shares.

As long as the trading price of our common stock is below \$5.00 per share, the open-market trading of our common stock will be subject to the penny stock rules.

The penny stock rules impose additional sales practice requirements on broker-dealers who sell securities to persons other than established clients and accredited investors (generally those with assets in excess of \$1 million or annual income exceeding \$200,000 or \$300,000 together with their spouses). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of securities and have received the purchaser s written consent to the transaction before the purchase. Additionally, for any transaction involving a

penny stock, unless exempt, the broker-dealer must deliver, before the transaction, a disclosure schedule prescribed by the SEC relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. These additional burdens imposed on broker-dealers may restrict the ability or decrease the willingness of broker-dealers to sell our common stock, and may result in decreased liquidity of our common stock and increased transaction costs for sales and purchases of our common stock as compared to other securities.

We do not plan on declaring or paying dividends.

We have never declared or paid a dividend on our capital stock, nor do we have any plans to do so in the future.

We may seek to effect a reverse stock split and the results of such a reverse stock split on the market price for our common stock are uncertain.

Our Board has approved resolutions authorizing, and our stockholders have approved, a reverse stock split of our common stock. The exact ratio of the reverse stock split would be determined by our Board, in its sole discretion. We cannot

18

predict the actual impact of a reverse stock split on the market price for our common stock. The history of similar reverse stock split actions for companies in like circumstances is varied. There is no assurance that the market price per share of our common stock after a reverse stock split will rise in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split. A number of companies that have completed reverse stock splits have experienced declines in the price of their stock after the reverse stock split. While a reverse stock split is intended to raise the market price for our common stock to a level that may be more attractive to investors and is not a reflection on our financial position, it is possible that the market price for our common stock will decline after we complete a reverse stock split. The market price of our common stock will also be based on our performance and other factors, some of which are unrelated to the number of shares outstanding. Additionally, the liquidity of our common stock could be adversely affected by the reduced number of shares that would be outstanding after a reverse stock split.

#### ITEM 2. DESCRIPTION OF PROPERTY

We do not own any real estate properties. Our executive offices are located in Southborough, MA. We lease approximately 63,900 square feet at a base rent of \$85,168 per month, commencing January 2007 through June 2010. The rent increases to \$95,714 per month for the remainder of the lease through December 2012. Our European headquarters are located in Allschwil, Switzerland. We lease approximately 35,026 square feet at a base rent of CHF 81,769 [\$72,643] per month.

The company also leases small office facilities in several other locations including: Ryebrook, NY; Irvine, CA; Gaithersburg, MD; Neu-Isenburg, Germany; Moscow, Russia; Warsaw, Poland; Hungerford, UK; Illkirch, France; Breda, Netherlands; Petah Tikvah, Israel; Vienna, Austria; and Kiev, Ukraine.

These leases all expire at various dates through 2014.

Management believes that these facilities are adequate for our current and anticipated needs.

#### ITEM 3. LEGAL PROCEEDINGS

We are involved in various legal actions arising in the normal course of our business. We believe that the outcome of these matters will not have a material adverse effect on our financial position or results of operation.

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

None.

#### **PART II**

# ITEM 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES

#### **Market for our Common Stock**

Our common stock is quoted on the OTCBB under the symbol AVRO.OB.

The following table sets forth the high and the low bid price per share quoted on the OTCBB for the periods indicated:

	Н	igh	Low
Fiscal 2007			
Quarter ended December 31, 2007	\$	0.18 \$	0.07
Quarter ended September 30, 2007	\$	0.18 \$	0.11
Quarter ended June 30, 2007	\$	0.25 \$	0.09
Quarter ended, March 31, 2007	\$	0.21 \$	0.12
Fiscal 2006			
Quarter ended December 31, 2006	\$	0.20 \$	0.11
Quarter ended September 30, 2006	\$	0.20 \$	0.11
Quarter ended June 30, 2006	\$	0.17 \$	0.08
Quarter ended March 31, 2006	\$	0.24 \$	0.11

These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

As of March 17, 2008, the last reported sales price for our common stock was \$0.07.

As of March 17, 2008 there were forty one (41) stockholders of record of our common stock. In addition, there are beneficial owners of our common stock whose shares are held in street name and, consequently, we are unable to determine the actual number of beneficial holders of our common stock.

#### **Dividend Policy**

To date, we have not paid any dividends on our common stock and do not expect to declare or pay any dividends on such common stock in the foreseeable future. Payment of any dividends will be dependent upon future earnings, if any, our financial condition, and other factors as deemed relevant by our Board.

### **Securities Authorized for Issuance Under Equity Compensation Plans**

The following table sets forth information as of December 31, 2007 related to our equity compensation plans in effect as of that date.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights  (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)		Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation				
Plans approved by security holders	63,183,086	\$ (	0.16	36,113,290
Equity Compensation Plans not approved by security holders				
Total	63,183,086	\$ (	0.16	36,113,290

20

During 2007, an additional 48,794,500 options were granted at an average exercise price of \$0.16 per share and 14,820,043 options were cancelled at an average exercise price of \$0.17 per share.

#### **Recent Sales of Unregistered Securities**

During the last fiscal year, we issued the following unregistered securities. None of these transactions involved any underwriters, underwriting discounts or commissions, except as specified below, or any public offering.

On October 31, 2007, in connection with the debt financing transaction completed to raise capital to fund the acquisition of Hesperion (the Debt Financing Transaction ), we entered into a Securities Purchase Agreement (the Debt SPA ) between us and ComVest Investment Partners II LLC, a Delaware limited liability company (<u>ComVest</u>), Cumulus Investors, LLC, a Nevada limited liability company (<u>Cum</u>ulus), and Dr. Philip T. Lavin (<u>Lavin</u> and together with ComVest and Cumulus, each a <u>Buyer</u> and collectively, the <u>Buyers</u>) pursuant to which we sold Twenty Four Million Dollars (\$24,000,000) of senior secured notes (the <u>Senior Secured Notes</u>) and issued an aggregate of one hundred fifteen million two hundred thousand (115,200,000) shares of our common stock.

On November 5, 2007, we entered into an amendment to the Debt SPA pursuant to which, the parties agreed to amend the Schedule of Buyers to add Gene Resnick, M.D., (<u>Resnick</u>), MicroCapital Fund, Ltd., a Cayman-domiciled investment corporation, and MicroCapital Fund LP, a Delaware limited partnership, as additional buyers (the <u>Additional Buyers</u>) to participate in the Second Closing in place of the Buyer originally designated to participate in the Second Closing and to join the Additional Buyers as parties to the Securities Purchase Agreement. On November 5, 2007, we sold Senior Secured Notes in the aggregate principal amount of Two Million Dollars (\$2,000,000) and issued an aggregate of nine million six hundred thousand (9,600,000) Shares to the Additional Buyers. Resnick, our Chief Medical Officer, purchased a Senior Secured Note in the principal amount of One Hundred Twenty Five Thousand Dollars (\$125,000) and was issued six hundred thousand (600,000) Shares in connection therewith.

During 2007, we issued an aggregate of 375,000 shares of our common stock to Keith Lippert and John Heilshorn, the principals of Lippert/Heilshorn & Associates, Inc., in consideration for investor and public relations services provided to the Company. An additional 125,000 shares were issued to Messrs. Lippert and Heilshorn in January 2008 in respect of services rendered in the fourth quarter of 2007.

The offers and sales of these securities were deemed to be exempt from registration under the Securities Act, in reliance on Section 4(2) of the Securities Act and/or Regulation D promulgated thereunder as transactions not involving a public offering. The recipients of the securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to share certificates issued in such transactions. All recipients had adequate access to information about us.

#### ITEM 6. MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

You should read the following discussion of our financial condition and results of operations in conjunction with the consolidated financial statements and the notes to the consolidated financial statements included elsewhere in this report.

This discussion may contain forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, such as those set forth under Risk Factors.

#### **Company Overview**

We are an international clinical research organization ( CRO ) focused on providing our clients with global clinical research services and solutions throughout the drug development lifecycle. We serve a variety of clients in the pharmaceutical, biotechnology and medical device industries.

Our core competencies are in product agency registration support, trial design, site selection, project management, medical and site monitoring, data management, biostatistical analysis and reporting, pharmacovigilance, medical writing, and full clinical trial management and consulting services throughout the clinical trials lifecycle. We have the resources to directly implement or manage Phase I through Phase IV clinical trials and have clinical trial experience and expertise across a wide variety of therapeutic areas, including the following core focus areas: Oncology, Cardiovascular and Medical Devices.

We have pursued a strategy of seeking other complimentary businesses to acquire so that we can expand our geographic presence and CRO capabilities. We believe the expansion of our business through the acquisition of established CROs enables us to provide a multitude of services sooner and more effectively than if we were to build such services organically.

Averion International Corp. was originally organized under the name Clinical Trials Assistance Corporation (Clinical Trials) by the filing of Articles of Incorporation with the Secretary of State of the State of Nevada on April 22, 2002. On June 14, 2004, Clinical Trials acquired IT&E International Corporation, which was engaged in the life sciences staffing services business, and amended its Articles of Incorporation to change the corporate name from Clinical Trials to IT&E International Group.

In November 2005, we acquired substantially all the assets of Millennix, Inc. (Millennix), a CRO based in the State of New York that provided comprehensive clinical research services for Phase I through Phase IV clinical trials in oncology. On March 2, 2006, with the written consent of holders of the majority of our shares of common stock, we reincorporated into Delaware and filed a Certificate of Incorporation to change our corporate name to IT&E International Group, Inc.

On July 31, 2006, we expanded our CRO operation through the acquisition of Averion Inc. (formerly, Boston Biostatistics, Inc), a CRO located in the Commonwealth of Massachusetts, which provided comprehensive clinical research services for Phase I through Phase IV clinical trials,

with a focus on oncology, dermatology, nephrology, critical care and medical devices. The acquisition of Averion Inc. enabled us to diversify our portfolio of clinical trial support services and expertise and deepen our relationship with existing clients. In August of 2006, we expanded our CRO business into Europe with the formation of Averion Europe GmBH, which allowed us to assist our clients that wish to run clinical trials and gain access to patients internationally. On September 21, 2006, we filed an amendment to our Certificate of Incorporation to change our corporate name to Averion International Corp. Our common stock symbol was changed from ITER.OB to AVRO.OB in conjunction with the name change.

On October 3, 2007, we sold our former staffing services operating segment to members of management of that operating segment. The divestiture of our staffing services business segment enables us to focus on our core CRO business.

On October 31, 2007, we acquired Hesperion AG ( Hesperion ), an international CRO based in Switzerland. The acquisition of Hesperion significantly strengthened our presence in Europe and significantly improved our capabilities to manage complex larger global clinical trials for our clients.

Our industry continues to be dependent on the research and development efforts of pharmaceutical, biotechnology and medical device companies as major clients, and we believe this dependence will continue. Our client list includes several large pharmaceutical and biotechnology companies. With the strategic acquisition of Hesperion Ltd., we have expanded our customer base, which has diluted some of the financial impact of having a significant portion of our revenues concentrated solely in a few key clients. For the period ended December 31, 2007, approximately 25% of our total net service revenues were from two (2) clients, representing 13%, and 12% of total net services revenues, respectively. For the period ended December 31, 2006, 40% of our total net service revenues were from two (2) clients, representing 28% and 12% of total net service revenues, respectively. Although the expansion of our client base through the acquisitions of Averion Inc. and Hesperion Ltd. has increased our revenues, the loss of business from any of our major clients could have a material adverse effect on us.

Our revenue growth has and will continue to be highly dependent on our ability to attract, develop, motivate and retain skilled professionals. We closely monitor our overall attrition rates and patterns to ensure our personnel management strategy aligns with our growth objectives. There is intense competition for professionals with the skills necessary to provide the type of services we offer. If our attrition rate increases and were to be sustained at higher levels, our growth may slow and our cost of attracting and retaining clinical professionals could increase.

#### Sources of revenue

We generate revenue by providing services to our clients located primarily in the United States and Europe. During the fiscal year ended December 31, 2007, which included two months of results from the business acquired from Hesperion, approximately 80% of our net service revenue was generated in the United States and 20% in the rest of the world. As a result of the Hesperion acquisition, we expect the percentage of our net service revenue which is generated outside the United States to increase in fiscal year 2008.

Revenue from services provided on a time-and-materials basis is derived from the number of billable hours in a period multiplied by the rates at which we bill our clients. Revenue from services provided on a fixed-price basis is recognized as efforts are expended pursuant to the percentage-of-completion method. Revenue also includes reimbursements of travel and out-of-pocket expenses with equivalent amounts of expense recorded in direct expenses.

Most of our client contracts, including those that are on a fixed-price basis, can be terminated by our clients with or without cause either immediately or on short notice. All fees for services provided by us through the date of cancellation are generally due and payable under the contract terms.

We have found there is a wide range in unit pricing from one client to another and from one engagement to another, driven by business need, delivery timeframes, complexity of the engagement, operating differences, competitive environment and engagement size (or volume). As a pricing strategy to encourage clients to increase the volume of services that we provide to them, we may, on occasion, offer discounts. We manage our business carefully to protect our overall profit margins. We find that our clients generally purchase on the basis of total value, rather than minimum cost, considering all of the factors listed above and other factors including internal therapeutic expertise and quality of work performed.

While we are subject to the effects of overall market pricing pressure, we believe that there is a fairly broad range of pricing offered by different competitors for each service we provide. Although we believe that certain larger competitors may be able to leverage economies of scale and as a result may be able to offer lower pricing for certain services, we find that our unit pricing is generally competitive with other firms in our industry.

### **Direct expenses**

Direct expenses consist primarily of compensation, related payroll taxes and fringe benefits for our project-related staff, and contracted personnel, and other expenses, including non-reimbursable travel costs, directly related to specific contracts.

23

We may need to increase the levels of our employee compensation more rapidly than in the past to remain competitive without the ability to make corresponding increases in our billing rates. Compensation increases may reduce our profit margins, make us less competitive in pricing potential projects against companies with lower cost resources and otherwise harm our business, operating results and financial condition.

Our net service revenue is affected by our ability to efficiently manage and utilize our professionals, as well as fluctuations in foreign currency exchange rates. We define utilization as the total number of days billed to a client project in a given period divided by the total available days of our professionals during that same period. We manage employee utilization by continually monitoring project requirements and timetables to staff our projects efficiently and meet our clients—needs. The number of professionals assigned to a project will vary according to the size, complexity, duration and demands of the project. An unanticipated termination of a significant project could cause us to experience a higher than expected number of unassigned professionals, thereby lowering our utilization rates.

#### SG&A expenses

Sales, general and administrative expenses (SG&A) consist primarily of payroll and related fringe benefits for all administrative, financial and business development personnel and all support and overhead expenses not related to specific contracts including commissions and share-based compensation, as well as promotion, communications, management, finance, administrative, occupancy, marketing and depreciation and amortization expenses. In the fiscal years ended December 31, 2007 and 2006, we invested in all aspects of our business, including sales, marketing, IT infrastructure, human resources programs and financial operations.

#### Other income (expense)

Other income (expense) includes interest income, interest expense, debt discount amortization and foreign currency transaction gains and losses. The functional currencies of our subsidiaries are their local currencies. Foreign currency gains and losses are generated primarily by fluctuations in local currencies (including the Euro) against the Swiss Franc and U.S. dollar and by fluctuations between the Swiss Franc and the U.S. dollar.

#### Income tax expense (benefit)

Our net income is subject to income tax in those countries in which we perform services and have operations, including Switzerland, Germany, the United Kingdom, Israel, France, Austria, Poland, Russia, the Netherlands, the Czech Republic, Slovakia, the Ukraine, Hungary and the United States. In previous years, we accumulated net operating loss carry-forwards which will be available to offset U.S. taxable income into fiscal 2025. As a result of these net operating losses, our worldwide profit has been subject to a relatively low effective tax rate as compared to the statutory rates in the countries in which we operate.

#### **Application of Critical Accounting Estimates**

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. Preparation of these financial statements requires us to make estimates and assumptions that affect the reported amount of revenue and

expenses, assets and liabilities and the disclosure of contingent assets and liabilities. We consider an accounting estimate to be critical to the preparation of our financial statements when both of the following are present:

• the estimate is complex in nature or requires a high degree of judgment

24

• the use of different estimates and assumptions could have a material impact on the consolidated financial statements
We have discussed the development and selection of our critical accounting estimates and related disclosures with the Audit Committee of our Board of Directors. Those estimates critical to the preparation of our consolidated financial statements are listed below.
Revenue Recognition
Our services are performed under both time-and-material and fixed-price arrangements. All revenue is recognized pursuant to accounting principles generally recognized in the United States of America (GAAP.) Revenue is recognized as work is performed and amounts are earned in accordance with the SEC Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition in Financial Statements, as amended by SAB No. 104, Revenue Recognition. We consider amounts to be earned once evidence of an arrangement has been obtained, services are delivered, fees are fixed or determinable and collectibility is reasonably assured. For contracts with fees billed on a time-and-materials basis, we generally recognize revenue over the period of performance.
We comply with FASB Emerging Issues Task Force Rule No. 00-21 ( EITF 00-21 ), <i>Accounting for Revenue Arrangements with Multiple Deliverables</i> , which addresses how to account for arrangements that involve the delivery or performance of multiple products, services, and/or rights to use assets. Revenue arrangements with multiple deliverables are divided into separate units of accounting if the deliverables in the arrangement meet the following criteria: (1) the delivered item has value to the client on a stand-alone basis; (2) there is objective and reliable evidence of the fair value of undelivered items; and (3) delivery of any undelivered item is probable. Arrangement consideration is allocated among the separate units of accounting based on their relative fair values, with the amount allocated to the delivered item being limited to the amount that is not contingent on the delivery of additional items or meeting other specified performance conditions.
Fixed-price contracts are accounted for under the percentage-of-completion method. Under the percentage-of-completion method, we estimate the percentage-of-completion by comparing the actual number of work hours performed or units delivered to date to the estimated total number of hours or units required to complete each engagement. The use of the percentage-of-completion method requires significant judgment relative to estimating total contract revenue and costs to completion, including assumptions and estimates relative to the length of time to complete the

We account for goodwill as an indefinite life intangible asset in accordance with Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets* (SFAS No. 142) As such, SFAS No. 142 requires that goodwill be tested for impairment at least annually and requires that any such impairment be recorded as a charge to operations. At December 31, 2007 and 2006, we had no impairment in the carrying value of our goodwill.

project, the nature and complexity of the work to be performed and anticipated changes in other contract-related costs. Estimates of total contract revenue and costs to completion are continually monitored during the term of the contract and are subject to revision as the contract progresses.

profitability to decrease. When revisions in estimated contract revenue and efforts are determined, such adjustments are recorded in the period in which they are first identified. Provisions for estimated losses on individual contracts are made in the period in which the loss first becomes known. Depending on the specific contractual provisions and nature of the deliverable, revenue may be recognized as milestones are achieved or

Unforeseen circumstances may arise during an engagement requiring us to revise our original estimates and may cause the estimated

when final deliverables have been accepted.

Goodwill

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Long	-livec	l assets

Our long-lived assets include finite-life intangible assets, property and equipment and long-term notes receivable. We evaluate the recoverability of our long-lived assets whenever events or changes in circumstances indicate that their carrying

25

amounts may not be recoverable. Such circumstances would include a significant decrease in the market price of a long-lived asset, a significant adverse change to the manner in which the asset is being used or its physical condition, or a history of operating or cash flow losses associated with the use of the asset. In addition, changes to the expected useful lives of these long-lived assets may also be an indicator of impairment. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying value of the assets exceeds the fair value of the assets and the resulting losses are included in the statement of operations.

Share-Based Compensation

Effective January 1, 2006, we adopted SFAS No. 123R, Share-Based Payment (SFAS No. 123R) using the Modified Prospective Approach. SFAS 123R revises SFAS No. 123, Accounting for Stock Based Compensation (SFAS No. 123) and supersedes Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25). SFAS No. 123R requires the costs for all share-based payments to employees, including grants of employee stock options, to be recognized in financial statements based on their fair values at grant date, or the date of later modification, over the requisite period. In addition, SFAS No. 123R requires unrecognized cost related to options vesting after the date of initial adoption to be recognized in the financial statements over the remaining requisite period.

The grant date fair value of each stock option is based on the underlying price on the date of grant and is determined using an option pricing model. The option pricing model requires the use of estimates and assumptions as to (a) the expected volatility of the price of the stock underlying the stock option (b) the expected life of the option (c) the risk free rate for the expected life of the option and (d) forfeiture rates. The Company is currently using the Black-Scholes option pricing model to determine the grant date fair value of each stock option.

Share-based compensation expense recognized during a period is based on the value of the portion of share-based awards that is ultimately expected to vest during the period. The Company uses historical data to estimate pre-vesting option forfeitures.

Expected volatility is calculated based on a blended weighted average of historical information of the Company s stock and the weighted average of historical information of similar public entities for which historical information is available. The Company will continue to use a weighted average approach using its own historical volatility and other similar public entity volatility information until historical volatility of the Company is relevant to measure expected volatility for future option grants. The expected life of the option assumption is based on the simplified or safe-haven method outlined in the SAB No. 107, *Share-Based Payment*. The risk free rate is based on the U.S. Treasury bond rate commensurate with the expected life of the option. Forfeiture rates are estimated based upon past voluntary termination behavior and past option forfeitures.

We believe there is a high degree of subjectivity involved when using option-pricing models to estimate share-based compensation under SFAS No. 123R. Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions, are fully transferable and do not cause dilution. Because our share-based payments have characteristics different from those of freely traded options and because changes in the subjective input assumptions can materially affect our estimates of fair values (such as attrition), in our opinion, existing valuation models, including Black-Scholes, may not provide reliable measures of the fair values of our share-based compensation. Consequently, there is a risk that our estimates of the fair values of our share-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, expiration, early termination, or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that is significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates

stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee share-based awards is determined in accordance with SFAS No. 123R using an option-pricing model, that value may not be indicative of the fair value observed in a market transaction between a willing buyer and willing seller. If factors change and we employ different assumptions in the application of SFAS No. 123R in future periods than those currently applied under

SFAS No. 123R and those previously applied under SFAS No. 123 in determining our pro forma amounts, the compensation expense that we record in the future under SFAS No. 123R may differ significantly from what we have reported during the fiscal years ended December 31, 2007 and 2006 and what we have reported as our pro forma expense during the period prior to adoption of SFAS No. 123R.

Income Taxes

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations in multiple jurisdictions. We record liabilities for estimated tax obligations in the United States and other tax jurisdictions. Determining the consolidated provision for income tax expense, tax reserves, deferred tax assets and liabilities and related valuation allowance, if any, involves judgment. It is our policy to file tax returns as prescribed by the tax laws of the jurisdictions in which we operate. With the exception of a notice we have received from the Internal Revenue Service concerning an audit of the 2005 tax returns of Averion Inc., we are currently not under examination by any federal, state or local taxing jurisdiction. The 2002 to 2006 tax years for which we have filed tax returns with federal, state and local taxing jurisdictions remain subject to examination. In the normal course of business, we conduct operations in various state and local taxing jurisdictions. We may have exposure for examination or tax assessment by a state or local taxing jurisdiction where we have not historically filed tax returns. We believe any such potential tax assessment would not have a material impact on our financial position or results of operations. Our overall effective tax rate fluctuates due to a variety of factors, including changes in the geographic mix or estimated level of annual pretax income, the ability to utilize our accumulated net operating loss carryforwards and newly enacted tax legislation in each of the jurisdictions in which we operate.

Applicable transfer pricing regulations require that transactions between and among our subsidiaries be conducted at an arm s-length price. On an ongoing basis we estimate an appropriate arm s-length price and use such estimate for our intercompany transactions.

On an ongoing basis, we evaluate whether a valuation allowance is needed to reduce our deferred tax assets to the amount that is more likely than not to be realized. This evaluation considers the weight of all available evidence, including both future taxable income and ongoing prudent and feasible tax planning strategies. In the event that we determine that we will not be able to realize a recognized deferred tax asset in the future, an adjustment to the valuation allowance would be made resulting in a decrease in income in the period such determination was made. Likewise, should we determine that we will be able to realize all or part of an unrecognized deferred tax asset in the future, an adjustment to the valuation allowance would be made resulting in an increase to income (or equity in the case of excess stock option tax benefits). Deferred income taxes are provided under the liability method. The liability method requires that deferred tax assets and liabilities be determined based on the difference between the financial reporting and tax bases of assets and liabilities using the tax rate expected to be in effect when the taxes will actually be paid or refunds received. In estimating future tax consequences, we generally consider all expected future events other than the enactment of changes in tax law or rates. If it is more likely than not that some portion or all of a deferred tax asset will not be realized, a valuation allowance is recorded.

#### RECENT ACCOUNTING PRONOUNCEMENTS

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN48), effective for fiscal years beginning after December 15, 2006. FIN48 prescribes a recognition threshold and measurement attribute, as well as criteria for subsequently recognizing, derecognizing, and measuring tax positions for financial statement purposes and requires companies to make disclosures about uncertain tax positions, including detailed roll-forward of tax benefits taken that do not qualify for financial statement recognition. The Company adopted FIN 48 on January 1, 2007 as required and determined that the adoption of FIN 48 did not have a material impact on the Company s financial position and results of operations.

At December 31, 2007, the Company had unrecognized federal tax benefits of \$7.5 million. The Company has a valuation allowance against the full amount of its net deferred taxes in the United States. It is the Company s policy to provide a valuation allowance against deferred tax assets when it is more likely than not that some portion, or all, of its deferred tax assets will not be realized. Future changes to the unrecognized tax benefit will not have a material impact on the Company s effective tax rate due to the existence of the full valuation allowance. The Company does not reasonably anticipate the unrecognized tax benefit to change significantly within the next twelve months.

It is the Company s policy to file its tax returns as prescribed by the tax laws of the jurisdictions in which it operates. The Company is currently not under examination by any federal, state or local taxing jurisdiction. The 2002 to 2006 tax years for which the Company has filed tax returns with federal, state and local taxing jurisdictions remain subject to examination. In the normal course of business, the Company conducts operations in various state and local taxing jurisdictions. The Company may have exposure for examination or tax assessment by a state or local taxing jurisdiction where it has not historically filed tax returns. The Company believes any such potential tax assessment would not have a material impact on the financial position or the results of operations of the Company.

The Company s policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of the date of adoption of FIN 48, the Company did not have any accrued interest or penalties associated with any unrecognized tax benefits, nor was any interest expense recognized during the period ended December 31, 2007.

In December 2007, the EITF of the FASB reached a consensus on issue No. 07-1, *Accounting for Collaborative Arrangements* ( EITF 07-1 ). EITF 07-1 concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and its terms, the nature of the entity s business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement balances related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company does not expect EITF 07-1 to have a significant impact on the consolidated financial statements of the Company.

In December 2007, the FASB issued Statement No. 141-R, *Business Combinations* (SFAS No. 141-R). SFAS No. 141-R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, which would be business combinations in the year ending December 31, 2009 for the Company. The objective of SFAS No. 141-R is to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. The Company does not expect SFAS No. 141-R to have a significant impact on the consolidated financial statements of the Company.

In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, Effective Date of FASB Statement No. 157 (FSP FAS 157-2). FSP FAS 157-2 defers the effective date provision of SFAS No. 157. As a result of the issuance of FSP FAS 157-2, the provisions of SFAS No. 157 are effective for fiscal years beginning after November 15, 2008. We are currently evaluating the impact of adopting SFAS No. 157 on our financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS No. 159), which provides companies with an option to report selected financial assets and liabilities at fair value. This standard also establishes presentation and disclosure requirements to facilitate comparisons between companies that choose different measurement attributes for similar assets and liabilities. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of adopting SFAS No. 159; however, we do not expect it to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* (SFAS No. 160). SFAS No. 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008, which for the Company is the year ending December 31, 2009 and the interim periods within that fiscal year. The objective of this SFAS No. 160 is to improve the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements. SFAS No. 160 currently does not impact the Company as it has full controlling interest of all of its subsidiaries.

#### **Results of Operations**

Year Ended December 31, 2007 Compared with Year Ended December 31, 2006

The following table presents an overview of our results of continuing operations for the fiscal years ended December 31, 2007 and 2006.

	December 3	1, 2007	December 31, 2006			
(in thousands)	\$	% of revenue	\$	% of revenue		
Net service revenue	\$ 34,852	100% \$	13,251	100%		
Direct expenses	20,714	59%	8,246	62%		
SG&A expense	13,811	40%	8,869	67%		
Depreciation and amortization	1,796	5%	799	6%		
Restructuring and related charges	727	2%				
Net operating loss	(2,196)	(6)%	(4,663)	(35)%		
Other income (expense)	(1,398)	(4)%	24	NM		
Loss before income tax expense	(3,594)	(10)%	(4,639)	(35)%		
Income tax expense	298	1%				
Net loss from continuing						
operations	\$ (3,892)	(11)%\$	(4,639)	(35)%		

Net service revenue during 2007 increased \$21.6 million to \$34.8 million as compared to \$13.2 million during 2006, an increase of 163%. The increase in net service revenues in 2007 was primarily related to the inclusion of a full year of net service revenue associated with the business acquired from Averion Inc. and the completion of the Hesperion acquisition on October 31, 2007 which consequently contributed \$7.7 million in net service revenue, comprising two months of operations.

Direct expenses increased \$12.5 million for the year ended December 31, 2007 to \$20.7 million from \$8.2 million for the year ended December 31, 2006. The increase in direct expenses was primarily due to the inclusion of a full year of personnel costs associated with the net service revenue acquired from Averion Inc. and the acquisition of Hesperion, which contributed an additional \$2.9 million in direct expenses. As a percentage of net service revenues, direct expenses decreased to 59% during 2007 from 62% during 2006. The improvement in direct expenses as a percentage of net service revenues was principally the result of an increase in the number of clinical studies, primarily obtained through the acquisitions of Averion Inc. and Hesperion, and an associated increase in staff utilization on clinical study activities.

Selling, general and administrative expenses for the year ended December 31, 2007 were \$13.8 million or 39.6% of net service revenue, as compared to \$8.9 million or 66.9% of net service revenue for the year ended December 31, 2006. The increase in expenses of \$4.9 million primarily reflected the increased cost structure associated with the Averion Inc. acquisition and an increase in costs associated with supporting a larger, international public company. The improvement in selling, general, and administrative expenses as a percentage of net service revenue during 2007 as compared to 2006 was principally the result of increased net service revenue which offsets the effects of a 56% increase in selling, general and administrative expenses.

We implemented plans to reduce our workforce in order to improve operating efficiencies and reduce costs across our business. We expect these changes to allow us to better compete in the marketplace.

Under such plans, our active clinical research employee base declined by approximately 13%. We incurred \$0.7 million of restructuring charges for associated pay and benefits for affected personnel during 2007. During this period, we made associated payments of \$0.6 million and had payment obligations of \$0.1 million as of December 2007. We expect to make the remainder of the associated payments over the next three months. Through these reductions, we expect to generate savings in annualized operating expenses of approximately \$2.5 million.

Prior to divesting our staffing services segment on October 3, 2007, we also implemented plans to restructure our staffing services segment in order to improve operating efficiencies and reduce costs. Under such plan, we reduced our staffing services employee base. We incurred \$0.3 million of restructuring charges included in discontinued operations for associated pay and benefits for affected staffing services personnel during 2007. As of December 2007, we had payment obligations of \$0.1 million. We expect to make the associated payments over the next eight months.

Depreciation expense increased to \$0.8 million during 2007 as compared to \$0.3 million during 2006. This increase was primarily the result of the additional expense associated with depreciation of the fixed assets acquired from Averion Inc.

Amortization expense increased to \$1.0 million during 2007 as compared to \$0.5 million during 2006, primarily due to a full year s amortization of the values assigned to finite life intangibles acquired from Averion Inc. as well as two months of amortization of the values assigned to finite life intangibles acquired in connection with the Hesperion acquisition.

Interest expense increased to \$0.8 million during 2007 as compared to \$0.3 million during 2006, due to the increase in the number of days interest accrued on the principal amount outstanding on the notes issued in connection with the Averion Inc. merger. Additionally, there was interest expense of \$0.1 million in 2007 related to the \$26 million in Senior Secured Notes and the note issued to Cerep in connection with the Hesperion transaction. Interest income during 2007 was \$0.3 million, which was unchanged versus 2006.

During 2007, debt discount amortization expenses totaled \$0.6 million as compared to zero in 2006. The principal amounts of the Senior Secured Notes and the Cerep Note have been discounted to fair value and are being accreted to face value over the term of the notes.

During 2007, other expenses of \$0.3 million, primarily representing foreign exchange losses, were incurred over and above the expenses incurred during 2006.

The net loss from continuing operations for the year ended December 31, 2007 decreased to \$3.9 million, as compared to a net loss of \$4.6 million for the year ended December 31, 2006. The lower net loss was a result of the aforementioned increase in revenues and operating efficiencies achieved partially offset by the increase in other expense.

#### **Liquidity and Capital Resources**

We have financed our growth and operations from the issuances of debt and equity, and cash flows from operations. The CRO industry is generally not capital intensive. Our principal source of cash for operations 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 our 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 operating cash needs for the next twelve months. However, if we engage in further business expansion 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.

At December 31, 2007 we had cash and cash equivalents of \$7.4 million as compared to \$8.1 million at December 31, 2006, a decrease of \$0.7 million. Approximately \$1.9 million in cash was located outside of the United States at December 31, 2007.

Our primary operating cash needs are for the payment of salaries and fringe benefits, hiring and recruiting expenses, business development costs, capital expenditures, and facilities-related expenses.

Our net cash used by operating activities was \$2.5 million for the year ended December 31, 2007, compared with net cash used by operating activities of \$0.9 million for the year ended December 31, 2006. The primary factors contributing to the increase in our use of cash were increases in our accounts receivable and unbilled accounts receivable balances of \$0.9 million and \$0.6 million, respectively, coupled with decreases in deferred revenue and other liabilities of \$2.4 million and \$0.8 million, respectively. These uses were partially offset by an increase to our accounts payable balance of \$1.2 million as compared to the prior year. In addition, noncash adjustments during 2007 to our net loss increased \$1.9 million as compared to the prior year. These were primarily comprised of increases to depreciation and amortization of \$0.9 million as we included a full year of amortization of our finite life intangibles in 2007, the amortization of our original issue debt discount of \$0.6 million representing two months amortization of the discount associated with the issuance of our Senior Secured Notes in conjunction with the Hesperion financing, and an increase in stock-based compensation and stock issuance costs and the allowance for doubtful accounts of \$0.3 million and \$0.1 million, respectively.

Net cash used by investing activities was \$22.6 million for the year ended December 31, 2007, compared with net cash used by investing activities of \$5.4 million for the year ended December 31, 2006. On October 31, 2007, we paid approximately \$22.6 million, net of cash acquired, for the acquisition of Hesperion. On October 2, 2007, we received approximately \$0.6 million in net benefit from the sale of our staffing business. On July 31, 2006, we paid \$5.1 million in cash, net of cash acquired, and other consideration for Averion Inc. In addition, we paid approximately \$0.3 million more during 2007 as compare to 2006 for capital expenditures, relating primarily to a new ERP system implemented in the US.

Net cash provided by financing activities was \$24.2 million for the year ended December 31, 2007, compared with net cash provided by financing activities of \$8.0 million for the year ended December 31, 2006. During October and November of 2007, we received \$26.0 million in aggregate gross proceeds from the issuance of debt and equity to finance our Hesperion acquisition. On July 31, 2006, we received aggregate gross proceeds of \$5.0 million from the sale of 5,000 shares of Series D Convertible Preferred Stock to ComVest. The proceeds were used to acquire Averion Inc. Additionally, on November 28, 2006, the Company received \$3.6 million in aggregate proceeds from the sale of 27,333,329 shares of our common stock at a purchase price of \$0.15 per share, in conjunction with the Financing Transaction. Pursuant to the terms of the Placement Agency Agreement, we paid a cash fee equal to 7.5% of the aggregate gross proceeds or \$0.3 million to the Placement Agent and additional transaction costs of \$0.2 million.

#### **Off Balance Sheet Financing Arrangements**

As of December 31, 2007, 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**

Minimum future payments of our contractual obligations are as follows:

Less than 1											
		Total		year		1 to 3 years		3 to 5 years	Afte	r 5 years	
Obligations under capital leases	\$	33	\$	25	\$	8	\$		\$		
Commitment under sales leaseback		3,576		610		1,222		1,744			
Operating leases		15,835		3,848		6,525		4,662		800	
Interest payments		8,983		1,268		7,440		275			
Note repayment obligations*		36,195		813		29,682		5,700			
Deferred transaction obligation		3,683		3,683							
Total	\$	68,305	\$	10,247	\$	44,877	\$	12,381	\$	800	

<sup>\*</sup>original amounts, at maturity

In 2008, we anticipate capital expenditures of approximately \$2.1 million primarily for information technology infrastructure improvements, computer hardware and software and other technology oriented solutions. During January of 2008, we paid deferred transaction obligations of \$3.0 million primarily related to the payment of an obligation to Cerep in connection with the Hesperion acquisition. Our Senior Secured Notes contain certain financial and reporting covenants, which begin to be measured as of June 30, 2008. In addition, our Senior Secured Notes have a contingent payment obligation of \$0.5 million which becomes due and payable if those notes are outstanding at October 31, 2008.

# ITEM 7. FINANCIAL STATEMENTS

### FINANCIAL STATEMENTS

# INDEX TO FINANCIAL STATEMENTS

	Page
Averion International Corporation Financial Information:	
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets as of December 31, 2007 and 2006	F-2
Consolidated Statements of Operations for the years ended December 31, 2007 and 2006	F-3
Consolidated Statements of Stockholders Equity for the years ended December 31, 2007 and 2006	F-4
Consolidated Statements of Cash Flow for the years ended December 31, 2007 and 2006	F-5
Notes to Consolidated Financial Statements	F-6

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Averion International Corporation

We have audited the accompanying consolidated balance sheets of Averion International Corp. (the Company) as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders—equity and cash flow for the years then ended. These financial statements are the responsibility of the Company—s management. Our responsibility is to express an opinion on these financial statements 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 consolidated 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 audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for purposes 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 consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Averion International Corp. as of December 31, 2007 and 2006, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ SCHNEIDER DOWNS & CO., INC. Columbus, Ohio March 28, 2008

F-1

# AVERION INTERNATIONAL CORP. Consolidated Balance Sheets

# (Dollars in thousands, except share and per share amounts)

		Decem	ber 31,	
		2007		2006
Assets				
Current Assets:	¢.	7.204	ф	0.000
Cash and cash equivalents	\$	7,384	\$	8,098
Accounts receivable (net of allowance for doubtful accounts of \$376 and \$81 for 2007 and		14 202		4.542
2006, respectively)		14,293		4,543
Unbilled accounts receivable		2,571		1,878
Prepaid and other current assets		2,413		734
Assets held for sale from discontinued operations		26.661		1,349
Total Current Assets		26,661		16,602
Property and equipment, net		6,509		1,434
Goodwill		48,717		21,968
Finite life intangibles (net of accumulated amortization of \$1,043 and \$570 for 2007 and		12.460		4.612
2006, respectively)		13,469		4,613
Deposits Other and account and a second seco		658		145
Other non current assets	¢.	1,878	ф	44.760
Total Assets	\$	97,892	\$	44,762
Liabilities and Stockholders Equity				
Current Liabilities:				
	\$	2 727	\$	707
Accounts payable	Þ	2,737	ý.	
Accrued payroll and employee benefits  Current portion of capital lease obligations		3,405		1,042
Current portion of accrued lease obligations  Current portion of accrued lease obligations		25 610		23
		813		978
Current portion of notes payable Deferred revenue				
		18,532 510		5,029
Deferred rent				545
Deferred transaction obligation Other accrued liabilities		3,683 4,313		1.070
		4,313		1,079
Liabilities from discontinued operations		24.629		541
Total Current Liabilities		34,628		9,944
Capital lease obligations, less current portion		8		6 214
Notes payable, less current portion		24,266		6,214
Accrued lease obligations, less current portion		2,966		
Other long-term liabilities Total Liabilities		1,076 62,944		16,200
Total Liabilities		02,944		10,200
Commitments and contingencies				
Commitments and contingencies				
Stockholders equity:				
Common stock, \$.001 par value, 750,000,000 shares authorized, 625,632,455 and				
498,378,831 shares issued and outstanding, respectively		626		498
Convertible Warrants		164		164
Common stock to be issued		837		837
Additional paid-in capital		47,308		35,466
Other comprehensive loss		(316)		(7)
Retained deficit		(13,671)		(8,396)
Total Stockholders equity		34,948		28,562
Total Liabilities and Stockholders equity	\$	97,892	\$	44,762
Total Madifiets and Stockholders equity	Ψ	71,072	ψ	44,702

The accompanying notes are an integral part of these consolidated financial statements.

# **AVERION INTERNATIONAL CORP.** Consolidated Statements of Operations

#### (Dollars in thousands, except share and per share amounts)

Years ended December 31, 2007 2006 Net service revenue 34,852 13,251 Reimbursement revenue 5,080 1,314 Total revenue 39,932 14,565 Operating expenses: Direct expenses 20,714 8,246 Reimbursable out-of-pocket expenses 5,080 1,314 Sales, general and administrative expenses 13,811 8,869 Depreciation and amortization expense 1,796 799 Restructuring and related charges 727 19,228 Total operating expenses 42,128 Net operating loss (2,196)(4,663)Other income (expense): 323 Interest income 313 Interest expense (796)(289)Debt discount amortization (652)Other (273)24 Total other income (expense) (1,398)Loss from continuing operations before income taxes (3,594)(4,639)Income taxes 298 (4,639)Loss from continuing operations (3,892)Loss from discontinued operations (1,383)(487)Net loss (5,275)(5,126)Beneficial conversion feature (4,069)Net loss applicable to common stockholders \$ (5,275)\$ (9,195)Basic loss per common share: Net loss from continuing operations \$ (0.01)\$ (0.01)Loss from discontinued operations \$ \$ (0.00)(0.00)Beneficial conversion feature \$ (0.01)\$ Net loss applicable to common stockholders (0.01)\$ (0.02)Weighted average number of common shares outstanding 519,429,316 498,606,232

The accompanying notes are an integral part of these consolidated financial statements.

# AVERION INTERNATIONAL CORP. Consolidated Statements of Stockholders Equity

# (Dollars in thousands, except share amounts)

			Comm	ion				Oth	er T	Γotal
	Common S Shares	tock Amount	Stock To B	e Issued Amount			itional Paid-in Capital WarrantsC		ne <b>ißėtæ</b> ined Ear <b>sing</b> s (Deficit) E	kholders Equity
Balance,	Silaites	Amount	Silares	Amount	Shares	Amount	Capital Warrants	an Options 10s	s (Deficit) E	Aquity
December 31,										
2005	60,448,875	60		\$ 0	11,500	8,105	2,504 3,109	285	(3,270) 10	0,794
Issuance of common stock and Series E convertible preferred stock related to the purchase of										
Averion Inc	45,245,555	45			8,300	8,300	4,932		13	3,277
Revaluation of										
ComVest option							114	(114)		
Exercises of ComVest option to purchase Series D convertible										
preferred stock					5,000	4,069		(134)	3	3,935
Exercise of										
warrants	54,182,307	54					4,156(3,109)	(37)		1,064
Stock based							4-0			
compensation Common stock to							173			173
be issued to shareholders related to purchase of Millennix, Inc		,	1,285,714	837						837
Beneficial		_	r,203,71 <del>4</del>	037						037
Conversion feature Series D convertible										
preferred stock							4,069		4	4,069
Deemed dividends for Series D convertible										
preferred stock							(4,069)		(4	4,069)
Conversion of Series D convertible preferred stock to										
common stock	235,714,214	236			(16,500)	(12,175)	11,939			
Conversion of Series E convertible preferred stock to	75,454,551	76			(8,300)	(8,300)	8,225			

common stock Issuance of stock							
associated with							
private placement and associated							
costs	27,333,329	27	3,587				3,614
Warrant to							
purchase common							
stock issued in							
connection with							
PIPE financing			(164)	164			
Translation							
Adjustment					\$	(7)	(7)
Net Loss							