CLINICAL DATA INC Form 10-K June 19, 2007

#### **Table of Contents**

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### Form 10-K

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

For the fiscal year ended March 31, 2007

OR

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

For the transition period from to

# Commission File No. 0-12716 CLINICAL DATA, INC.

(Exact Name of Registrant as Specified in its Charter)

**Delaware** 

04-2573920

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

One Gateway Center, Suite 702, 02458

(Zip Code)

Newton, Massachusetts

(Address of Principal Executive Offices)

Registrant s telephone number, including area code: (617) 527-9933

**Securities registered pursuant to Section 12(b) of the Act:** 

Common Stock, \$.01 par value

The NASDAQ Stock Market LLC (NASDAQ Global Market)

Securities registered pursuant to Section 12(g) of the Act:

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES o  $NO \, b$ 

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES o NO b

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. YES b NO o.

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

Large accelerated filer o Accelerated filer o Non-accelerated filer b

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES o NO b

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold on the NASDAQ Global Market as of the last business day of the registrant s most recently completed second fiscal quarter (September 30, 2006) was \$72,405,439.

The number of shares outstanding of the registrant s common stock as of June 5, 2007 was 10,071,872.

### DOCUMENTS INCORPORATED BY REFERENCE

None.

# INDEX TO FORM 10-K

# FOR THE FISCAL YEAR ENDED MARCH 31, 2007

		Page
	PART 1	
ITEM 1.	Business	1
ITEM 1A.	Risk Factors	30
ITEM 1B.	Unresolved Staff Comments	45
<u>ITEM 2.</u>	<u>Properties</u>	45
ITEM 3.	Legal Proceedings	45
<u>ITEM 4.</u>	Submission of Matters to a Vote of Security Holders	46
	PART II	
<u>ITEM 5.</u>	Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases	
	of Equity Securities	46
<u>ITEM 6.</u>	Selected Consolidated Financial Data	48
<u>ITEM 7.</u>	Management s Discussion and Analysis of Financial Condition and Results of Operations	49
ITEM 7A.	Quantitative and Qualitative Disclosures about Market Risk	60
<u>ITEM 8.</u>	<u>Financial Statements and Supplementary Data</u>	61
<u>ITEM 9.</u>	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	61
ITEM 9A.	<u>Controls and Procedures</u>	61
ITEM 9B.	Other Information	62
	PART III	
<u>ITEM 10.</u>	Directors, Executive Officers, and Corporate Governance	63
<u>ITEM 11.</u>	Executive Compensation	66
<u>ITEM 12.</u>	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder	
	<u>Matters</u>	76
<u>ITEM 13.</u>	Certain Relationships and Related Transactions, and Director Independence	78
<u>ITEM 14.</u>	Principal Accounting Fees and Services	79
	PART IV	
<u>ITEM 15.</u>	Exhibits and Financial Statement Schedules	80
<u>SIGNATURES</u>		81
Ex-21.1 Subsidiarie		
	Deloitte & Touche LLP  2 Certification of the C.F.O.	
Ex-31.1 Section 302 Certification of the C.E.O. Ex-31.2 Section 302 Certification of the C.F.O.		
Ex-32.1 Section 906 Certification of the C.E.O. and C.F.O.		

#### **Table of Contents**

#### NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In particular, forward-looking statements regarding our expected performance and financial results in future periods which include words such as expect(s), feel(s), believe(s), would, may, anticipate(s), and similar expressions based upon management s current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the preceding forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements which speak only as of the date of the filing of this Form 10-K. The following factors known to management, including those set forth in Item 1A of this report entitled, Risk Factors, could cause actual results to differ materially from those described in such forward-looking statements: our ability to raise cash or to produce cash from operations sufficient to fund our current level of activities, including clinical trials; the effects of regulatory decisions and approvals (or failure to obtain approvals) on our drug candidates and other existing products; our ability to continue to attract new customers and obtain new and expanded business opportunities from existing customers; management of our growth and successful integration of our operations with those of acquired subsidiaries; continued growth in demand in the United States and abroad for products and consulting services such as those offered by us and the effect of intensifying competition among a rising number of companies offering products and services similar to those offered by us. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events, or otherwise. In addition, we encourage you to review the risk factors contained in Item 1A of this Annual Report on Form 10-K and in our other reports, registration statements and other documents filed from time to time with the SEC which describe a number of additional risks and uncertainties that could cause actual results to differ materially from those expected in the forward-looking statements made in this Form 10-K.

#### **PART I**

### ITEM 1. BUSINESS

#### General

Clinical Data, Inc. (the Company, we, us, our, etc.) is a Delaware corporation headquartered in Newton, Massachusetts. We manage our businesses in three segments (i) Molecular Services which includes PGxHealth LLC (PGxHealth) and Cogenics, Inc. (Cogenics), (ii) Clinics & Small Hospitals which includes Vital Scientific NV (Vital Scientific) and Electa Lab s.r.l. (Electa Lab) and (iii) All Other which includes corporate-related items and income and expense not allocated to reportable segments.

Under our PGxHealth<sup>TM</sup> brand name and division, we focus on biomarkers and related test development, validation and commercialization activities with a primary focus on improving the efficacy and safety of drugs for individuals. These genetic tests are marketed to providers, payers and consumers and are available by prescription only. PGxHealth is also seeking to develop and commercialize our first drug, Vilazodone, a novel dual serotonergic antidepressant compound being studied for treatment of depression along with a potential companion pharmacogenetic test that will be developed and likely marketed by our PGxHealth division. PGxHealth will also continue to seek opportunities similar to Vilazodone to develop and commercialize promising therapeutics with potential companion pharmacogenetic tests.

Through our Cogenics<sup>TM</sup> brand name and division, we offer a wide range of molecular and pharmacogenomics services which are marketed and provided to pharmaceutical, biotech, academic, agricultural and government clients to assist them in endeavors relating to human, animal and plant genomes. The Cogenics unit offers a broad range of services including sequencing, genotyping, gene expression, bio-banking and others, which together represent one of

the broadest offerings in this industry. Furthermore, these services are offered in both regulated and unregulated environments. Cogenics operates CLIA-certified laboratories (Clinical Laboratory Improvement Amendments of 1988) and performs the genetic tests for PGxHealth.

1

#### **Table of Contents**

Our Vital Scientific and Electa Lab units participate in the *in vitro* diagnostic (IVD) testing markets and manufacture and distribute clinical laboratory instrumentation and related assays. Vital Scientific is headquartered in the Netherlands and Electa Lab is headquartered in Italy. We provide our IVD products and services in Europe, Asia and the U.S. through distributors and original equipment manufacturer (OEM) partnerships.

#### **Company History**

We were formed in 1972 to offer ambulatory diagnostic monitoring for clinical and research applications. Our transformation began in 2005 when we established our molecular and pharmacogenomics services business in the third and fourth quarters of fiscal 2006 through the acquisition of Genaissance Pharmaceuticals, Inc. (Genaissance), Icoria, Inc. (Icoria) and Genome Express S.A. (Genome Express). The acquired businesses had a significant impact on the reported results of operations and financial position for the latter half of fiscal 2006 and all of fiscal 2007. Prior to the acquisitions, Genaissance, Icoria and Genome Express reported significant operating losses and used significant cash in their respective operations. These operating losses may continue for the next twelve months or longer depending upon business developments and research and development efforts, particularly those related to Vilazodone and PGxHealth.

On October 6, 2005 we completed the acquisition of Genaissance, a leader in the discovery and application of human gene variation for the development of a new generation of DNA-guided tests and therapeutic products with an established market presence in pharmacogenomics and molecular services. The acquisition of Genaissance enabled us to advance and commercialize our PGxPredict<sup>TM</sup> line of genetic tests, which we more broadly call Therapeutic Diagnostics<sup>TM</sup>, with the intention of marketing these tests to allow healthcare providers to optimize the use of specific therapies in individuals. A subset of these tests utilizes products and technologies that were already commercialized by Genaissance. These technologies also have the potential to generate other products for future commercialization through PGxHealth. In addition, we advanced our in-licensed therapeutic, Vilazodone, through its first pivotal Phase III clinical trial and we expect results from this trial late in the second quarter of fiscal 2008. Through this acquisition, we also gained the know-how to in-license and further develop intellectual property from outside parties to develop and commercialize genetic tests and therapeutics. The acquisition of Genaissance was an important step in our objective to grow our business and revenues in the strategic areas of pharmacogenomics and molecular services, genetic testing, and targeted therapeutics.

On December 20, 2005, we completed the acquisition of Icoria, a biotechnology company, which analyzes biological function at the level of gene expression and biochemical pathways to discover and validate novel biomarkers for the research community. Icoria s income was primarily generated from government grants.

On March 7, 2006, we purchased all of the issued and outstanding shares of the French company, Genome Express. Genome Express is focused on providing genomics and post-genomics technology contract services, and genetic sequencing and molecular biology services, and on performing integrated genomics analysis. This acquisition further expanded our footprint in Europe for the provision of pharmacogenomics and molecular services and our genetic tests.

On December 26, 2006, to reflect our integration of these acquisitions, we changed the name of Genaissance to Cogenics, and added the Cogenics brand name to the names of Icoria (Cogenics Icoria) and Genome Express (Cogenics Genome Express). These new names reflect the comprehensive and complementary range of molecular and pharmacogenomics services offered by these entities. On November 20, 2006, we formed PGxHealth LLC, a subsidiary of Cogenics, to centralize the development and commercialization of genetic tests and our sole therapeutic, Vilazodone. PGxHealth s tests will assist providers and payers in determining the most appropriate therapeutic for a particular patient, which should assist in the reduction of therapeutic and/or medical costs and improvement of clinical outcomes. Intellectual property, infrastructure, personnel and other assets from Genaissance are the basis for

### PGxHealth.

Vital Scientific and Electa Lab instruments are marketed worldwide through distributors and OEM partnerships. Worldwide we have an installed base of over 15,000 units. Vital Scientific and Electa Lab provide our IVD products and services in Europe, Asia and the U.S.

2

#### **Table of Contents**

For revenue and operating information including geographic data on each of our segments described above, please see Note 16 to our consolidated financial statements.

#### **OUR INDUSTRIES:**

### Diagnostic and Genetic Testing Industries

The worldwide healthcare industry is struggling to reduce cost trends relating to medications and medical care. There is a renewed focus on providing optimal treatment with medicines resulting in improved patient outcomes and reductions in costs. In the past, many of the mechanisms for realizing these goals proved to be too costly or ineffective. Sub-optimal treatment resulting from the trial and error approach to prescribing, inconsistencies with suggested best practice protocols, adverse drug events, and inaccurate or incomplete diagnoses remain all too frequent.

Scientific advances in genomics and biomarker identification have set the stage for fundamentally improving healthcare delivery. An individual s genetic profile will increasingly play an important role in clinical decision making, diagnosis of disease and the selection of the most appropriate treatment for each patient, resulting in a more personalized approach to patient care. Genetic markers associated with drug safety and response in individuals will be developed into genetic tests and commercialized both together with and independent of pharmaceutical products as personalized medicine is more broadly adopted by the healthcare industry.

With the introduction of genetic and pharmacogenetic tests, choosing which therapeutic agent or other medical intervention to prescribe will be based in greater part on science rather than on experiential bias, economics, marketing, or simple trial-and-error approaches as is often the case today. By utilizing these tests, the prescription of medicine will be based less often on efficacy demonstrated in an unselected population but will rather be based on each individual s likelihood of response. A new approach to clinical care that incorporates pharmacogenetic tests will focus on lowering unit drug cost, increasing efficacy of treatments provided to specific individuals, reducing adverse drug events, and achieving therapeutic goals for individual patients more rapidly, thus reducing morbidity.

The molecular diagnostic market in the U.S. was approximately \$1.44 billion in 2005, and is expected to grow to \$4.31 billion in 2012, with a compound annual growth rate of 17% from 2005 to 2012 (Source: Frost and Sullivan). The majority of available assays are in oncology, gene/defects/inherited diseases, metabolism, and infectious diseases. There are more than 900 labs worldwide performing laboratory-developed assays. Most of these labs (90%) are located in North America, Western Europe and Japan (Source: SG Cowen 2001). The growth of this market will be determined, in part by, the availability of validated pharmacogenetic biomarkers with demonstrated clinical utility. Each year, these labs announce or publish multiple genotype-phenotype associations that subsequently fail to be repeated in other studies. It is essential that these genotype-phenotype associations be validated in independent populations and that the association represents an important utility in the clinic.

Competitors to our genetic discovery, testing and therapeutics businesses include companies fitting a variety of models and who often are also business partners with PGxHealth. While no one company is directly comparable with PGxHealth s model, the genetic testing business of PGxHeatlh competes directly or indirectly with: (i) molecular testing kit companies such as Qiagen, Third Wave Technologies and Roche Diagnostics; (ii) other genetic or pharmacogenetic testing laboratories such as Myriad Genetics, Genzyme Diagnostics, Molecular Diagnostics Laboratories, Athena Diagnostics (owned now by Thermo-Fisher Scientific) and others; (iii) full service and reference labs such as LabCorp, Quest Diagnostics, and Prometheus Laboratories; (iv) university/hospital laboratories such as Harvard Partners, the University of Chicago, University of Utah, ARUP Laboratories and others; and (v) genetic marker and biomarker discovery and diagnostic companies such as Celera Diagnostics, Epidauros, Genomic Health and Pathway Diagnostics. Insofar as other genomic platform or technology providers, such as Illumina, Affymetrix, or

Luminex, seek to establish CLIA laboratories for commercialization of diagnostics, these could also become competitive. Similarly, the use of biomarkers to reposition drugs is being pursued by companies such as Perlegen Sciences, Vanda Pharmaceuticals, and deCode Genetics. Our competition in the sector of using pharmacogenomics to enable the

3

#### **Table of Contents**

development of companion diagnostics to pharmaceutical products include companies such as Perlegen Sciences and Gene Logic and the internal capabilities of large pharmaceutical companies.

The Cogenics laboratories that supply pharmacogenomics testing to pharmaceutical, biotech, academic, agricultural and government clients compete across sectors as well including: (i) platform or technology providers such as Illumina, Affymetrix, or Luminex; (ii) providers of pharmacogenetic services for clinical trials such as LabCorp, Epidauros, DXS, Covance, Quest, MDS and others; (iii) in-house academic centers across the US and Europe.

Healthcare insurers, employers, governments and others are constantly seeking innovative ways to manage rising healthcare costs without compromising care. The share of prescription drug dollars paid by private insurers increased substantially over the past decade from 26% in 1992 to 48% in 2002 (Source: Kaiser Family Foundation; Prescription Drug Trends Report, June 2006). Suboptimal care, rising costs and inappropriate utilization of healthcare services have all led to the need for significant reforms in the current system and the application of new approaches to therapeutic and medical cost containment. Unfortunately, many of the programs implemented to reduce costs such as disease management, case management, and drug formularies, have had only modest impacts on pharmacy and medical cost trends.

We believe that advances in biomarker identification, the field of pharmacogenomics, laboratory practices and platforms and the practice of medicine set the stage for the use of genetic markers and related pharmacogenetic tests to determine which individuals will experience optimal benefit from specific therapies. This approach may result in better clinical outcomes while at the same time lead to reductions in the total cost of care. Many health plans and employers are beginning to view pharmacogenetic testing as a key next step in managing increasing medical cost trends. We will continue to aggressively work with physicians, hospitals, payers, pharmacy benefits managers, associations, coalitions, information companies and other healthcare constituents to set the stage for market introduction and adoption of our pharmacogenetic tests. There is an education process required for the adoption of pharmacogenetic tests to optimize the use of therapies and enhance clinical outcomes to take place. Our ultimate objective is to facilitate market introduction and adoption of the proprietary tests provided by PGxHealth. We currently provide the FAMILION® tests, associated with cardiac channelopathies including Long QT Syndrome and Brugada Syndrome, and our PGxPredict<sup>TM</sup> tests for warfarin, clozapine, and rituximab. PGxHealth also receives royalties for the sublicense of its intellectual property for thiopurine S-methyltransferase (TPMT) to Prometheus Laboratories and Specialty Laboratories. We continue to apply our efforts and expertise to the development of new pharmacogenetic tests, focusing in particular in the areas of the central nervous system (CNS)/psychiatry, cardiology and oncology.

The genetic testing market is rapidly growing. Certain barriers continue to exist to expanding and penetrating this market. They include:

demonstrating pharmacogenetic and medical economic data to support test adoption and reimbursement;

antiquated reimbursement formulas that do not adequately reflect the value of pharmacogenomic tests and the level of R&D and licensing costs required to bring tests to market;

education for providers on how and when to incorporate pharmacogenetic testing into their delivery of care;

the availability of validated pharmacogenetic associations producing tests with appropriate sensitivity and specificity for the specific clinical utility;

the complexity of the genetic underpinnings of disease and drug response;

other parties who have opposing interests in seeing these tests commercialized; uncertainty about the predictive value of genetic tests to accurately identify patients; and ethical, legal, regulatory, and social considerations.

4

#### **Table of Contents**

### Development and Marketing of Drugs

The healthcare industry faces intense pressure to become more productive and cost effective, with forecasts that U.S. healthcare spending will double by 2016, to \$4.1 trillion per year. Prescription drug spending is anticipated to be \$497.5 billion by 2016, more than double the expected level for 2006, with an average annual growth rate of 8.6 percent until 2016 (Source: National Health Statistics Group at the Centers for Medicare and Medicaid Services, February 2007). New drugs remain expensive to develop and carry a high price at release, often displacing less expensive alternatives that may be just as effective. Two of the pharmaceutical and biotechnology industry s most challenging issues are the high cost and low success rate of developing drugs. According to the Tufts Center for Drug Development, the pre-approval cost for each new drug is estimated to be \$802 million (Source: J DiMasi, RW Hansen, HG Grabowski. The price of innovation: new estimates of drug development costs. *Journal of Health Economics* 22 (2003) 151 185).

Approved drugs often face intense competition. The period of market exclusivity for the first drug in a new therapeutic class is typically much shorter today than it was a few years ago because of the length of time from inception to approval. This has a played a large role in causing marketing expenditures to increase rapidly as companies attempt to maintain or increase market share. Marketers are under intense pressure to maximize the revenue generated from approved products in order to meet corporate and investor revenue and earnings goals. In addition, pharmaceutical companies continue to face increasing competition from generic drugs, as patents on more than 200 brand-name drugs will expire over the next several years. Similarly, growing pressure for the development of biosimilars , the generic version of proprietary biologics, threatens the exclusivity of biologics. Generic drugs account for more than half of all prescriptions dispensed today. Thus, an increasingly preferred path to maintaining revenue growth and profitability is to decrease the size of clinical trials, improve success rates and identify means to achieve differentiation in a crowded market.

Confronted by the ever-expanding compendium of available pharmaceuticals and the increasing need to control spending on drugs, providers and payers face the difficult task of deciding which drugs should be prescribed to specific patients and are suitable for reimbursement. Healthcare providers make these decisions based on medical outcome studies and economic benefit factors but have little, if any, knowledge beforehand of which individual patients are most likely to benefit from a specific drug. Managed care plan designs including drug formularies, prior authorizations, and utilization review employed by payers, Prescription Benefit Managers and employers also impact the provider s decisions as to which drugs should be prescribed for a specific patient. However, even today, the vast amount of drugs are still broadly prescribed based on diagnosis and not the likelihood of safety and response on the part of the individual taking the drug. Thus, healthcare payers, providers and patients would benefit from the knowledge of which drug would be most efficacious and safest for a specific patient or patient population potentially resulting in more appropriate and safer interventions, optimized patient care, and improved therapeutic and medical costs. These economic and clinical outcomes are also applicable in the international markets where health coverage and programs are often sponsored by governments and other payers.

The medical community generally acknowledges that most drugs work more effectively for some patients than for others. The drug approval process is built on a foundation of statistical significance for the mean effect of a drug in a population; some patients benefit from a drug more than others, some not at all, and some may be harmed. Pharmaceutical and biotechnology companies historically have not considered genomic differences between patients in developing and implementing clinical trials or in the marketing of therapeutics. In particular, most findings in this area have not been incorporated into the commercialization plan of their drugs. Consequently, development efforts for a compound may cease when the overall population benefit is not demonstrated even though the drug may be effective for a portion of the population. Even if a drug gains approval, the ability to successfully market the drug or to obtain approval for third party reimbursement may be compromised if the overall efficacy is modest or less than other agents

in the class. Furthermore, after approval, some companies encounter real-world efficacy and safety challenges. In some instances, drugs have had to be abruptly removed from the market, primarily for safety concerns. Also, some drugs have become less attractive as other drugs are introduced into the market due to safety concerns and/or response rates, while these drugs might have cost and outcome advantages if targeted to the optimal populations.

5

#### **Table of Contents**

If, early in drug development, companies sought to understand more clearly the characteristics that defined the population of patients more likely to respond favorably to a product, subsequent development efforts could be more effectively targeted. Typically referred to as enrichment techniques, these are tools that are only starting to be employed throughout the drug development process. For example, if clinical trials are conducted in the subset of severe congestive heart failure, approval might still be gained for the broader designation of congestive heart failure without limitation as to severity. Similarly, genetic biomarkers can be applied, together with appropriate statistical analysis, to identify patient populations that are more or less likely to respond to a drug. Such biomarkers could then be used to enrich subsequent studies for patients more likely to respond, potentially reducing the size and length of these studies but not necessarily restricting the approval of the drug for the general, unselected population. These enriched trials may be smaller since they would be designed for patients likely to respond and the effect would be expected to be more pronounced given the smaller trial size. This should result in faster, cheaper Phase III trials and an accelerated timetable for approval. In addition, the commercialized product would be clearly differentiated from other agents within its class or therapeutic area, possibly by superior efficacy but certainly by better scientific, functional, or mechanistic data. Similarly, if pharmaceutical and biotechnology companies could identify the patients most likely to have an unwanted side effect based on genetic variation, they could more closely monitor these patients or eliminate them from participating in clinical trials, improving the risk-benefit ratio of treatment.

Pharmaceutical and biotechnology companies may, therefore, have a better understanding of the cost required to complete the development of a drug and the likely economic return on their investment before proceeding to Phase III and beyond if the integration of biomarkers to the program was considered earlier in the development program. In addition, if these companies could use biomarkers to predict drug response, they might be able to improve the marketing of their drugs by identifying those patients for which particular drugs are most likely to be effective or with the least likelihood of having an adverse reaction. This may, in turn prevent severe adverse reactions from occurring, which might force a drug to be withdrawn from the market and improve compliance by the patient once treatment is initiated. Furthermore, healthcare providers and payers could benefit economically from predictive information that would enable a physician to prescribe the most appropriate and safest medication at the earliest possible time.

The development of biomarkers is not limited to the drug development process but can be applied to drugs that have already received marketing approval, in order to improve their risk-benefit ratio. Clearly adverse drug reactions and inadequate efficacy contribute to healthcare costs and modest outcomes. For example, it has been reported that adverse drug events (ADEs) play a significant role in driving costs and negatively impacting clinical outcomes (Source: Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs, *Research Action*, Issue I, www.ahcpr.gov March 2001).

Incidence rates of ADEs vary from 2 per 100 admissions to 7 per 100 admissions among the hospitals that have conducted ADE studies;

Patients who experienced ADEs were hospitalized an average of 8 to 12 days longer than patients who did not suffer ADEs, and their hospitalization cost \$16,000 to \$24,000 more;

Over 770,000 people are injured or die each year in hospitals from ADEs;

National hospital expenses to treat patients who suffer ADEs during hospitalization are estimated at between \$1.56 and \$5.6 billion annually; and

Studies indicate that anywhere from 28 to 95 percent of ADEs can be prevented.

These increased costs due to drug-induced adverse drug events are disproportionately associated with drugs metabolized by enzymes known to have reduced or non-functional genetic variants (Source: *Journal of the American Medical Association (JAMA)* 286: 2270-2279, 2001).

Numerous drugs that are efficacious, safe and in some instances, less costly than others prescribed in a therapeutic area have been relegated to second- and third-line therapy behind more expensive and in some instances less safe and less effective therapies. This often occurs due to heterogeneity of effect across individuals or subsets of the population. For example, response to beta-blockers varies from 60% to 85%,

6

#### **Table of Contents**

depending on the drug and definition of response chosen (Sources: Lindholm LH, Carlberg B, Samuelsson O. Should beta blockers remain first choice in the treatment of primary hypertension? A meta-analysis. *Lancet.* 2005 Oct 29-Nov 4; 366(9496): 1545-53. 2. Messerli F H, Grossman E, Goldbourt U. Are beta-blockers efficacious as first-line therapy for hypertension in the elderly: a systematic review. *JAMA* 1998;279(23):1903-1907) and response to selective-serotonin reuptake inhibitors for depression is less than 50% (Source: Reference for antidepressants: Sequenced Treatment Alternatives to Relieve Depression (STAR\*D) Study, *American Journal of Psychiatry*. January, 2006). The ability to use a biomarker to predict with higher confidence which patient will respond well to a particular drug may impact total cost of care by increasing the probability of response, which could lead to less morbidity, higher productivity, and less mortality. By understanding genetic variation and its relationship to drug response, it is possible to determine which individuals may benefit more from such a drug, thus re-establishing its position as a useful and perhaps less expensive alternative. Approximately 10% of drugs approved by the FDA have pharmacogenomic information in their label. (Source: Table of Valid Genomic Biomarkers in the Context of Approved Drug Labels: http://www.fda.gov/cder/genomics/genomic\_biomarkers\_table.htm).

# Fee-for-service Pharmacogenomics and Molecular Biology Services

The field of molecular biology was originally a narrow discipline involving a small number of specialists when discoveries in recombinant DNA technology in the 1970 s led to revolutionary advances in the science. As the field matured, the introduction of automation and the bundling of reagents into quality-controlled application kits made the manipulation of recombinant DNA even more accessible to larger numbers of scientists and to the mainstreaming of genomics technologies into many life science laboratories. PhorTech International estimates that of the total 152,700 life science researchers in the US, approximately 40% are now using DNA sequencing and related genomics analyses in their work (Source is: http://www.phortech.com/2005seq.htm).

The 1980 s through the start of the 24 century saw the success of the Human Genome Project and the International HapMap Project as major global initiatives to map and sequence the human genome. These programs allowed scientists to begin to ask questions about the role of gene structure and function in many biological processes in humans, including aging, growth and differentiation, and disease. The mapping of the genetic variation among individuals known as genotyping has become important to the understanding of why certain individuals are more or less susceptible to disease or respond differently to drug treatments. The impact of genetics on drug safety and efficacy has become known as pharmacogenomics, and has been recognized by the FDA as an important new element in its Critical Path Initiative to increase the efficiency of drug discovery and development. For instance, Genentech s Herceptin, Astra Zeneca s Iressa and Novartis Gleevec are examples of drugs that have been found to be effective only in well-defined patient populations with unique pharmacogenomic profiles. As more is learned about the impact of genetics on drug function in humans, the more pharmaceutical companies are incorporating pharmacogenomics studies into their product discovery and development pathways. Many of these companies are lacking in resources and expertise in pharmacogenomics and often look to outside sources for assistance.

Just as the drug industry two decades ago began to leverage the resources of an outsourcing service industry for managing and conducting clinical trials, and manufacturing pharmaceutical ingredients and products, pharmacogenomics and molecular biology services have become amenable to the outsourcing model. With the global market for genomics technology and related services exceeding \$7 billion in 2006 (Source: *Genetic Engineering and Biotechnology News:* Biobusiness Channel: Article May 15 2007 (Vol. 27, No. 10). *BioMarket Trends:* The Future of Genome Synthesis and Design Implications for U.S. Economy.Rob Carlson, Ph.D., Jim Newcomb, Steven Aldrich) a specialty subsection of the \$10 billion Contract Research Organization (CRO) industry has evolved to provide contract genomics research services to pharmaceutical, biotechnology and life science researchers in commercial, government and academic institutions worldwide (Source: Contract Pharma: CRO Industry Update: Growth, Expansion, and New Opportunities by Kristin Brooks, May 2006). Currently 20-22% of overall pre-clinical and clinical trial research, in the pharmaceutical industry is outsourced to CROs (Source: Contract Pharma: CRO Industry

Update: Growth, Expansion, and New Opportunities Kristin Brooks). However in certain segments of genomics technology, such as DNA sequencing, upwards of 31% of the work is

7

#### **Table of Contents**

now outsourced to off-site service organizations (Source: PhorTech International 2005/2006 U.S. MSPPSA report on DNA Sequencing Market Analysis, September 9, 2005). According to Bio Economic Research Associates, the overall market for genomics services is growing rapidly and is expected to expand at rates as high as 10-20% annually (Source: Genome Synthesis and Design Futures, Cambridge, MA February 21, 2007 published by *Bio Economic Research Associates*).

The customer base of the genomics services industry spans the public and private sectors globally and segments into:

researchers in academia and government laboratories answering basic science questions about gene structure and expression in plant, animal and lower species;

drug discovery departments in pharmaceutical and biotechnology companies doing pathway analyses using gene expression tools to find new drug targets or biomarkers;

academic and applied industrial researchers performing biodistribution studies of recombinant vaccine and gene therapy candidates;

applied clinical departments in pharmaceutical and biotechnology companies exploring the role of genetic variation among human clinical trial patients in genotyping studies as it relates to selective sensitivity to, or metabolism of, drug candidates and issues in personalized medicine;

quality control and related process development and manufacturing departments in biopharmaceutical firms seeking to adhere to current Good Manufacturing Practices (cGMP) regarding DNA sequence identity, DNA copy number, residual DNA and other requirements of the Chemistry, Manufacturing and Controls (CMC) sections in Investigational New Drug (IND) or New Drug Applications (NDA) and in post-launch cGMP manufacturing;

customers or marketers of tests for genotypic markers of family inheritance patterns and other related tests such as disease susceptibility in animals (e.g., scrapie disease susceptibility in sheep); and

molecular biology reagent, instrument and research tools companies requiring molecular biology services for quality control, component or other OEM contribution to their businesses.

The competitive structure of the pharmacogenomics and molecular biology services industry is more dynamic and less concentrated than in more mature segments of the CRO business. Because of the large capital expense of genomics analysis instrumentation and the need for trained and dedicated molecular biology staff, the largest service provider segment, upwards of 60% of the market, is served by the in-house core laboratory found at most academic institutions and companies significantly engaged in genomics research (Source: PhorTech International 2005/2006 U.S. MSPPSA report on DNA Sequencing Market Analysis, September 9, 2005). These facilities also typically offer services to off-site customers. While currently the dominant participant in the segment, core laboratories are under current pressure to justify the partial or total subsidy they must typically receive from their parent organizations to supplement user fees to continue operating. With commercial suppliers of services offering larger critical mass, aggressive pricing and better customer service, core laboratory growth is slowing while outsourcing expansion is migrating to the private vendors of services.

Commercial off-site competitors include larger participants from the traditional clinical diagnostics testing (such as Quest, LabCorp) and CRO sectors (Quintiles, Covance, PPD, Bioreliance) as well as the service divisions of genomics analysis instrument vendors such as Affymetrix, Illumina, Sequenom, 454-Roche, and Luminex. Niche service competitors, often offering a narrow line of services, include Seqwright, GATC, Genewiz, MWG, Agencourt in

sequencing, Expression Analysis and Gene Logic in microarray and Epidauros and Gentris in genotyping.

The bases of competition in this fee-for-service arena are typical of the larger CRO industry:

provide a complete and comprehensive portfolio of services that spans the customer s total requirements;

8

#### **Table of Contents**

offer the best and most reliable cutting edge technology service platforms commercially available;

meet or exceed the customer s turnaround time needs;

generate the highest quality data and value-added analyses;

provide an aggressive and competitive price that follows the technology maturation curve; and

offer reliable, convenient, user-friendly customer-centric services.

To capitalize on the growing trend to outsource genomics analyses to service providers, our Cogenics division was established to provide a broad and comprehensive offering of services to researchers with needs in molecular biology and pharmacogenomics analysis. Cogenics is well positioned to compete as it provides the widest range of services in the genomics outsourcing industry, a broad portfolio of over 500 lines of business encompassing DNA Sequencing, Genotyping, Gene Expression Analysis, QPCR, Genomic Stability Testing, Biodistribution and DNA & RNA Extraction and Banking

#### In Vitro Diagnostic (IVD) Testing

The worldwide market for human blood testing is estimated at \$20.0 billion per year for diagnostic tests performed in hospitals and commercial laboratories worldwide. Clinical chemistry testing of blood, which includes such tests as cholesterol and glucose, represents a major segment of this market. The U.S. continues to be the largest single market for IVD testing.

Domestically, the present focus on reducing health care costs and increasing health care availability has encouraged the movement of blood testing from centralized laboratories into the patient care setting. Revenues from clinical laboratory testing are growing as a result of the aging of the population, increased healthcare awareness, and expanding insurance coverage. In addition, the physician market benefits from the shift of diagnostic testing from hospitals to alternate sites.

Worldwide there is an increasing need for greater efficiency in disease management. Clinical laboratories, both large and small, are seeking total support from diagnostic companies to enable them to establish a pre-determined cost per patient outcome. Our primary focus is to provide a complete range of blood analysis instrumentation and diagnostic assays for use in clinics and hospitals internationally and domestically.

The healthcare industry is subject to extensive government regulation. Government and private insurance carriers fund the cost of a significant portion of medical care offered in the U.S. and government funding is the source of healthcare spending internationally. The impact of cost containment on healthcare expenditures in the future is difficult to predict. Our technology is subject to regulatory control by the U.S. Food and Drug Administration (FDA) and the European IVD Directive and other regulatory agencies in various countries around the world.

#### **OUR COMPANIES**

#### **PGxHEALTH**

Our Strategy

Our market approach and commercialization programs consist of: (i) developing and commercializing proprietary genetic tests to improve the use of therapeutics by individual patients; (ii) developing and/or in-licensing the intellectual property and other assets to support these efforts; (iii) advancing our therapeutic Vilazodone and work relating to associated genetic marker discovery; and (iv) working with providers, payers and other key healthcare constituents to ensure uptake and adoption of pharmacogenetics in clinical care with the goal of improving cost and outcomes in the U.S. and international markets.

### **Developing and Commercializing Genetic Tests**

We intend to continue to develop and commercialize genetic tests that will assist providers and payers in determining the most appropriate therapeutic for a particular patient. These tests are and will continue to be

9

#### **Table of Contents**

developed based on intellectual property that we license from others as used in our *FAMILION* tests, *PGxPredict*<sup>TM</sup>:RITUXIMAB test, and *PGxPredict*<sup>TM</sup>:WARFARIN test, on intellectual property developed internally such as that used in our *PGxPredict*<sup>TM</sup>:CLOZAPINE test, and/or a combination thereof. Development programs may at times be funded and managed exclusively by PGxHealth or alternatively by collaborations with pharmaceutical, biotechnology, academic, payer and other partners. We may also develop and commercialize non-proprietary and semi-proprietary tests in order to maintain our business as a complete provider of pharmacogenetic tests and take advantage of channels we developed. In addition, genetic information relevant to the cause of a specific disease may be identified as a result of these development projects. We may choose to develop genetic tests based on this information or out-license it for development by others.

Our tests are available by prescription to providers located primarily in the U.S., Canada and Europe at this time. These tests may be comprised of a single point of genetic variation such as a single nucleotide polymorphism (SNP) or other genetic variants, or of haplotypes of a gene or multiple genes and may be developed in conjunction with a pharmaceutical product or be a stand-alone test. These tests, which are performed in our CLIA-certified laboratories in New Haven, Connecticut and Morrisville, North Carolina or may be partnered with other test providers, may be used to identify patients most likely to respond to a drug, patients who may have an unwanted side effect or patients who may respond best to a certain dose of a drug. The effect of such a test may be to reduce the trial and error approach to prescribing and to more rapidly identify the appropriate drug or dose for a given patient. This approach may result in a reduction in the total cost of care by avoiding prolonged periods of ineffective therapy, reduced morbidity and reduced adverse drug events or side effects.

During this last fiscal year, PGxHealth has formed relationships with parties that seek to assist PGxHealth in distribution of our tests in the U.S. and abroad and those that are interested in having PGxHealth advance and commercialize genetic tests from their biomarkers. Examples include an agreement executed with CVS pharmacy benefit manager (PBM) subsidiary PharmaCare to explore commercialization of our current test portfolio as well as development of new pharmacogenetic tests. Subsequent to this agreement being executed, CVS has acquired Caremark (one of the two largest PBM s in the U.S.). Recently, we formed two relationships for European distribution of our Long QT test *FAMILION*, Lab 21 and Diagene based in the U.K. and Switzerland, respectively. In addition, PGxHealth has actively in-licensed genetic markers to advance its genetic test development. For example, we announced the inlicensing of a patent portfolio from Innate Pharma in France in September of 2006, which led to the launch of the *PGxPredict:RITUXIMAB* test in the fourth quarter of fiscal 2007.

# Pursue Strategic Acquisitions

We continually evaluate opportunities that may provide us with, among other things, intellectual property, new technologies and key personnel or capabilities that could augment our genetic test franchise development. From time to time, we may pursue acquisitions which we believe will meet these goals.

#### Our Offerings: Genetic Tests

We currently have five genetic tests available to the provider community. The *FAMILION* family of tests has been available since May 2004. The PGxPredict family of tests was launched in 2006 with the availability of *PGxPredict:WARFARIN*, followed by *PGxPredict:CLOZAPINE* and *PGxPredict:RITUXIMAB* in early 2007. The fifth test, the TPMT genetic test, is out-licensed and offered through other laboratories and we receive royalties on sales of this test.

The FAMILION Tests Launched in May 2004 through our CLIA-certified laboratory in New Haven, Connecticut, the FAMILION suite of tests continues to reach a broadening market of physicians and patients in the U.S. and now in Europe. In July 2006, we announced the completion of our 1,000th FAMILION test and in

November and December 2006 announced agreements with Lab21 and Diagene to market and sell our *FAMILION* tests in Europe. The *FAMILION* tests detect mutations in 5 ion channel genes associated with cardiac channelopathies, which are rare, potentially lethal heart

10

#### **Table of Contents**

conditions, including Long QT Syndrome (LQT) and Brugada Syndrome. These conditions are caused by genetic mutations that result in abnormalities in the potassium and sodium channels of the heart and predispose affected individuals to an abnormal heart rhythm (arrhythmia). Familial LQT and Brugada Syndromes are commonly seen in apparently healthy, active adolescent patients. If left undiagnosed and untreated, these conditions can be fatal. Treatment options include life-style modification, the prescription or avoidance of specific classes of drugs, and the insertion of an implantable cardioverter/defibrillator. The results of these tests may assist physicians in choosing the most appropriate course of treatment for each patient. We have intellectual property rights relating to the five genes that have been identified as explaining the majority of two cardiac channelopathies, familial LQT and Brugada Syndromes, with each of the genes having multiple causative mutations. It is estimated that approximately 100,000 (1/3000) individuals in the U.S. have Long QT Syndrome yet many more individuals present every year with symptoms that could representative of this disease. As we discover more mutations contributing to this disease, the number of individuals who may be at risk increases. The majority of patients with LQT Syndrome are seen by a subset of cardiologists called electrophysiologists.

Our *FAMILION* test has more than doubled its growth in revenue year over year totaling \$3.4 million and we are adding marketing resources to further penetrate the market.

QT prolongation can also be acquired from the administration of a medication or can occur in patients with other cardiovascular disorders, such as congestive heart failure. More than 50 approved prescription drugs, in various therapeutic classes, are known to prolong the QT-interval (Source: YGYap and AJ Camm. Drug induced QT prolongation and torsades de pointes. Heart 2003;89:1363-1372). Drug-induced LQT has led to the withdrawal from the market of such well-known drugs as the heartburn agent Propulsid® and the antihistamine Seldane®. In December 2004, we entered into a license agreement with Vanderbilt University, which grants us exclusive commercial rights to a patent that claims screening patients for susceptibility to drug-induced cardiac arrhythmias by testing for the presence of a common polymorphism in KCNE1, an important cardiac ion-channel gene. With our Cogenics division, we have entered into co-marketing agreements with Quintiles Transnational and Spacelabs Healthcare to offer pharmacogenetic testing related to QT prolongation in the context of clinical trials, particularly through QT trials as required by regulatory agencies for most new compounds in development.

In 2007, we intend to develop and launch a genetic test for Catecholaminergic Polymorphic Ventricular Tachycardia, or CPVT. CPVT is a rare familial arrhythmogenic syndrome with a prevalence of about one in 10,000. This test will be marketed and sold to pediatric and adult electrophysiologists and cardiologists, similar to those who diagnose and treat LQT and Brugada syndromes.

PGxPredict:CLOZAPINE In January 2007, we announced the launch of PGxPredict:CLOZAPINE, a proprietary test indicated for physicians contemplating the initiation of clozapine treatment or for clozapine-treated patients whose white blood cell counts are falling. This test, available by prescription only, genotypes a two-SNP haplotype in the HLA-DQB1 gene which we have shown to be associated with clozapine-induced agranulocytosis in two independent cohorts. Clozapine-induced agranulocytosis (CIA) is a life-threatening decrease of white blood cells; the clozapine label requires frequent blood testing of patients in order to prescribe this drug.

Clozapine is an atypical antipsychotic prescribed for treatment-resistant schizophrenia, as well as for recurrent suicidal behavior in patients with schizophrenia and schizoaffective disorders. Schizophrenia is a chronic mental health condition affecting 1% of the US population, equivalent to approximately 2.4 million Americans (Source: Diagnostic and Statistical Manual of Mental Disorder, 4th Edition Text Revision (DSM-IV®-TR). American Psychiatric Association, Washington, DC. 2000; p 308). Clozapine is generally regarded as one of the most effective antipsychotic drugs and is the only antipsychotic to have demonstrated superiority to a comparator in a head-to-head

trial. Phase II of the Clinical Antipsychotic Trials for Interventions Effectiveness investigation confirmed that clozapine was more effective than newer atypical antipsychotics for patients who had previously discontinued from a

11

#### **Table of Contents**

different atypical antipsychotic treatment (Source: McEvoy JP, Lieberman JA, Stroup TS, Davis SM, Meltzer HY, Rosenheck RA, Swartz MS, Perkins DO, Keefe RSE, Davis CE, Severe J, and Hsiao JK. 2006). Effectiveness of clozapine versus quietiapine and risperidone in patients with chronic schizophrenia who did not respond to prior atypical antipsychotic treatment was favorable (Source: *American Journal of Psychiatry*, 163:600-610). Despite being highly efficacious, clozapine is reserved for treatment resistant cases due to the serious risk of agranulocytosis, as well as cardiovascular and metabolic side effects.

Branded and generic clozapine make up just 7.1% of the market share of antipsychotics, and generate annual sales of approximately \$175 million in the U.S. (Source: IMS Health, IMS National Sales Perspectives<sup>TM</sup>, March 2007). Clozapine, one of the most efficacious antipsychotic compounds, may be underprescribed, in part due to the risk of CIA but also to the burdensome but mandatory blood monitoring requirements throughout the treatment period, which may be many years. This test will allow providers to assess a patient s risk for the development of CIA, and inform their assessment of the risk/benefit ratio of treatment with clozapine. Furthermore, the ability to predict the risk of a patient developing CIA may permit modifications in the blood monitoring system in place for clozapine, alleviating the burden on patients and enhancing patient compliance with clozapine treatment. This test will benefit treatment by leading to the safer use of clozapine, one of the most efficacious drugs for the treatment of schizophrenia. Clozapine could ultimately move from a third-line to a second-line treatment option as this severe side effect of agranulocytosis is mitigated. We believe the opportunity exists to apply this approach to other treatments for schizophrenia.

We have also identified genetic variants that may contribute to risk of developing schizophrenia and may ultimately contribute to a genetic diagnostic test that assesses this risk and/or defines schizophrenia subtypes.

PGxPredict:RITUXIMAB In October 2006, we announced the in-licensing of intellectual property relating to the FCGRIIIa gene(encoding the Fc gamma IIIA receptor to which rituximab binds), a receptor for monoclonal antibodies. Based on this intellectual property, on January 30, 2007 we launched the PGxPredict:RITUXIMAB test that provides information on a patient s likelihood of response to rituximab monotherapy in follicular, CD20-positive B-cell non-Hodgkin s lymphoma. Follicular non-Hodgkin s lymphoma, or NHL, is an indolent disease, diagnosed in approximately 58,000 new patients per year in the United States and approximately 347,00 Americans are living with NHL (Source: Data Monitor, 2006). Rituximab (Rituxan<sup>®</sup>, Genentech/Biogen-Idec and Mabthera®, Hoffmann-La Roche) is a monoclonal antibody used alone or in combination with chemotherapy to treat follicular NHL. However, rituximab monotherapy is only effective in 57% of patients and carries significant toxicity in 57-70% of patients (Source: Rituxan® product insert). A four week course of rituximab treatment costs \$10,000 to \$12,000, making it a very expensive treatment with low efficacy and high toxicity. The test genotypes a SNP in the FCGRIIIa gene that results in the amino acid change of a valine to a phenylalanine at position 158 of the protein. This SNP has been functionally demonstrated to be associated to affect affinity of rituximab binding to the receptor. Two independent clinical studies have shown that patients who carry this genetic variant were significantly more likely to respond to rituximab monotherapy and that this association was robust over time, whether measured at three months or 12 months of treatment. The results of the test will identify patients as being More Likely or Not More Likely to respond. We expect to further advance this test and leverage the patent portfolio we in-licensed.

*PGxPredict:WARFARIN* The *PGxPredict:WARFARIN* test predicts how individual patients will respond to warfarin, a well-established anti-clotting agent often prescribed after cardiovascular events such as heart attack and stroke, for prophylaxis of clot formation in the setting of major surgery and for the treatment of other clotting disorders. Warfarin is the most widely used oral anti-coagulant in the world, and the nineteenth most prescribed drug in the U.S. (Source: Frost and Sullivan, 2007). It is estimated that there are 2 million patients on warfarin in the U.S. at any given time and 400,000-500,000 new patients are prescribed warfarin each year. Despite warfarin s well-established efficacy, determining the correct dose can be a challenge as there is wide variation from patient to patient.

#### **Table of Contents**

Different patients can derive the same clinical benefit from dosages that differ significantly making warfarin one of the most difficult drugs to dose appropriately. An incorrect dose can lead to serious side effects, including life-threatening bleeding, or to recurrent clotting and disease. The optimal maintenance dose of warfarin for each patient is difficult to establish. It can take a month or more of frequent monitoring of the prothrombin time (known as PT, a test for blood coagulability) before a stable maintenance dose of warfarin is identified. Genetic variability in two genes, VKORC1 and CYP2C9, is felt to account for more than 50% of the variability in warfarin dosing. In November 2005, the Clinical Pharmacology Subcommittee of the FDA s, Advisory Committee for Pharmaceutical Sciences has strongly advocated for the inclusion of genotype information in the prescribing of warfarin. They agreed that (Source: Food and Drug Administration s (FDA) Advisory Committee for Pharmaceutical Sciences http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4194M1.pdf):

sufficient mechanistic and clinical evidence exists to use lower doses of warfarin for patients with genetic variations in CYP2C9 that lead to reduced activity and genotyping patients in the induction phase of warfarin therapy would reduce adverse events and improve achievement of stable INR in patients with genetic variations in CYP2C9; and

sufficient mechanistic and clinical evidence exists to use lower doses of warfarin for patients with genetic variations in VKORC1 that lead to reduced VKORC1 activity and genotyping patients in the induction phase of warfarin therapy would reduce adverse events and improve achievement of stable INR in patients with genetic variations in VKORC1.

We have non-exclusively in-licensed rights under a variety of issued patents and pending patent applications owned by the University of Washington and the University of North Carolina Chapel Hill (UNC-CH) relating to *PGxPredict:WARFARIN*.

Thiopurine S-methyltransferase, or TPMT genetic test The TPMT test provides a genetic assessment of a patient s ability to metabolize the thiopurine class of drugs, which are commonly used in a wide range of therapeutic areas, including oncology, rheumatology, organ transplantation and vasculitis. The activity of the TPMT enzyme varies significantly among individuals who have different haplotypes of the TPMT gene. Pursuant to license agreements that we acquired from DNA Sciences in May 2003, we receive royalties based on net sales of this laboratory-developed test.

We are actively pursuing the development of additional tests which are either the next generation of the current tests commercialized by PGxHealth or represent novel tests that have applicability to additional specific therapeutics or therapeutic classes.

#### Our Pharmaceutical Product: Vilazodone

Depression is a highly prevalent disease with significant morbidity and mortality. The most commonly prescribed first-line treatment is to choose among the available Selective Serotonin Reuptake Inhibitors, known as SSRIs, which have been shown to have response rates of less than 50%. Prior to treatment, providers cannot determine to which of the many SSRIs a patient will respond. Since it can take many weeks to determine if a patient is a responder and since side effects are common in the first few weeks of treatment, physicians view as helpful a test that would help determine responder status at the time of diagnosis. In the face of no or poor response, treatment options include switching to a different agent or adding a second drug which may be a 5HT1A agonist. A single drug which combines these two mechanisms of action, such as Vilazodone, or a pharmacogenetic test to identify responders to a first-line agent should improve initial response rates, resulting in decreased morbidity and cost of care.

Genaissance acquired a worldwide exclusive license to develop and commercialize Vilazodone from Merck KGaA (Merck), Darmstadt, Germany in September 2004. We are proceeding with the development of Vilazodone for the treatment of depression. Vilazodone is a small molecule which is both an SSRI and a 5HT1A partial agonist, thus combining in one molecule the current first-line and a second-line therapy for depression. In February 2006, we initiated a Phase III randomized, double-blind, placebo-controlled trial of Vilazodone for the treatment of Major Depressive Disorder at ten U.S. centers and enrollment of 410 subjects was completed in March 2007. This study includes pharmacogenetic analyses for biomarkers of response to

13

#### **Table of Contents**

Vilazodone. We are applying our expertise in genetic biomarkers to attempt to identify biomarkers of response with the intention of developing a companion genetic test for Vilazodone response. Results of this clinical trial are expected September 2007. Prior to this study, Vilazodone had been assessed in 15 Phase I and five Phase II trials involving a total of 369 healthy subjects and 1,163 depressed patients, and found to have an acceptable safety profile for this stage of development. In previous trials with positive controls, Vilazodone failed to demonstrate significant efficacy against placebo but demonstrated efficacy comparable to that of the positive controls, approved antidepressants in wide use. At least one long-term safety study and one additional pivotal study will be required prior to filing an NDA, which could be accomplished as early as the end of calendar year 2009. With success, Vilazodone would be an early example of a drug launched with the use of a companion pharmacogenetic test, and the first in its therapeutic area, to target a segment of a population where response would be greater than in the total population.

In December 2006, under the terms of our license agreement with Merck, we completed the transfer of the technology to manufacture Vilazodone in order to proceed with plans to produce a commercial supply of the drug. If we are successful in the continuation of our development of Vilazodone, we will be obligated to pay Merck certain milestone payments, all of which are payable in our common stock, including a payment of 2.5 million within 30 days after initiation of the final discovery study. A milestone payment of 12.5 million also would be due within 30 days of acceptance of an NDA filing in the US or a MAA filing in the European Union for the first indication of Vilazodone. In addition, separate 9.5 million payments each would be due within 30 days of receipt of approval of the NDA or MAA, and the first sale of Vilazodone in the US or EU. Also under our license agreement with Merck, we have provided that Merck with options to co-develop and co-commercial Vilazodone with us based upon the achievement of development plan milestones, and if we are successful in commercializing Vilazodone and its companion biomarker, Merck also will be entitled to certain royalty payments.

#### **COGENICS**

# **Our Strategy**

Our strategy is to build the Cogenics division to be the dominant global supplier of pharmacogenomics and molecular biology services to pharmaceutical and biotechnology companies, government and academic research institutions. We will leverage our extensive base of technical know-how, and more than seventeen years of expertise, to compete aggressively in the market, serve our customers and enhance shareholder value. As we also currently perform CLIA-based tests in our laboratories that are marketed by the PGxHealth division, we are additionally committed to maintaining the highest standards of performance, delivery and turn around time that will ensure the success of PGxHealth.

#### **Our Offerings**

### Global Pharmacogenomics and Molecular Biology Services

Our offerings are focused globally on enabling pharmaceutical, biotechnology, academic, agricultural and other customers to derive and study genetic data from any biological source. We have developed a robust set of services, know-how and informatics capabilities that enable our customers to identify genes and genetic variation, and to understand gene expression and function in plants, animals, humans and lower organisms. Cogenics provides the widest range of services in the genomics outsourcing industry and includes a broad portfolio of over 500 lines of business. Our experience includes completing more than 900 clinical trial projects for most of the top 20 pharmaceutical companies in the world. Our customer base is diverse and no single client represented more than 10% of Cogenics business in fiscal year 2007.

We employ a field sales force in the U.S. and Europe to proactively sell our services and, we market our offerings globally through our website which includes an e-commerce portal for DNA sequencing. We are positioned to accept biological samples from customers located anywhere in the world with access to commercial shipping services and we routinely deliver our product of data, analysis and interpretation through electronic communication channels. In this way, we have coordinated hundreds of multi-site and multinational clinical trial genotyping studies over the past 17 years.

14

#### **Table of Contents**

Our sample analysis activity is performed in laboratory facilities in Houston, Texas, Morrisville, North Carolina and New Haven, Connecticut in the U.S. and in Takeley, UK and in Meylan, France in Europe. Revenue is generated by providing comprehensive DNA and RNA services as outlined here and described in more depth below:

isolating and banking DNA and RNA samples;

sequencing DNA samples on both the traditional (ABI3730) and next generation (454-Roche) automated sequencing platforms;

performing genotyping assays on several different instrument platforms; which measure the genetic variation present among DNA samples;

performing gene expression profiling, and confirmatory validation analysis on Affymetrix and Agilent microarray platforms and ABI QPCR instrumentation;

providing genetic stability testing using DNA sequencing, QPCR and related molecular biology services for biopharmaceutical manufacturers;

developing and providing laboratory-based assays to assist data generation and analysis during small molecule drug-based clinical trials as well as gene therapy and recombinant vaccine studies; and

Performing metabolomics studies to generate biochemical profiles of samples on a liquid chromatography-mass spectrometer platform.

# GLP-Compliant RNA and DNA Banking Services

We have developed an innovative program for the long-term storage of RNA and DNA that combines purification processes proven to produce high quality nucleic acids, chain-of-custody documentation through a validated laboratory information management system (LIMS), sample security, and retrieval efficiency under Good Laboratory Practices (GLP). Our RNA/DNA Banking Program supports the receipt, storage, maintenance, standardization, quality control, and redistribution of RNA/DNA for clients requiring large scale, high quality, controlled archiving. Cogenics has adopted an interactive project management approach to developing custom RNA/DNA archiving. This flexibility allows us to address technical issues specific to the systems and processes of each customer.

In addition, we have addressed customers — needs for sample anonymization and are able to receive samples with identifying information, recode samples during the accessioning process, and ultimately anonymize samples upon request for future analysis. Both process and informatics solutions are employed to ensure that sample anonymization is performed in compliance with regulatory standards.

# Custom DNA Sequencing Services

We have multiple sequencing technologies in our laboratories to accommodate both high-throughput and highly complex projects. Depending upon the nature of a project, we will develop an optimal sequencing strategy to generate consistent, high quality sequence data for use in applications spanning basic research and those to be submitted to the FDA or other regulatory agencies, including:

FDA submission quality sequencing This sequencing work is designed for presentation in a report that can be incorporated into an application to be submitted to the FDA or other regulatory agencies;

*Express Sequencing* This service is designed to give customers a quick look at high accuracy double or single strand sequence data from one or multiple clones, in which the data is returned to the customer within a very short period of time after receiving the sample;

High throughput sequencing services This service involves sequencing many clones from a genomic or an expressed sequence tag library utilizing high-throughput automated systems; and

Large scale genomic sequencing services In this service, we construct libraries from a variety of genomic constructs and assemble them into full-length sequences, which can represent hundreds or

15

#### **Table of Contents**

thousands of genes. This can be performed using traditional Sanger sequencing on the ABI 3730 platform. Alternately, we can perform directly whole genome sequencing, Expressed Sequence Tag sequencing, identification of small RNAs, transcriptome analysis, and metagenomics on our newly acquired Roche 454 FLX instrument capable of generating up to 100 mega bases of sequencing information in a single run.

#### **Custom Genotyping Services**

Our service offerings in genotyping enable our customers to identify genetic variations and specific biomarkers for a wide range of applications. These include:

creating better informed, or smarter, clinical trials through the design of protocols that result in enrichment for response via the inclusion of those patients most likely to benefit from the proposed therapeutic product;

facilitating earlier go/no-go decisions on whether to proceed to the next phase of clinical trial testing, which should result in more efficient use of clinical resources;

reducing the size and, hence, the cost, of late-stage clinical trials by enrolling patients who are most likely to respond to a drug and/or are least likely to suffer an adverse reaction; and

testing for individual susceptibility to disease or response to pharmaceutical treatments.

The key components of our offerings are:

A broad range of platform options including genotyping by RFLP mapping, by mass spectrometry (Sequenom), by sequencing (ABI 3730), by microarray (Affymetrix and Agilent) and on the Luminex instrument acquired in early 2007;

A comprehensive catalog numbering in the hundreds of standardized genotyping assays for commonly requested SNP assays such as the liver drug metabolizing cytochromes and transporter genes. These are available for non-regulated or regulated environments;

The ability to design, discover, develop and validate custom genotyping assays and then analyze samples with these validated assays on multiple platforms in non-regulated or regulated environments. In support of custom biomarker discovery, we may access our HAP<sup>TM</sup> Database, which contains highly informative, proprietary measures of genetic variation for more than 8,000 pharmaceutically relevant genes;

GLP, compliant genotyping services for assessing genomic variation among patients in a clinical trial, thereby permitting pharmaceutical and biotechnology companies to incorporate genomic variation information in their regulatory filings. For instance, we develop, validate, and run GLP-compliant genotype testing in support of global clinical trials (Phase I through Phase IV) for a wide variety of drug metabolism and drug target genes. GLP genotyping methods are developed and validated in accordance with SOPs detailing our formal validation program. Our GLP assays include full chain-of-custody documentation, QA data audits, and comprehensive data review to ensure that results are suitable for regulatory submission. Cogenics services in this area to date have been utilized in over 900 clinical trials; and

Genotyping testing under the CLIA requirements are performed for the PGxHealth Division in our laboratories licensed by the states of Connecticut and North Carolina. Our most recent site audit by Connecticut CLIA was in May of 2007 where Cogenics performs several genotyping by sequencing tests for PGxHealth.

# Gene Expression Profiling Services

Our gene expression profiling service provides a snapshot of the genes expressed in an organism, tissue or cell at a specific time. By comparing the expression of genes in a normal organism to a mutant organism, for example, we can ascertain information about the function of those genes with modified expression patterns,

16

#### **Table of Contents**

as well as gain insight into the effect of such genes. By determining how a modified gene, exposed to a chemical agent, or other biological permutations affect the expression patterns of large complement of genes, we gain insight into biochemical and biological pathways that may be relevant to the development of therapeutics and diagnostics.

We provide GLP-compliant RNA preparation, transcript profiling and data analysis and microarray services using Affymetrix Genechip® Gene Expression Analysis Arrays, Agilent Oligo microarrays and the proprietary MirChip<sup>tm</sup> technology we developed with Rosetta Genomics, as well as Laser Capture Micro dissection and the ability to process paraffin-embedded tissues on a fee-for-service basis.

We are able to complement our microarray gene expression profiling service with confirmatory microarray validation studies using Quantitative Polymerase Chain Reaction technology in both unregulated and regulated environments.

In September of 2006, Cogenics joined with other participants of the Micro Array Quality Control (MAQC) Consortium in publishing the results of the FDA-led initiative to assess the precision, reproducibility and comparability of microarray gene expression data. Cogenics contribution was unique in the generation and analysis of multi-platform gene expression data and resulted in three publications in the September 2006 issue of Nature Biotechnology. Cogenics is continuing to participate in the current MAQC Phase II study which is expanding upon the initial Phase I results.

## Genetic Stability Testing Services

Genetic Stability Testing, or GST, services assist clients in meeting the regulatory guidelines established for the development and maintenance of genetically engineered bacteria or cell lines that produce biotechnology products. We analyze and provide a comprehensive report on the genetic integrity of cell banks used to produce recombinant proteins, monoclonal antibodies, gene therapy, and vaccine products, which is essential for creating a reliable process that produces a pure biologic product in high-yield quantities. We believe that the need for these services is increasing rapidly because there are a growing number of biotechnology products entering the clinical development pipeline. Under this system, we conduct studies under the requirements of GLP and cGMP, as promulgated by the FDA. Our compliance with these regulations is defined in our quality policy manual and our standard operating procedures. Our quality assurance department reviews all project documentation and final reports to insure that they are compliant with applicable GLP/cGMP regulations. Our GST services include:

*DNA sequencing* We offer a number of alternative strategies to circumvent issues associated with having insufficient DNA and provide our clients with complete sequence data;

Copy number A service we provide that monitors the number of copies of a gene contained within a cell. Demonstrating that cells experience predictable changes in their copy number during production scale-up assures regulatory authorities that the process is well controlled;

*Insertion number* A service that is similar to copy number but it is an additional analysis that is utilized to measure the stability of a cell bank;

Plasmid loss or rearrangement A plasmid is an artificial stretch of DNA used to insert specified genes into a cell. For plasmid-based gene expression systems, the loss or rearrangement of the plasmid can be a major practical problem in high yielding strains, affecting the growth of cells. We have assays to detect the percentage of cells that are missing or have undergone a loss or rearrangement of their plasmid; and

*Phage detection* Phages are bacterial viruses, which can kill or alter the bacterium s growth cycle or expression levels. Our phage detection service is designed to detect contamination of a bacterial cell bank.

17

#### **Table of Contents**

## Custom Core Molecular Biology Services

Many of the custom services that we perform require the application of molecular biology techniques either upstream or downstream from the main service provided. As a result, we have the ability to perform a number of molecular biology techniques, which can be offered as a complement to another service, or as a stand-alone service. Some of the more frequently requested services that we offer are described below.

*Polymerase chain reaction* known as PCR, can be used to amplify a specific sequence of interest from plasmid, viral, or genomic DNA. We also have the expertise to provide reverse transcription PCR for amplification of an RNA product.

Subcloning A procedure used to transfer a DNA region of interest into a vector that is more suitable for procedures such as DNA sequencing and gene expression. We can provide a strategy for subcloning a variety of different sequence fragments, including PCR products, into standard vector systems.

Library screening During the gene discovery process, customers may find only a portion of a gene of interest. We can use such a gene fragment to screen a library of clones and isolate the full-length cDNA of interest.

Southern blot analysis This analysis is used to determine the gene copy number and map the insertion location.

*DNA preparation* Many of our customers need large amounts of DNA for sequencing or probe generation. We have the ability to isolate DNA on a large-scale basis.

## Metabolomics and Biochemical Profiling Services

Metabolomics Biochemical profiling provides a way of measuring the net change in the abundance of small molecules, and therefore addresses systemic changes at the biochemical level. Metabolomics provides a functional readout of biochemical changes which, when combined with gene expression results, enable us to construct a more comprehensive picture of the mechanisms that are altered within biological systems. We utilize proprietary methods to separate the thousands of components present in a biological sample according to both their physicochemical characteristics and their mass using mass spectrometry. The complex data from these analyses is deconvoluted using proprietary methods developed by us.

Cogenics has entered into a number of collaborative research agreements to further the growth of its metabolomics technology platform. These include:

a research collaboration with the University of Pittsburgh Cancer Institute to identify biomarkers to improve the diagnosis of non-small cell carcinoma;

a research collaboration with the UNC-CH and the National Institute or Environment Health Sciences, or NIEHS, to study the mechanism of acetaminophen toxicity in the liver. The research is focused on identifying better diagnostics for assessing liver damage and individual patient response to therapeutic treatment;

a research collaboration with the Bowles Center for Alcohol Studies which is affiliated with UNC-CH to identify markers for alcohol-induced liver and brain damage and dependence, using our systems biology platform; and

a master research agreement with Duke University Medical Center in the area of metabolomics and biomarker discovery.

# Collaborations, Partnerships and Business Development Initiatives

In connection with the commercialization of our services and technology, we enter into third-party agreements from time to time in the ordinary course of business. These third-party agreements may be with partners in the agricultural, government, pharmaceutical, biotechnology industries or academic centers. For example, we have provided Scrapie Genotyping Services for the Governments of Cyprus and Greece through a

18

#### **Table of Contents**

third party distributor located in each country. We may also sign agreements with CROs, or with similar companies that service the clinical trial industry, to distribute our products.

## Advanced Technology Program

In June 2002, we were awarded a five-year, \$11.7 million grant from the National Institute of Standards and Technology, known as NIST, to develop innovative tools for drug target discovery through the analysis of complex coherent data sets. Initially, we partnered with LION Biosciences, Inc., in 2004 with Agilent Technologies, and most recently with IO Informatics, Inc. as a joint venture partners under this grant. This grant, the largest bioinformatics grant ever awarded by NIST s Advanced Technology Program, or ATP, history at that time, supports the development of methods and tools for the creation, evaluation and analysis of coherent data sets.

Systems biology treats gene expression, protein expression, and biochemical processes as measurable components that can be engineered to accomplish specific therapeutic tasks. Assessing how these components influence each other to determine the response of a system, however, requires software that can discern and manage disparate data types. The ATP partnership leverages IO Informatics revolutionary intelligent multidimensional object, referred to as IMO, a mobile, extensible database record that transforms specific pieces or even parts of data into objects that scientists can describe, utilize, share, and relate to across application and database boundaries. The IMO will be applied to data accumulated through our proprietary Gene to Cell System<sup>tm</sup> approach to pharmaceutical and life science discovery. This suite of technologies is intended to increase the number and success rate of validated targets for product development by the pharmaceutical and other life sciences industries.

We have already successfully completed three technical milestones in this ATP grant. These consisted of the development, validation and analysis of two increasingly complex coherent data sets, and the production of prototype data coherence tools. The data sets were based on our investigation of liver injury in rats induced by acetaminophen, a common pain reliever. We are now in the final phase of this grant.

## National Institute of Environmental Health Sciences (NIEHS)

In September 2002, Icoria, now Cogenics Icoria, was awarded a five-year contract from the NIEHS for \$23.8 million to provide microarray processing services and to participate in toxicology research with NIEHS and five university-based labs (Cooperative Research Members, or CRMs). Collectively, this is referred to as the Toxicogenomics Research Consortium, or TRC. In April 2003, the NIEHS exercised an option in its existing contract with Icoria, providing for up to an additional \$8.4 million for toxicogenomics studies specifically earmarked for Cogenics Icoria to perform research for the National Toxicology Program, or NTP. Data generated from this toxicogenomics research will be included in the NTP s program to better understand the effects of short and long-term exposures to chemicals. The data will become part of the Chemical Effects in Biological Systems database, a publicly accessible relational database that will contain information on the biological effects of chemicals and other agents and their mechanism of action.

As a Cost Reimbursement Plus Fee Contract, our ability to recognize revenues from the NIEHS contract has been wholly dependent upon the pace of work provided to us by the NIEHS. Our past revenue performance was reflective of a brisk pace of research by the NIEHS and the TRC. During the third quarter of fiscal year 2006, we experienced a slowdown in the pace of work, in part due to leadership changes at the NIEHS. We anticipate that this slowdown will persist until research priorities within the NIEHS are fully implemented. We further anticipate that the full value of this contract will be recognized as revenue.

#### Medical Research Council

In June 2006, Cogenics was re-selected as an official supplier to the Medical Research Council (MRC) for DNA sequencing along with two other DNA sequencing companies, continuing a relationship with the MRC across all 35 UK sites for five years.

19

#### **Table of Contents**

## Agilent Technologies, Inc.

In June 2006, Agilent Technologies, Inc. recertified Cogenics for the third year as a Certified Microarray Service Provider for Agilent gene expression microarrays, and that certification was extended to include Agilent array-based comparative genomic hybridization (aCGH) experiments, an emerging field of study.

Cogenics received the certifications after its laboratory completed training and passed a rigorous set of assessments that included proficiency in analyzing Agilent 60-mer oligo microarrays using the complete Agilent system: sample quality control using the Agilent 2100 Bioanalyzer, sample labeling using Agilent reagents and protocols, hybridization using SureHyb chambers, microarray analysis using the Agilent scanner and feature extraction software, and final data-analysis using the GeneSpring bioinformatics platform.

In April 2007, Agilent announced that Cogenics was the first Certified Microarray Service Provider for Agilent s microRNA (miRNA) microarrays. With this certification Cogenics becomes the initial service provider to offer expression profiling of miRNA on the Agilent platform, giving scientists in research institutions and drug discovery programs immediate access to this important tool for understanding gene regulation.

# Algynomics, Inc.

In October 2006, Cogenics signed an agreement to provide genomic testing services to the pain research community based on Algynomics proprietary panel of genetic markers. This panel is designed to examine the genetic basis or underpinnings of human pain sensitivity, pain conditions, and responses to existing and new pharmacological agents used to treat pain, inflammation and mood disorders. The genetic panel is the result of more than ten years of rigorous pain research performed at the University of North Carolina's Center for Neurosensory Disorders located within UNC's School of Dentistry, and has been licensed to Algynomics for commercialization. The Cogenics genetic pain panel, initially offered as a complex microarray-based genotyping service was launched at the October 2007 American Society of Human Genomics Annual Meeting in New Orleans. The proprietary panel provides researchers with access to more than 3,000 SNP's for drug and diagnostic development to help determine an individual's susceptibility to pain.

#### VWR International

Also in October 2006, VWR International, Inc. announced a strategic alliance with Cogenics to utilize VWR s comprehensive sales network to generate qualified leads for DNA sequencing services for Cogenics in Europe s industrial and academic bioresearch markets. The multi-year agreement gives Cogenics access to VWR s 400-plus sales representatives and 20-plus VWR BioScience Managers throughout Europe to promote Cogenics DNA sequencing services and to identify qualified customer leads.

#### **Quintiles Transnational Corp**

In November 2006, Cogenics announced a strategic alliance with Quintiles Transnational Corp to offer to Quintiles customers our proprietary services related to the evaluation of drug-induced QT prolongation. The pharmacogenomics analyses are performed in the New Haven, Connecticut, laboratories of Cogenics. As part of the alliance, the two companies may also collaborate on the study of drug-induced QT prolongation for potential development of new products or services. This multi-year agreement will help sponsors and regulatory agencies further the understanding of the contribution of genetics to the QT-prolonging effects of drugs.

## Spacelabs Healthcare Clinical Trial Services

In March 2006, together with Spacelabs Healthcare Clinical Trial Services, we announced a partnership to offer our proprietary services related to the testing of drug-induced QT prolongation to Spacelabs customers through Cogenics. This agreement will assist drug development researchers and governmental regulatory agencies in improving the utility of the trials in detecting or ruling out meaningful QT prolonging effects by controlling for genetic variables.

20

#### **Table of Contents**

## **Roche Diagnostics**

In March 2006, Cogenics and Roche Diagnostics signed a co-marketing agreement in support of the installation by Cogenics of a 454 Genome Sequencer FLX (454GS FLX) system in its facility in Meylan, France. Cogenics is currently offering 454 GS FLX Next Generation sequencing technology as a fee-for-service offering to clients worldwide, with applications ranging from whole genome sequencing to genome wide expression profiling, and is collaborating with Roche to co-market the service.

# **Cogenics Market and Competition**

We believe that Cogenics has earned a reputation as a leading provider of genomics services. This reputation has allowed Cogenics to obtain key contracts with major pharmaceutical and biotechnology companies throughout the world. Cogenics is a fee for service contractor and typically takes no ownership position in the intellectual property rights of the services it performs under contract. Several factors influence the current competitive business conditions faced by the division. First, the total amount of DNA sequencing is increasing due to genome sequencing initiatives, and competitive pressures are increasing in the pharmaceutical industry. Major pharmaceutical companies have made significant financial commitments to pharmacogenomics and gene therapy approaches. Additionally, companies in both the pharmaceutical and biotechnology sectors are facing increasing competitive pressures to reduce fixed expenditures. Pharmaceutical companies are increasingly outsourcing routine procedures to maximize the innovative aspects of their internal efforts. The biotechnology sector has accepted the virtual company model, which supports further outsourcing of routine development efforts. Cogenics has many attributes, which have enabled it to compete in this complex environment. Cogenics is recognized as a quality leader among contract molecular biology service providers and has operated under the direction of industry professionals for many years.

We face competition in our GLP compliant and/or research sequencing, genotyping and associated pharmacogenomics and molecular services from individual researchers at laboratories within institutions such as the National Institutes of Health, who are capable of performing the work themselves, to core laboratories inside companies such as Amgen Inc., GlaxoSmithKline and Pfizer, Inc. Core laboratories can exist either in an academic or government setting or within a medium to large company, which can provide services at a much-reduced rate due to subsidizing of overhead expenses. We also face competition from several companies and new entrants in the genomics services market attempting to copy our footprint by offering DNA sequencing, genotyping and/or related molecular biology services.

Commercial competitors include larger participants from the traditional Clinical Diagnostics Testing (such as Quest, LabCorp) and CRO sectors (Quintiles, Covance, PPD, Bioreliance) as well as the service divisions of genomics analysis instrument vendors such as Affymetrix, Illumina, Sequenom, 454-Roche, and Luminex. Niche service competitors, often offering a narrow line of services, include Seqwright, GATC, Genewiz, MWG, Agencourt in sequencing, Expression Analysis and Gene Logic in microarray and Epidauros and Gentris in genotyping.

#### IVD TESTING VITAL SCIENTIFIC AND ELECTA LAB

#### **Our Strategy and Markets**

The worldwide market for human blood testing is estimated at \$20 billion per year for diagnostic tests performed in hospitals and commercial laboratories worldwide.

Clinical laboratory testing capabilities have become increasingly sophisticated and healthcare institutions continue to recognize greater value in these essential technologies for the improvement of disease management. The growth

drivers in this market are the increasing chronic disease population and the rising demand for quick and accurate results tempered by the cost restraints imposed on delivering high quality healthcare at an optimal price. Consequently, clinical laboratory analyzers are expanding capabilities and introducing technological advancements in order to provide comprehensive testing solutions that facilitate more efficient, accurate, near-patient/point-of-care (POC) that also streamline laboratory procedures at a reduced cost.

21

#### **Table of Contents**

While clinical laboratory analyzers only comprise around a quarter of the entire clinical diagnostics market, reagent sales are often dependant upon instrument placements, meaning that increased analyzer unit sales to build an installed base, is crucial to securing future growth in the profitable clinical diagnostics industry. Delivering customer satisfaction and service excellence is also key to maintaining a stable base of service while creating opportunities for new technology and product sales to the call point. There is also a noticeable trend towards near-patient/POC testing indicating that revenues are likely to shift away from the reference laboratory market to the smaller laboratory and hospitals.

The current reference laboratory space is dominated by routine clinical chemistry testing, making up approximately 86% of test volume in 2002 (reported by Frost and Sullivan, 2003), while accounting for only 69% of revenues. Clinical chemistry testing of blood, which includes such tests as electrolytes, cholesterol and glucose, still represents the major segment of this market and the U.S. is the largest single market for IVD testing.

In recent years, the reference laboratory testing sector has consistently lost market share to small hospital-based laboratories, which continues to grow with the acceptance of near-patient/POC testing as well as the increase in availability of tests that are waived under CLIA regulations. The analyzer market for smaller bench-top and freestanding broad menu technology is increasing as a result.

Significant growth is also being realized in the emerging IVD marketplaces of India and China, with growth rates above 15% as an increasing number of diagnostic tests are performed as part of the physician or clinic visit. Vital Scientific has had a strong presence in both of these markets for over 15 years and has established a profitable installed base in the thousands of units.

#### **Our Products**

Vital Scientific represents our global basic chemistry analyzer business which we manufacture in the Netherlands. Vital Scientific has established distribution arrangements across 100 countries through more than 50 distribution partners with an over 25,000 instrument user base including OEM partnerships with Dade Behring Inc., Hycor Biomedical Inc. and Spinreact S.A. The key product offerings from Vital Scientific are general biochemistry desktop and freestanding analyzers, including ISE modules.

Electa Lab manufactures specialized and focused analyzer platforms in our Italian facilities and sells through direct sales, distribution networks and OEM partnerships. Electa Lab s key product offerings are chemistry desktop and benchtop analyzers, including Erythrocyte sedimentation rate (ESR), spectrophotometry, chemiluminescence and coagulation analyzers

## Clinical Chemistry

Clinical chemistry systems use photometric or electrochemical detection principles to quantify substances of diagnostic interest (referred to as analytes) in patient blood, urine, and other body fluids. Commonly performed tests include cholesterol, triglycerides, electrolytes, and glucose. We offer a range of automated and semi-automated clinical chemistry systems to meet the testing requirements of the smaller laboratory.

Our line of clinical chemistry systems is a family of products which include modular automated diagnostic instruments and the reagents, standards and other consumable products required to perform commonly requested diagnostic tests. Each of our products listed below has been cleared for marketing in the U.S. by the FDA and complies with European IVD regulations. These include:

The Vitalab Selectra-XL, a floor model 360 test per hour random-access, walk-away clinical chemistry analyzer offering a wide range of testing including clinical chemistry, special proteins, drugs of abuse (DOA), therapeutic drug monitoring (TDM), and electrolytes;

The Vitalab Selectra E, (also trade-named Selectra II and Vitalab Flexor-E), a walk-away 180 test per hour clinical chemistry analyzer, capable of performing over 70 different diagnostic tests using reagents from almost all manufacturers;

22

#### **Table of Contents**

The Vitalab Junior a walk-away 90 test per hour clinical chemistry analyzer, also capable of performing over 70 different diagnostic tests using reagents from a wide range of producers;

The Viva series of analyzers, dedicated systems designed for TDM and for the detection of DOA, which are marketed by Dade Behring in over thirty countries worldwide. These analyzers were designed specifically for use with the Dade Behring Emit<sup>®</sup> line of diagnostic assays for TDM and DOA;

The HY-TEC 288 is a fully automated enzyme immunoassay system that was developed and is manufactured for Stratagene Corporation (formerly Hycor Biomedical, Inc.) of La Jolla, California. The HY-TEC 288 is a reagent system that permits the testing of 8 autoimmune tests and 900 allergens;

The Vitalab 300 semi-automated clinical chemistry analyzer, which permits a full range of testing including endpoints, kinetic and bichromatic measurements; and

A complete menu of over 20 clinical chemistry tests formulated and/or packaged by us for our range of clinical chemistry instruments.

# Hematology

ESR is a time-honored laboratory method for determining the acute phase response to inflammation. It measures the rate at which red blood cells in a test tube separate from blood plasma over time to become sediment in the bottom of the test tube. The sedimentation rate increases in various disease processes.

We offer ESR analyzers and disposables produced for us by our Electa Lab subsidiary. Our products are marketed under the Excyte<sup>tm</sup> family trademark as automated ESR analyzers and consist of five models. The Excyte analyzers are UL certified and correlate well to the modified Westergren method. They require the use of Excyte ESR tubes, which are available in both vacuum and non-vacuum models. The Excyte family of analyzers includes:

The Excyte 10, Excyte M and Excyte M Scan which are 10 position, random access ESR analyzers offering a range of functions including on-board mixing and barcode label scanning on the Excyte M Scan;

The Excyte 40 and the Excyte 20 were designed for larger laboratories. Both feature random access, an on-board QC program, storage of up to 500 patient results and optional printer and barcode scanners. The Excyte 40 is a 40 position analyzer and the Excyte 20 is a 20 position analyzer; and

The optional Excyte Slider® offers positive patient identification through all stages of testing.

#### Hemostasis

Hemostasis is a biochemical process that protects the body from blood loss caused by vascular damage. Within seconds of damage, constriction of the vessel and formation of a temporary hemostatic platelet plug occurs. Platelet aggregation triggers the coagulation cascade that leads to clot formation. Coagulation systems provide detailed information used to diagnose bleeding and clotting disorders.

We offer the Fibron-1 Coagulometer and related assays for *in vitro* coagulation testing of citrated human plasma in the clinical laboratory. This analyzer is designed for the small laboratory.

# Distribution

We market to clinics and small hospitals through a dealer network in Europe, the U.S., the Far East, Latin America, Eastern Europe and China.

# **Product Development**

To develop new IVD products, we employ chemists, mechanical, electronic and systems engineers, augmented by specialized contract vendors, and further supported by a staff of professionals from a central-European contract software group. Research and development is performed at a number of our companies and

23

#### **Table of Contents**

may be shared between companies through licensing agreements when appropriate. We maintain mechanical prototyping and automated assembly operations in the Netherlands.

Research and development spending, including capitalization of certain software development costs, was approximately \$2.3 million during fiscal 2007, \$3.0 million during fiscal 2006 and \$2.9 million during fiscal 2005.

We intend to develop new products where we perceive a demand and believe that the products may be effectively marketed. There is no assurance that any developments or enhancements will be successfully completed or that, if developed, any of the products will be successfully marketed.

## **Manufacturing**

We have been manufacturing instrumentation for the commercial market since 1956 through our subsidiary, Vital Scientific, which we acquired in 1984. Our Dutch operations received ISO 9001 and EN13485 certification and is FDA registered and complies with European IVD regulations.

## **IVD Testing Market and Competition**

In the sale of clinical laboratory technology, we are subject to intense competition in the worldwide marketplace. Blood analysis is a well-established field in which there are a number of competitors, which have substantially greater financial resources and larger, more established marketing, sales and service organizations. We believe that we compete favorably on our capabilities, the quality of our products, and our ability to manufacture and produce our products in a timely fashion.

In offering products and services to smaller laboratories, we compete with numerous other companies. These include much larger and well-financed companies such as Bayer, Roche Diagnostics, Alfa Wasserman and with companies such as Polestar Labs, Polymedco, and many other smaller American and European companies who distribute in this field.

In developing instruments for private-label sales by third parties, and in marketing directly to distributors, we compete with numerous other companies. These include much larger and well-financed companies such as Bayer, Roche Diagnostics, and Thermo Electron who are direct marketers in this field, and with companies such as Integrated Technologies Ltd., Medical Innovations, Inc. and many other smaller European and American companies, which are OEM marketers in this field. We believe that we compete favorably on our capabilities, the quality of our products, and our ability to manufacture and produce our products in a timely fashion.

#### OTHER BUSINESS MATTERS

#### **Government Regulation**

# PGxHealth Regulation

Regulation by governmental entities in the U.S. and other countries will be a significant factor in the development, manufacturing and marketing of any product that our customers or we develop. Various federal and, in some cases, state statutes and regulations govern or influence the manufacturing, safety, labeling, storage, record keeping, performance and marketing of human therapeutic and diagnostic products or services. The extent to which these regulations may apply to our customers or to us will vary depending on the nature of the product or service.

Virtually all of the pharmaceutical products being developed by our customers and our own therapeutic, Vilazodone, will require regulatory approval by governmental agencies prior to commercialization. In particular, the FDA and similar health authorities in foreign countries will impose on these products an extensive regulatory review process before they can be marketed. This regulatory process typically involves, among other requirements, preclinical studies, clinical trials and often post-marketing surveillance of each compound. This process can take many years and requires the expenditure of substantial resources. Delays in obtaining marketing clearance could delay the commercialization of any therapeutic or diagnostic products

24

#### **Table of Contents**

developed by us or our customers, impose costly procedures on activities, diminish competitive advantages and lessen our potential revenues or royalties. Any products we or our customers develop may not receive regulatory approval in a timely fashion or at all.

The FDA regulates human therapeutic and diagnostic products in three broad categories: drugs, biologics and medical devices. Products developed using our technologies could potentially fall into any of these three categories or into a category combining two or more of these product types.

The FDA generally requires the following steps for pre-market approval of a new drug or biologic product:

preclinical laboratory and animal tests;

submission to the FDA of an investigational NDA, which must become effective before clinical trials may begin;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication:

submission to the FDA of an NDA if the FDA classifies the product as a new drug, or a biologic license application if the FDA classifies the product as a biologic; and

FDA review of the NDA or biologic license application in order to determine, among other things, whether the product is safe and effective for its intended uses.

The FDA classifies medical devices, which include diagnostic products, as class I, class II or class III, depending on the nature of the medical device and the existence in the market of any similar devices. Class I medical devices are subject to general controls, including labeling, pre-market notification and good manufacturing practice requirements. Class II medical devices are subject to general and special controls, including performance standards, post-market surveillance, patient registries and FDA guidelines. Class III medical devices are those which must receive pre-market approval, or PMA, by the FDA to ensure their safety and effectiveness, typically including life-sustaining, life-supporting, or implantable devices or new devices, which have been found not to be substantially equivalent to currently marketed medical devices. It is impossible to say at this time which of these categories will apply to any diagnostic product incorporating our technologies.

The Centers for Medicare & Medicaid Services, commonly referred to as CMS regulates all laboratory testing (other than research) performed on humans in the U.S. through CLIA. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations has the responsibility for implementing the CLIA Program. So-called laboratory-developed or in-house developed tests are currently regulated under CLIA. At this time, the tests offered by PGxHealth are performed in our Cogenics laboratories and are regulated under CLIA as laboratory-developed tests. It is unknown whether these tests may eventually be subject to 510(k) or PMA approval by the FDA as described below. According to the FDA, the FDA currently exercises enforcement discretion over the regulation of these tests. Whether or not the FDA has the legal authority to regulate laboratory developed tests must be determined.

FDA-regulated devices must, in most cases, receive either pre-market notification clearance under section 510(k) or approval pursuant to the more costly and time-consuming PMA process. A PMA application must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device, typically including the results of clinical trials, bench tests, laboratory and animal studies. A section 510(k) clearance will be granted if the submitted information establishes that the proposed device is substantially equivalent to a legally marketed class I or class II

medical device or a class III medical device for which the FDA has not called for PMAs. While less expensive and time-consuming than obtaining PMA clearance, securing section 510(k) clearance may involve the submission of a substantial volume of data, including clinical data, and may require a lengthy substantive review.

Even if regulatory clearance is obtained, a marketed product and its manufacturer are both subject to continuing review. Discovery of previously unknown problems with a product may result in withdrawal of the product from the market, which could reduce our revenue sources and hurt our financial results, in addition to

25

#### **Table of Contents**

exposing us to product liability claims. Violations of regulatory requirements at any stage during the process, including preclinical studies and clinical trials, the review process, post-marketing approval or in manufacturing practices or manufacturing requirements may result in various adverse consequences to us, including:

the FDA s delay in granting marketing clearance or refusal to grant marketing clearance of a product;

withdrawal of a product from the market; or

the imposition of civil or criminal penalties against the manufacturer and holder of the marketing clearance.

Generally, similar regulatory requirements apply to products intended for marketing outside the U.S.

In March 2005, the FDA issued guidance that encourages pharmaceutical and biotechnology companies to use pharmacogenomics during the drug development process and clarifies how the data should be submitted to FDA and how FDA will evaluate it. In September 2006, the FDA issued draft guidance for *In Vitro Diagnostic* Multvariate Index Assays, or IVDMIA. Per the guidance, an IVDMIA is a test system that employs data, derived in part from one or more in vitro assays, and an algorithm that usually, but not necessarily, runs on software, to generate a result that diagnoses a disease or condition or is used in the cure, mitigation, treatment, or prevention of disease (Source: http://www.fda.gov/cdrh/oivd/guidance/1610.html). It is not known whether any of our tests or tests developed with its partners may be subject to this guidance.

In August 2006, we announced that we had received a letter from the FDA regarding the regulation of genetic testing. The letter invited us to meet with the FDA to discuss the nature and appropriate regulatory status of our tests and, if any regulatory requirements apply, the least burdensome ways that we may fulfill them. We have provided the FDA with all requested information and have received no notice of deficiencies or that we are not in compliance with applicable regulations.

We use DNA isolated from clinical samples from individuals in developing our intellectual property consisting of genetic biomarkers and their association with specific phenotypes such as drug response. In some cases, a CRO with which we have a contract collects these blood samples with accompanying personal and medical information about each individual. In other cases, we contract directly with clinical sites to collect the samples plus personal and medical information without the assistance of a CRO. Our CRO may prepare, subject to our approval, the sample collection protocol and the patient informed consent form, and may identify the clinical sites which collect the samples. The individual clinical sites recruit the patients for each clinical study and, following the study protocol, explain and obtain the signed and witnessed informed consent documents from each patient. The informed consent form includes the patient s authorization to use the patient s sample and data derived from it for developing commercial products. Our contract with the CRO and contracts with individual clinical sites require an independent institutional review board to approve the study protocol, the patient informed consent form and the transmission of the samples to us. Either we do not know the identity or we have in place procedures to maintain the confidentiality of any of the individuals from whom we receive clinical samples. We believe that these procedures comply with all applicable federal, state and institutional regulations.

#### **Cogenics**

# **Governmental Approval**

Cogenics is not dependent upon governmental approval of its current services. However, many of its clients will submit applications for new drugs or devices to the FDA. A significant portion of the projects undertaken by Cogenics are in support of such applications and thus are subject to compliance with standards such as GLP and cGMP

established by the FDA and its foreign counterparts. Cogenics employs personnel and utilizes procedures, which it deems necessary to comply with these regulatory standards. Although Cogenics and its services are not themselves subject to FDA approval, Cogenics complies with these regulatory standards in order to undertake this type of project for its clients. By virtue of its work in support of its client submissions to the FDA and other regulatory bodies, Cogenics is subject to inspections by the FDA and other federal, state and local agencies regarding specific FDA submission projects it has worked on.

26

#### **Table of Contents**

Regulatory affairs audit teams from its pharmaceutical and biotech clients frequently inspect Cogenics s facilities and procedures to ascertain whether Cogenics complies with applicable regulations. To date, Cogenics has not been found in material noncompliance with the FDA or customer requirements. If significant violations were discovered during a client or governmental inspection, Cogenics might be restricted from undertaking additional submission projects until the violations were remedied. In the event that remedying such violations required significant time or financial resources, such violations could have a material adverse impact upon Cogenics.

## **Governmental Regulations and Environmental Laws**

Cogenics is subject to regulations concerning laboratory and occupational safety practices, the use and handling of hazardous chemicals and radioisotopes, and environmental protection. Additionally clinical molecular diagnostics tests performed by Cogenics on behalf of customers require adherence to CLIA regulations in the US. Cogenics believes that it is in general compliance with such applicable federal, state and local regulations and does not estimate the costs to comply with these regulations will be material.

While the FDA does not currently regulate our genotyping facility, CLIA defines standards that constitute good clinical laboratory practice. Although this is a federal law, each state is responsible for administering the statute. The state of Connecticut issued a CLIA license for our facility in New Haven and the state of North Carolina issued a CLIA license for our facility in Morrisville. Both of these facilities can provide clinical genetic test results in support of therapeutic or medical interventions. A CLIA-licensed clinical laboratory can be inspected by the state at any time to insure that we are in compliance with CLIA regulations.

In addition, in June 2004, the Animal and Plant Health Inspection Service (APHIS), a division of the United States Department of Agriculture (USDA) approved our high-throughput genotyping facility in New Haven, Connecticut, to genotype sheep to determine their susceptibility to scrapie under National Scrapie Eradication Program, or NSEP. We subsequently began processing samples under a contract that the USDA awarded to us as part of NSEP.

Due to the home-brew genetic testing component of our business, such as our *FAMILION* Test, we routinely receive protected health information, or PHI. PHI is health information that can be used to identify an individual, such as a person s name, Social Security Number, telephone number, and address. We are required under the Health Insurance Portability and Accountability Act of 1996 to maintain the privacy of PHI, and we are committed to doing so.

## IVD Testing Regulation

Where necessary, we obtain government approval to market our products and may have to obtain prior approval from certain European regulatory bodies or the FDA to market products that we develop. In Europe, we are subject to EN13485 and CE (Conformité Européne) marking and IVD registration requirements. The cost of obtaining approvals for new products may be high and the process lengthy, with no assurance that new product approvals will be obtained.

To date, neither the FDA nor the European medical regulatory bodies have developed industry-wide performance standards with respect to the safety and effectiveness of the products presently marketed by us. Although we intend to use our best efforts to comply with domestic and international standards, when and if developed, there can be no assurance that all of our products will be compliant. Any failure to receive approvals for our future products or noncompliance with any international performance standards promulgated in the future could have a material adverse effect on us and our results of operations. Furthermore, any material change in the existing rules and regulations or any new regulations developed might adversely affect us and our results of operations.

27

#### **Table of Contents**

## **Intellectual Property**

#### **PGxHealth**

We rely on patents, trade secrets, non-disclosure agreements, and copyrights to protect our proprietary technologies and information. In addition, our goal is to license to third parties certain components of our intellectual property that is peripheral to our core products and services.

As of March 31, 2007, we have a patent estate consisting of six issued U.S. patents, 18 pending U.S. patent applications, and 16 pending foreign patent applications. Two of the issued U.S. patents are co-owned: one by Duke University and another by the University of Cincinnati. We have also exclusively and non-exclusively in-licensed rights under a variety of issued patents and pending patent applications. We have exclusively in-licensed rights under one issued U.S. patent owned by Yale University (exclusively sublicensed to Siemens Medical Solutions Diagnostics); one issued U.S. patent owned by St. Jude Children s Research Hospital (exclusively sublicensed to Prometheus Laboratories Inc. and Specialty Laboratories, Inc.); one issued U.S. patent owned by Vanderbilt University; four issued U.S. patents, two pending U.S. patent applications, three issued foreign patents, and ten pending foreign patent applications, owned by the University of Utah; six issued U.S. patents, four pending U.S. patent applications, 46 issued foreign patents, and 185 pending foreign patent applications, owned by Merck and one issued U.S. patent, four pending U.S. patent applications, eight pending foreign patent applications, owned by Innate Pharma. We have non-exclusively in-licensed rights under a variety of issued patents and pending patent applications owned by the University of Washington, the UNC-CH, and the Mayo Foundation for Medical Education and Research.

The patents and patent applications that we own, or under which we have exclusively and non-exclusively licensed rights, are directed generally to:

Vilazodone, our lead therapeutic product;

detection of familial LQT Syndrome;

detection of drug-induced LQT Syndrome;

associations between genetic markers and drug response (efficacy and safety) and disease endpoints, specifically including rituximab response, heparin-induced thrombocytopenia, cytokine release syndrome, warfarin response, irinotecan response, clozapine-induced agranulocytosis, thiopurine metabolism, statin response, progression and onset of Alzheimer s disease, and schizophrenia;

processes for assembling genetic markers and for determining clinical associations; and

coupled amplification and sequencing of DNA.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We generally protect this information with reasonable security measures, including confidentiality agreements that provide that all confidential information developed or made known to others during the course of the employment, consulting or business relationship shall be kept confidential except in specified circumstances. Agreements with employees provide that all inventions conceived by the individual while employed by us are our exclusive property.

# **Cogenics**

## Patents and Proprietary Technology

Cogenics is a fee for service contractor and typically takes no ownership position in the intellectual property rights of the services it performs under contract. We do rely on patents, trade secrets, non-disclosure agreements, and copyrights to protect our own proprietary technologies and information.

Cogenics actively seeks patent protection in the U.S. and in significant foreign countries for inventions and technologies for which it deems such protection commercially advisable. Cogenics relies on trade secrets and technical know-how in order to maintain its competitive advantage and scientific expertise. It is the

28

#### **Table of Contents**

practice of Cogenics to enter into confidentiality agreements with employees, consultants, advisors, and any third party to whom it discloses confidential information. There can be no assurance that such confidential information will not be disclosed or that similar trade secrets or expertise will not be independently developed, or that access to such information could not be gained inadvertently. Cogenics is, by nature of its work, privy to certain confidential information of its customers. In order to attract and maintain clients Cogenics enters into confidentiality agreements with its customers, as both parties deem appropriate. There can be no assurance that such confidential information will not be disclosed or that similar trade secrets or expertise will not be independently developed, or that access to such information could not be gained inadvertently.

# **IVD Testing**

We do not believe that our IVD testing business, as a whole, is or will be materially dependent upon the protection afforded by patents, and a substantial majority of our revenues in this segment is attributable to products without patent protection.

## **Backlog**

Backlog in our molecular services segment totaled approximately \$8.0 million at March 31, 2007 as compared to \$7.3 million at March 31, 2006 and is expected to be fulfilled by March 2009. The backlog for all our segments in aggregate was \$14.7 million at March 31, 2007 as compared to \$13.6 million at March 31, 2006, and it is expected to be fulfilled by March 2009.

# Seasonality

Our second fiscal quarter (July, August and September) and the fourth quarter (January, February and March) is often impacted by seasonal vacillations in business volumes and related revenues. European academic and pharmaceutical clients take vacations in late July and August and as a result, volumes during this period of Cogenics services are less strong than other periods. Our European IVD manufacturing facilities normally closes its operations for two weeks during this period and medical practices in the U.S. also experience a decline in voluntary procedures such as examinations, which results in a decline in testing. Consequently, we may experience a decline in revenue growth and net income from first fiscal quarter levels during our fiscal second quarter, reflecting this slowdown in business activity. A similar phenomenon happens in the third quarter as volumes tend to be very robust before the holidays in December but are historically low directly after the holidays and recover in the first quarter.

## **Employees**

The Company had 459 full-time and equivalent employees as of March 31, 2007. Of this total, approximately 304 employees are employed in the U.S. and 155 are employed in Europe.

#### **Environmental Matters**

We do not believe that compliance with Federal, state or local regulations relating to the protection of the environment has any material effect on our financial or competitive position.

# **Significant Customers**

Within our clinics and small hospitals segment during fiscal 2007, sales to one significant customer amounted to approximately 15% of consolidated revenues. Approximately 8% of accounts receivable at March 31, 2007 were receivable from this customer. No customers within our Molecular Services segment comprised 10% or more of our

consolidated revenues.

# **Discontinued Operations**

During fiscal 2007, we determined that Vital Diagnostics, Pty. (Vital Diagnostics) and Clinical Data Sales and Service, Inc. (CDSS) did not fit with our strategic direction and the capital resources derived from the sale of the these two businesses could be better allocated to investments and growth opportunities to increase our

29

#### **Table of Contents**

presence in the pharmacogenomics and molecular services markets. Accordingly, we classified these two businesses as discontinued operations and their results of operations, financial position and cash flows are separately reported for all periods presented.

### Vital Diagnostics

We received offers from two groups to purchase Vital Diagnostics, a distributor focused on selling scientific instrumentation, equipment and reagents in Australia and New Zealand and previously a component of our Small Clinics and Hospitals operating segment. During the second quarter of fiscal 2007, we accepted the most favorable offer which was to sell our 92.5% interest for net proceeds of \$1.0 million. The transaction closed on November 13, 2006. The buyers included Adrian Tennyenhuis, Vital Diagnostic s general manager and holder of the 7.5% minority interest, and New River Management IV, LP, an affiliate of Third Security, which is funded and controlled by Third Security, LLC which, in turn, is controlled by Randal J. Kirk, our Chairman of the Board. We recorded a loss on disposal of approximately \$178,000 in connection with the sale during the year ended March 31, 2007.

#### **CDSS**

We engaged Lazard Freres & Co. LLC (Lazard) to seek a buyer for CDSS, a seller of products and services from scientific instrumentation, equipment and reagents to lab management and consulting services to physician s office laboratories (POL). CDSS previously comprised our POL segment. Lazard identified a list of potential buyers, who were contacted, and we received several letters of interest to purchase CDSS. We accepted the most favorable offer which was to sell CDSS to Adrian Tennyenhuis and New River Management IV, LP for net proceeds of approximately \$7.0 million. Earlier in the fiscal year on November 13, 2006, Adrian Tennyenhuis, in partnership with New River Management IV, LP, purchase Vital Diagnostics—see above. The transaction, structured as a share purchase, closed on June 18, 2007. We recorded a loss on disposal of approximately \$7.0 million in connection with the sale during the year ended March 31, 2007.

For summarized financial information on the Discontinued Operations, please see Note 3 to the Consolidated Financial Statements.

# ITEM 1A. RISK FACTORS

Investment in our securities involves a high degree of risk. Investors should carefully consider the following factors, among others, relating to Clinical Data:

#### **Risk Factors Relating to Our Business and Operations**

We do not have sufficient cash resources available to fund our current level of activities beyond the second quarter of fiscal 2008, including our Phase III clinical trial program for our lead product candidate, Vilazodone. Over the near-term, we will need to satisfy substantial capital requirements to pursue our development and commercialization strategies and to further optimize operations.

At currently projected rates of expenditure, we believe that additional funding will be required to operate our business and our subsidiaries beyond the second quarter of fiscal 2008, including the funding of Phase III clinical trials for our lead drug candidate, Vilazodone. Although we completed a private placement of our common stock of approximately \$17.0 million in June 2006, any future equity or other fundraising may not be successful. The level of market interest in providing further financing to life sciences companies could have a material adverse effect on our ability to raise funds. Moreover, our independent auditors issued an unqualified opinion on our 2007 consolidated financial statements that included a material uncertainty related to our ability to continue as a going concern, which could

adversely impact our ability to raise additional capital. Further, if we do secure additional capital through a sale of our securities, dilution to our then existing shareholders may result.

If we are unable to secure additional funds when we need them, we may be required to delay, reduce or eliminate some or all of our programs. We may also be forced to license compounds or technology to others that we would prefer to develop internally until a later, and potentially more lucrative, stage. If we are required

30

#### **Table of Contents**

to raise additional funds through collaborations and other licensing arrangements, we may have to relinquish our rights to some of our technologies or grant licenses on unfavorable terms.

Over the near-term, our future capital requirements to continue the development and enhancement of our technologies, capture market share, in-license and develop genetic tests and to seek to complete the commercialization of our drug candidates will be substantial and will be influenced by many factors. Such factors include the amount of milestone payments which we may receive or be required to pay under collaboration, licensing or other agreements, the progress and cost of research and development projects, especially the Phase III program for Vilazodone, our lead drug candidate, and expenses which may be required for the filing, defense and enforcement of patent rights. If we are unable to secure adequate financing over the near-term, we will not be able to pursue our product development, commercialization and intellectual property strategies as currently planned.

Given our current product development efforts and our recent acquisitions of both Genaissance Pharmaceuticals, Inc. and Icoria, Inc., each of which has historically incurred significant net losses, we expect to incur net losses for the foreseeable future.

We have incurred operating losses since the fiscal year ended March 31, 2006. At March 31, 2007, we had an accumulated deficit of approximately \$83.4 million. We expect to incur substantial additional operating losses over the next several years as our research, development, pre-clinical testing and clinical trial activities increase, particularly with respect to our current lead product candidate, Vilazodone.

To become profitable, we, either alone or with collaborators, must successfully develop, manufacture and market our current and future product candidates, including Vilazodone, and other products and continue to leverage our existing technologies to generate product and services revenue. It is possible that we will never have significant product sales revenue.

In previous clinical trials performed by others, Vilazodone failed to demonstrate significant efficacy and we may be unable to develop a commercially viable drug.

We expect to unblind the top line (preliminary) efficacy data of our current Vilazodone Phase III trial by the end of August of this year, and we expect that the data that combines this top line efficacy data and the biomarker data will be reviewed and analyzed by the end of September 2007. Until the top line efficacy data is analyzed and reviewed in conjunction with the biomarker data, we will not know whether Vilazodone has the potential to become a product that has commercial value. However, it is possible that the top line efficacy data, when unblinded, may not show that Vilazodone is effective in any or a sufficient number of patients for us to use our biomarker data to attempt to develop a commercially viable product. In addition, our review and analysis of the top line efficacy data with the biomarker data may not demonstrate sufficient correlation to warrant continued development of Vilazodone. Prior to filing an NDA with respect to Vilazodone, we will be required to complete at least one long-term safety study and one additional pivotal study. We currently expect that such a filing could occur by the end of calendar year 2009, after which our ability to market Vilazodone will depend upon regulatory review by the FDA. In addition, even if these additional studies demonstrate that Vilazodone is effective in a subset of the population that has a yet to be determined genetic marker, the potential addressable market of people with any such genetic marker may not be large enough to demonstrate a sufficient commercial market opportunity to either attract a marketing partner or to justify establishment of a dedicated sales force. The outcome of this process is uncertain, and delays in the process and/or failure to obtain FDA approval or gain market acceptance for Vilazodone could adversely impact our commercial prospects.

Personalized medicine is an emerging field, and therefore regulatory approval of our drug and related diagnostic tests may take longer and be less predictable than approval for untargeted medicines. Ultimately, personalized

medicine may prove to be an unsuccessful industry, which would have a material adverse impact on our business and prospects.

Personalized medicine is an emerging field and represents a new approach to patient care, one which ultimately may not prove successful. Our business strategy involves seeking marketing approval for our drug candidates with the use of a diagnostic test to pre-screen subsets of patient populations most likely to receive

31

#### **Table of Contents**

therapeutic benefit or minimal side effects. This approach to drug development may not work scientifically and may be unsuccessful as a commercial alternative to existing patient care.

Moreover, the FDA has issued guidelines on the approval process for drugs with associated diagnostics, and it remains to be seen how the FDA will develop and implement standards for evaluation of integrated products such as ours. For example, for any given drug we do not know how effective our diagnostic must be in pre-screening patients in order to achieve FDA approval for the launch of clinical trials or marketing approval upon their completion. Any genetic association that we locate may not be viewed by the FDA as valid indicators for pre-screening patients. Further, we may be unable to meet the current guidelines, or other future standards, issued by the FDA. In addition, because our approach involves the application of new technologies, various governmental regulatory authorities may subject our products to additional review. As a result, these authorities may grant regulatory approvals more slowly than for untargeted medicines. If we are unable to obtain FDA approval or experience a delay in such approval, the development of our drug candidates and diagnostics may not occur or may occur more slowly than anticipated, and our business would suffer as a result.

# If our assumption about the role of genes in diseases or drug response is wrong, we may not be able to develop useful products.

The products we hope to develop involve new and unproven scientific approaches. They are based on the assumption that information about an individual s genes may help scientists to better understand complex disease processes. Scientists generally have a limited understanding of the role of genes in diseases, and few products based on gene discoveries have been developed. Of the products that exist, all are diagnostic products. To date, we know of no therapeutic products based on disease-gene discoveries. If our assumption about the role of genes in the disease process is wrong, our gene discovery programs may not result in products.

# We may not successfully develop or derive revenues from any products.

We use our technology and research capabilities to identify genes and gene variations that contribute to certain diseases and then develop or license drug candidates and/or diagnostic products that may be effective in patient populations with the identified gene variations. Although we have identified genes and polymorphisms that we believe are likely to cause certain diseases, we may not be correct and may not be successful in identifying any other similar genes or in developing drugs or diagnostic products based on these discoveries. Many experts believe that some of the diseases we are targeting are caused by both genetic and environmental factors. Even if we identify specific genes that are partly responsible for causing diseases, any therapeutic or diagnostic products we develop as a result of our genetic work may not detect, prevent, treat or cure a particular disease. Any pharmaceutical or diagnostic products that we or our collaborators are able to develop will fail to produce revenues unless we:

establish that they are safe and effective;
successfully compete with other technologies and products;
ensure that they do not infringe on the proprietary rights of others;
establish that they can be manufactured in sufficient quantities at reasonable costs;
obtain and maintain regulatory approvals for them; and
can market them successfully.

We may not be able to meet these conditions. We expect that it will be years, if ever, before we will recognize significant revenue from the development of therapeutic or diagnostic products.

We may not derive significant revenues from our diagnostic tests.

We currently offer our *FAMILION* test, as well as DNA-based diagnostic tests for Warfarin, Clozapine-Induced-Agranulocytosis and Rituximab and are currently developing additional DNA-based diagnostic tests. Our ability to derive revenues from these tests will depend, among other things, on continued certification of

32

#### **Table of Contents**

our reference laboratory under CLIA by the State of Connecticut and our continued compliance with applicable regulatory requirements and on acceptance of the test by physicians. In addition, we may not be able to secure broad third-party insurance or other reimbursement for our tests. The path, timing and amount of third party reimbursement are unknown at this time. Accordingly, patients may have to pay for certain tests themselves and may be unwilling or unable to do so. As a result of these factors, we cannot predict whether or not we will be able to derive significant revenues from these tests.

If physicians and patients do not accept and use our drugs, we will not achieve sufficient product revenues and our business will suffer.

Even if the FDA approves Vilazodone or any other drug candidates developed by us, physicians and patients may not accept and use them. Acceptance and use of any drug we develop will depend on a number of factors including:

perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of the drug;

published studies demonstrating the cost-effectiveness of the drug relative to competing products;

development of an associated genetic screening diagnostic with the capability of producing accurate results;

availability of reimbursement for our products from government or healthcare payers; and

effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of a drug candidate to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to develop new and enhanced products that achieve widespread market acceptance, we may be unable to recoup product development costs, and our revenues and earnings may decline.

Our future success depends on our ability to broadly market existing technologies, products, and services, and to develop and introduce new product and service offerings and grow our business in the blood analysis instrumentation, diagnostic assays DNA-based diagnostic and therapeutic products and human biomarker markets. We expect to commit substantial resources to developing new products and services, as well as to continue marketing the existing products and services. If the market for these products and services does not develop as anticipated, or demand for our current product and service offerings does not grow or grows more slowly than we expect, we will have expended substantial resources and capital without realizing sufficient revenue, and our business and operating results could be adversely affected.

If our products are not granted adequate reimbursement from third-party payors, we may unable to successfully commercialize our products and we may never achieve widespread market acceptance of our products.

Our ability to successfully sell our drug and companion biomarker tests in the United States and other countries depends on the availability of adequate reimbursement from third-party payors such as private insurance plans, managed care organizations and Medicare and Medicaid. Virtually all of our revenues for such products will be dependent on customers who rely on third party reimbursement. Third-party healthcare payors in the United States are increasingly sensitive to containing healthcare costs and heavily scrutinize new technology as a primary factor in increased healthcare costs. Third-party payors may influence the pricing or perceived attractiveness of our products and services by regulating the maximum amount of reimbursement they provide or by not providing any

reimbursement. Medical community or third-party healthcare payors may deny or delay acceptance of our products or may provide reimbursement at levels that are inadequate to support adoption of our technologies.

If these payors do not reimburse for our drugs or companion biomarker tests, or only provide reimbursement significantly below the costs of such products, our potential market and revenues will be

33

#### **Table of Contents**

significantly limited. Use of our products may never become widely reimbursed, and the level of reimbursement we obtain may never be sufficient to permit us to generate substantial revenue.

We are entering into new business areas and may not have the expertise, experience and resources to pursue all of our businesses at once.

Individually, each of Clinical Data, Genaissance, Genome Express and Icoria has had experience in their respective areas of expertise, but we have never pursued all of the facets of these businesses at once. As a result, we may not have the experience, the appropriate expertise, or the resources to pursue all businesses in our combined company and we may discover that some of the new facets of the combined business are not what we previously believed and are not financially viable.

If we are unable to develop and/or in-license or otherwise acquire new products and technologies, we may not be able to grow our company successfully.

To date, we have relied significantly on acquisitions and in-licensing of intellectual property for our growth. For example, in 2005 we acquired three companies, including Genaissance Pharmaceuticals, Inc., which provided us with our lead drug candidate, Vilazodone and most of the assets in our PGxHealth division. If we are unable to develop products and services internally, or to acquire companies or other technologies, we may not be able to continue our growth or to establish a leadership position in our industry. Additionally, even if such companies and/or other assets are available, we may not be able to acquire them on reasonable terms.

Due to recent merger activity, it may be more difficult to obtain additional financing at favorable terms, if at all.

Because we have operated as an integrated enterprise for only one full fiscal year, and as a combined company we have a significant history of losses, it may be more difficult to encourage investment in our company through public and additional private stock offerings, arrangements with corporate partners, credit facilities or from other sources. We may never realize enhanced liquidity in the public markets because the overhang in the public markets as a result of recent merger transactions may dissuade new investors. If we are unable to secure adequate financing over the near-term, we will not be able to pursue our product development and commercialization strategies as currently planned.

Because a significant portion of our total assets will be represented by goodwill that are subject to mandatory annual impairment evaluations, we could be required to write-off some or all of this goodwill, which may adversely affect our financial condition and results of operations.

We accounted for the acquisitions of Genaissance, Genome Express and Icoria using the purchase method of accounting. The purchase prices for these businesses were allocated to identifiable tangible and intangible assets and assumed liabilities based on estimated fair values at the date of consummation of the respective mergers. The unallocated portions of the purchase prices were allocated to goodwill. Approximately 37% of our total assets at March 31, 2007 are goodwill and other intangibles, of which approximately \$20.1 million is goodwill. In accordance with SFAS No. 142, goodwill is not amortized but is reviewed annually or more frequently if impairment indicators arise. The unamortized values of other intangibles are reviewed if certain conditions exist. During the fourth quarter of fiscal 2007, we assessed the recoverability of the intangibles acquired in the Icoria acquisition and were required to record an impairment charge of \$2.6 million as the assets were not considered recoverable. When we perform future impairment tests, it is possible that the carrying value of goodwill or other intangible assets could exceed their implied fair value and therefore would require adjustment. Such adjustment would result in a charge to operating income in that period. Once adjusted, there can be no assurance that there will not be further adjustments for impairment in future periods.

#### **Table of Contents**

We may be unable to successfully complete the integration of the businesses of Genaissance, Genome Express and Icoria.

During fiscal year 2006, we consummated mergers with Genaissance and Icoria, and acquired all of the capital stock of Genome Express. The integration of these businesses has required and continues to require significant efforts from each company, including the coordination of product development, sales and marketing efforts and administrative operations. We have employees widely dispersed across our operations in Massachusetts, Rhode Island, Connecticut, California, Texas, North Carolina, and other domestic and foreign locations, which has increased the difficulty of integrating operations. The continuing challenges involved in this integration include, but are not limited to:

retaining existing customers and strategic partners of each company; coordinating research and development activities to enhance introduction of new products and technologies, especially in light of rapidly evolving markets for those products and technologies;

preserving the value of various research and development, collaboration, distribution, manufacturing and other important relationships;

effectively managing the diversion of management attention from business matters to integration issues;

combining product offerings and incorporating acquired technology and rights into product offerings effectively and quickly; and

developing and maintaining uniform standards, controls, procedures, and policies.

As of March 31, 2007, we identified a material weakness in internal control over financial reporting, and concluded that our disclosure controls were not effective. If we fail to maintain an effective system of internal and disclosure controls, we may not be able to accurately report our financial results or prevent fraud. As a result, investors may be misled and lose confidence in our financial reporting and disclosures, and the price of our common stock may be negatively affected.

The Sarbanes-Oxley Act of 2002 requires that we report annually on the effectiveness of our internal control over financial reporting. A significant deficiency means a deficiency in the design or operation of internal control that adversely affects our ability to initiate, authorize, record, process or report external financial data reliably in accordance with generally accepted accounting principles such that there is more than a remote likelihood that a misstatement of the annual or interim financial statements that is more than inconsequential will occur and not be detected. A material weakness is a significant deficiency, or a combination of significant deficiencies, that result in more than a remote likelihood that a material misstatement of the annual or interim financial statements will occur and not be detected by management before the financial statements are published.

In connection with the assessment of our internal control over financial reporting for this Annual Report on Form 10-K, as further described in Item 9A, management and our registered public accounting firm determined that as of March 31, 2007 our disclosure controls and procedures were ineffective because of the material weakness in our internal control over financial reporting. In addition, in the future, our continued assessment, or the subsequent assessment by our independent registered public accounting firm, may reveal additional deficiencies in our internal controls and disclosure controls, some of which may require disclosure in future reports.

Although we have made and are continuing to make improvements in our internal controls, if we are unsuccessful in remediating the material weakness impacting our internal control over financial reporting and disclosure controls, or if we discover other deficiencies, it may adversely impact our ability to report accurately and in a timely manner our

financial condition and results of operations in the future, which may cause investors to lose confidence in our financial reporting and may negatively affect the price of our common stock. Moreover, effective internal and disclosure controls are necessary to produce accurate, reliable financial reports and to prevent fraud. If we continue to have deficiencies in our internal control over financial reporting and disclosure controls, they may negatively impact our business and operations.

35

#### **Table of Contents**

#### We may not be able to successfully integrate companies that we acquire in the future.

Our success will depend in part on our ability to continually enhance and broaden our product offerings in response to changing technologies, customer demands and competitive pressures. From time to time, we may pursue acquisitions of businesses that complement or expand our existing business, including acquisitions that could be material in size and scope.

Any future acquisitions involve various risks, including:

difficulties in integrating the operations, technologies and products of the acquired companies;

the risk of diverting management s attention from normal daily operations of the business;

potential difficulties in completing projects associated with in-process research and development;

risks of entering markets in which we have no or limited direct prior experience and where competitors in such markets have stronger market positions;

initial dependence on unfamiliar supply chains or relatively small supply partners;

insufficient revenues to offset increased expenses associated with the acquisition; and

the potential loss of key employees of the acquired companies.

The failure to successfully integrate businesses acquired in the future could have a material adverse impact on our business and results of operations.

### We are dependent upon certain key personnel.

We are highly dependent upon the principal members of our management, legal and scientific staff, including Andrew J. Fromkin, our President and Chief Executive Officer, C. Evan Ballantyne, our Chief Financial Officer, Caesar J. Belbel, our Chief Legal Officer and Carol Reed, M.D., our Chief Medical Officer. The loss of the service of any of these persons could seriously harm our business operations, product development and commercialization efforts.

We must implement additional and expensive finance and accounting systems, procedures and controls in order to grow our business and organization and to satisfy new reporting requirements, which will increase our costs and require additional management resources.

Beginning with our annual report for our fiscal year ended March 31, 2008, to be filed in June 2008, we will be required to comply with the internal control reporting requirements mandated by Section 404 of the Sarbanes-Oxley Act of 2002. Compliance with Section 404 of the Sarbanes-Oxley Act will increase our costs and require additional management resources. We have begun upgrading our finance and accounting systems, procedures and controls and will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements. If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting, if we fail to maintain or implement adequate controls, or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the date of our fiscal 2008 annual report for which compliance is required, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the

accuracy of our periodic reports filed under the Exchange Act. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

In order to conduct clinical trials and to market our drugs, we will have to develop methods or make arrangements with third parties to produce these drugs using approved methods and at commercially viable rates.

In order to conduct clinical trials and ultimately to market any drugs we may develop, we or our third party contractors will need to obtain chemicals and components, and in some cases licenses for proprietary formulation technology, necessary for the manufacture of the products from third parties. We or our contractors

36

#### **Table of Contents**

will then need to implement the necessary technology in order to produce the drugs to exacting standards set by us and the regulatory bodies. This is an uncertain and time consuming process, and any disruption in it may delay or harm our ability to continue clinical development. For drugs which have reached the last stage of clinical trials, we or our contractors will have to develop methods to scale up the production of the drug at commercially viable rates. If we are not able to scale the process in a timely manner or do not have the ability to produce the drug economically, we may not be able to enter the market with a viable product. This would harm our financial and commercial prospects.

The manufacture of our products for clinical trials and commercial purposes is subject to cGMP regulations promulgated by the FDA. The manufacture of diagnostic products subject to FDA approval are also subject to the FDA s quality system requirements (QSR). In the event that we are unable to develop satisfactory manufacturing facilities or obtain or retain third party manufacturing for our products, we will not be able to commercialize such products as planned. We may not be able to enter into agreements for the manufacture of future products with manufacturers whose facilities and procedures comply with cGMP, QSR and other regulatory requirements. Our current dependence upon others for the manufacture of our products may adversely affect our ability to develop and deliver such products on a timely and competitive basis and, in the longer term, the profit margin, if any, on the sale of future products and our ability to develop and deliver such products on a timely and competitive basis.

If we cannot successfully form and maintain suitable arrangements with third parties for the manufacturing of the products we may develop, our ability to develop or deliver products may be impaired.

We have little experience in manufacturing products for commercial purposes and do not have manufacturing facilities that can produce sufficient quantities of drugs for large scale clinical trials. Accordingly, we must either develop such facilities, which will require substantial additional funds, or rely on contract manufacturers for the production of products for development and commercial purposes. In order to conduct our Phase III clinical trial of Vilazodone, we have to contract with third parties to manufacture a sufficient supply of the drug for the trial and to produce tablets containing Vilazodone in amounts sufficient for the clinical trial. While we signed contracts with suppliers for the production of Vilazodone material and tablets for the launch of our Phase III clinical trial and received sufficient materials to complete the trial, we will likely be required to initiate an additional pivotal study, which will require additional amounts of Vilazodone.

New drug and diagnostic development involves a lengthy and complex process, and we may be unable to commercialize any of the products we develop.

We have limited experience in developing drugs and diagnostics.

Before we can develop diagnostic tests and commercialize any new products, we will need to:

collect and analyze DNA samples;

conduct high-density whole genome association studies to discover and replicate the relationship between genetic variations in the DNA samples and therapeutic response;

undertake clinical trials to validate the efficacy, safety, toxicology, pharmacology, pharmacokinetics and other aspects of our drug candidates, and predictiveness of any related diagnostic tests;

expend significant resources;

maintain and expand our intellectual property rights;

obtain marketing approvals from the FDA and other regulatory approvals; and

find collaborative partners with manufacturing and commercial capabilities for our current and future drug candidates and related diagnostics.

37

#### **Table of Contents**

The process of developing new drugs and diagnostic tests takes several years. Our product development efforts may fail for many reasons, including:

the failure of products in the research and development stage;

the high cost of clinical trials and our lack of financial and other resources;

the inability to locate partners with sufficient resources to assist in conducting clinical trials; and

the lack of clinical validation data to support the effectiveness of our products.

Success in early clinical trials often is not replicated in later studies, and few research and development projects result in commercial products. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for revenues from those product candidates. In addition, as we develop products, we may partner with third parties or be required to make significant investments in product development, and marketing and selling resources. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we may abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business.

Our operations may be affected by unexpected problems frequently encountered in connection with the development and transition to other technologies and by the competitive environment in which we operate.

Even if we are successful in establishing genetic associations and validating them through clinical trials, there is no guarantee that we will be successful in our product development efforts. Even if we develop products for commercial use, these products may not be accepted by the research, diagnostic, medical and pharmaceutical marketplaces or be capable of being offered at prices that will enable us to become profitable. Our products may not ultimately prove to be useful for commercial markets, meet applicable regulatory standards, or be successfully marketed.

# Our international operations and sales expose us to foreign currency exchange rate fluctuation risks.

The costs of importation of instruments and other products are subject to foreign currency fluctuations. In fiscal 2007, sales to customers outside the United States accounted for approximately 61.6% of our revenues. We anticipate that international sales will continue to account for a significant portion of our revenues. Most of our sales to international distributors are denominated in Euros. To the extent that our sales and operating expenses are denominated in foreign currencies, our operating results may be affected by changes in exchange rates. Such gains and losses may be material and may adversely affect our future operating results. While we sometimes engage in limited, transaction specific, foreign currency hedging transactions to reduce our risk, such hedging transaction may not allow us to avoid any currency exchange rate fluctuation risks.

# **Risk Factors Relating to Our Intellectual Property**

If we are unable to protect effectively our intellectual property, we may not be able to operate our business and third parties may use our technology, both of which would impair our ability to compete in our markets.

Our success will depend in significant part on our ability to obtain and maintain meaningful patent protection for certain of our technologies and products throughout the world. Patent law relating to the scope of claims in the technology fields in which we will operate is still evolving. The degree of future protection for our proprietary rights is uncertain. We will rely on patents to protect a significant part of our intellectual property and to enhance our

competitive position. However, our presently pending or future patent applications may not issue as patents, and any patent previously issued to us or our subsidiaries may be challenged, invalidated, held unenforceable or circumvented. Furthermore, the claims in patents which have been issued to us or our subsidiaries or which may be issued to us in the future may not be sufficiently broad to prevent third parties from producing competing products similar to our products. In addition, the laws of various foreign

38

#### **Table of Contents**

countries in which we plan to compete may not protect our intellectual property to the same extent as do the laws of the United States. If we fail to obtain adequate patent protection for our proprietary technology, our ability to be commercially competitive will be materially impaired.

The patent positions of life science companies are generally uncertain and involve complex legal and factual questions. Our business could be hurt by any of the following:

our pending patent applications may not result in issued patents;

the claims of any issued patents may not provide meaningful protection;

we may be unsuccessful in developing additional proprietary technologies that are patentable;

our patents may not provide a basis for commercially viable products or provide us with any competitive advantages and may be challenged by third parties; and

others may have patents that relate to our technology or business.

Third parties have filed, and in the future are likely to file, patent applications covering biomarkers and related methods that our PGxHealth division has developed or may develop or technology upon which our technology platform depends. If patent offices issue patents on these patent applications and we wish to use the biomarkers or technology, we would need to obtain licenses from third parties. However, we might not be able to obtain any such license on commercially favorable terms, if at all, and if we do not obtain these licenses, we might be prevented from using certain technologies or taking certain products to market.

In addition to patent protection, we will also rely on protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade-secrets and proprietary information, we generally seek to enter into confidentiality agreements with our employees, consultants and strategic partners upon the commencement of a relationship. However, we may not obtain these agreements in all circumstances. In the event of unauthorized use or disclosure of this information, these agreements, even if obtained, may not provide meaningful protection for our trade secrets or other confidential information. In addition, adequate remedies may not exist in the event of unauthorized use or disclosure of this information. The loss or exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects.

If third parties make or file claims of intellectual property infringement against us, or otherwise seek to establish their intellectual property rights, we may have to spend time and money in response and cease some of our operations.

Third parties may claim that we are employing their proprietary technology without authorization or that we are infringing on their patents. We could incur substantial costs and diversion of management and technical personnel in defending against any of these claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief which could effectively block our ability to further develop, commercialize and sell products. In the event of a successful claim of infringement, courts may order us to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing available products.

Any patent protection we obtain for our products may not prevent marketing of similar competing products.

Patents on our products may not prevent our competitors from designing around and developing similar compounds or compounds with similar modes of action or tests that may compete successfully with our products. Such third party compounds may prove to be superior to our products or gain wider market acceptance and thus adversely affect any revenue stream that we could otherwise expect from sales of our products.

39

#### **Table of Contents**

#### Any patents we obtain may be challenged by producers of generic drugs.

Patents covering innovative drugs, which are also commonly referred to as branded drugs or pioneer drugs, face increased scrutiny and challenges in the courts from manufacturers of generic drugs who may receive benefits such as limited marketing co-exclusivity if the challenge is successful. Such patent challenges typically occur when the generic manufacturer files an Abbreviated New Drug Application with the FDA and asserts that the patent or patents covering the branded drug are invalid or unenforceable, forcing the owner or licensee of the branded drug to file suit for patent infringement. If any patents we obtain covering our pharmaceutical products are subject to such successful patent challenges, our marketing exclusivity may be eliminated or reduced in time, which would thus adversely affect any revenue stream that we could otherwise expect from sales of our products.

### **Risk Factors Relating to Our Industry**

Our biopharmaceutical or diagnostic product candidates must undergo rigorous clinical trials and regulatory approvals, which could substantially delay or prevent their development or marketing.

Any biopharmaceutical and some of our diagnostic products that we develop will be subject to rigorous clinical trials and an extensive regulatory approval process implemented by the FDA and analogous foreign regulatory agencies. This approval process is typically lengthy and expensive, and approval is never certain. Positive results from pre-clinical studies and clinical trials do not ensure positive results in late stage clinical trials designed to permit application for regulatory approval. We do not know when, or if, all the required clinical trials for Vilazodone will be completed. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, alternative therapies, competing clinical trials and new drugs approved for the conditions we are investigating. As a result of all of these factors, our trials may take longer to enroll patients than we anticipate. Such delays may increase our costs and slow down our product development and the regulatory approval process. Our product development costs will also increase if we need to perform more or larger clinical trials than planned. The occurrence of any of these events will delay our ability to generate revenue from product sales and impair our ability to become profitable, which may cause us to have insufficient capital resources to support our operations.

Because of the risks and uncertainties in biopharmaceutical development, products that we or our collaborators develop could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If we or our collaborators do not receive these necessary approvals, we will not be able to generate substantial product or royalty revenues and may not become profitable. We and our collaborators may encounter significant delays or excessive costs in our efforts to secure regulatory approvals. Factors that raise uncertainty in obtaining these regulatory approvals include the following:

we must demonstrate through clinical trials that the proposed product is safe and effective for its intended use;

we have limited experience in conducting the clinical trials necessary to obtain regulatory approval; and

data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which could delay, limit or prevent regulatory approvals.

Regulatory authorities may delay, suspend or terminate clinical trials at any time if they believe that the patients participating in trials are being exposed to unacceptable health risks or if they find deficiencies in the clinical trial procedures. In addition, our or our collaborators failure to comply with applicable regulatory requirements may result in criminal prosecution, civil penalties and other actions that could impair our ability to conduct our business.

We initiated a pivotal Phase III clinical trial of Vilazodone for the treatment of depression in February 2006. We will need to complete all aspects of this Phase III trial and additional trials before filing an NDA for marketing approval of this product for this indication. While we believe the NDA could be filed by the end of

40

#### **Table of Contents**

calendar 2009, this clinical trial or subsequent clinical trials or other development efforts may be delayed for any of the reasons described above, and may take longer than anticipated to initiate and/or to complete.

#### Concerns regarding the use of genetic testing results may limit the commercial viability of any products we develop.

Other companies have developed genetic predisposition tests that have raised ethical concerns. It is possible that employers or others could discriminate against people who have a genetic predisposition to certain diseases. Concern regarding possible discrimination may result in governmental authorities enacting restrictions or bans on the use of all, or certain types of, genetic testing. Similarly, such concerns may lead individuals to refuse to use genetic tests even if permissible. These factors may limit the market for, and therefore the commercial viability of, products that our collaborators and/or we may develop.

# If we were sued for product liability, we could face substantial liabilities that may exceed our resources.

We may be held liable if any product we develop, or any product which is made using our technologies, causes injury or is found unsuitable during product testing, manufacturing, marketing, sale or use. These risks are inherent in the development of chemical, agricultural, pharmaceutical, and other such healthcare products and related methodologies. If we choose to obtain product liability insurance but cannot obtain sufficient insurance coverage at an acceptable cost or otherwise protect against potential product liability claims, the commercialization of products that we or our commercial partners develop may be prevented or inhibited. If we are sued for any injury caused by our products, such liability could have a material adverse effect on our business and results of operations.

# We may not be able to compete successfully with other companies and government agencies in the development and marketing of products and services.

A number of companies are attempting to rapidly identify and patent genes that cause diseases or an increased susceptibility to diseases. Competition in this field and our other areas of business, including drug discovery and development, is intense and is expected to increase. We have numerous competitors, including major pharmaceutical and diagnostic companies, specialized biotechnology firms, universities and other research institutions, and other government-sponsored entities and companies providing healthcare information products. Our collaborators, including Roche and Merck, may also compete with us. Many of our competitors, either alone or with collaborators, have considerably greater capital resources, research and development staffs and facilities, and technical and other resources than we do, which may allow them to discover important genes or develop drugs based on such discoveries before we do. We believe that a number of our competitors are developing competing products and services that may be commercially successful and that are further advanced in development than our potential products and services. To succeed, we must discover disease-predisposing genes, characterize their functions, develop genetic tests or therapeutic products and related information services based on such discoveries, obtain regulatory and other approvals, and launch such services or products before our competitors. Even if we are successful in developing effective products or services, our products and services may not successfully compete with those of our competitors, including cases where the competing drugs use the same mechanism of action as our products. Our competitors may succeed in developing and marketing products and services that are more effective than ours or that are marketed before ours.

Competitors have established, and in the future may establish, patent positions with respect to gene sequences related to our research projects. Such patent positions or the public availability of gene sequences comprising substantial portions of the human genome could decrease the potential value of our research projects and make it more difficult for us to compete. We may also face competition from other entities in gaining access to DNA samples used for research and development purposes. Our competitors may also obtain patent protection or other intellectual property rights that could limit our rights, or our customers—ability, to use our technologies or databases, or commercialize

therapeutic or diagnostics products. In addition, we face, and will continue to face, intense competition from other companies for collaborative arrangements with

41

#### **Table of Contents**

pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions and for licenses to proprietary technology.

We expect competition to intensify as technical advances are made and become more widely known. Our future success will depend in large part on maintaining a competitive position in the genomic field. Rapid technological development may result in products or technologies becoming obsolete before we recover the expenses we incur in developing them.

Our ability to compete successfully will depend, in part, on our ability, and that of our collaborators, to:

develop proprietary products;

develop and maintain products that reach the market first, and are technologically superior to, and more cost effective than, other products on the market;

obtain patent or other proprietary protection for our products and technologies;

attract and retain scientific and product development personnel;

obtain required regulatory approvals; and

manufacture, market and sell products that we develop.

Intense competition could reduce our market share or limit our ability to increase market share, which could harm our financial performance.

The medical products industry is rapidly evolving and developments are expected to continue at a rapid pace. Competition in this industry, which includes our medical instrumentation, reagent and consulting services businesses, is intense and expected to increase as new products, technologies and services become available and new competitors enter the market. Our competitors in the United States, Europe and Pacific-Asia are numerous and include, among others, large, multi-national diagnostic testing and medical products companies. Our future success depends upon maintaining a competitive position in the development of products, technologies and services in our areas of focus. Our competitors may:

develop technologies, products and services that are more effective than our products or services, or that render our technologies, products or services obsolete or noncompetitive;

obtain patent protection or other intellectual property rights that would prevent us from developing our potential products; or

obtain regulatory approval for the commercialization of their products more rapidly or effectively than we do.

Also, the possibility of intellectual property rights disputes with competitors holding domestic and foreign patent and other intellectual property rights may limit or delay expansion possibilities for our businesses. In addition, many of our existing or potential competitors have or may have substantially greater financial and managerial resources, research and development capabilities, and clinical, manufacturing, regulatory and marketing experience.

We operate in a very competitive environment.

We expect to encounter intense competition from a number of companies that offer products in our targeted application areas. We anticipate that our competitors in these areas will include:

health care and other companies that manufacture laboratory-based tests and analyzers;

diagnostic and pharmaceutical companies;

molecular services business;

companies developing drug discovery technologies;

42

#### **Table of Contents**

companies developing molecular diagnostic and genetic tests; and

companies developing point-of-care diagnostic and genetic tests.

If we are successful in developing products in these areas, we will face competition from established companies and numerous development-stage companies that continually enter these markets. In many instances, competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. Moreover, these competitors may offer broader product lines and have greater name recognition than us and may offer discounts as a competitive tactic.

In addition, several development-stage companies are currently making or developing products that compete with or will compete with our potential products. Competitors may succeed in developing, obtaining approval from the FDA, or marketing technologies or products that are more effective or commercially attractive than our current or potential products or that render our technologies and current or potential products obsolete. Competitors may also develop proprietary positions that may prevent us from successfully commercializing products.

# Our medical device products require government approval to be marketed.

We have obtained or are in the process of obtaining all necessary government approvals to market our current products in the United States and the European Union. However, we will likely need to obtain approval of certain European regulatory bodies and the FDA to market many of the new products that we may develop or obtain the rights to distribute. Domestically, certain of our products are classified as medical devices under the Food, Drug and Cosmetics Act. As such, if and when these products are offered for sale in the United States, these products will be subject to continuing regulation and oversight by the FDA. The cost of obtaining such approvals may be high and the process lengthy, with no assurance that such approvals will be obtained.

To date, neither the FDA nor the European medical regulatory bodies have developed industry-wide performance standards with respect to the safety and effectiveness of the products that we presently market. Although we intend to use reasonable efforts to comply with international standards, when and if developed, there can be no assurance that our products as currently configured will be in compliance. Any failure to receive and maintain approvals for our products, or noncompliance with any international performance standards promulgated in the future, could have a material adverse effect on our business. Furthermore, any material change in the existing rules and regulations or the adoption of any new regulations could adversely affect us.

#### Risk factors relating to Clinical Data s common stock

### Future sales of our common stock or other securities may dilute our stockholders.

We may sell common stock or other securities in the future in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock or other securities, existing stockholders who previously purchased our securities may be materially diluted by such subsequent sales.

If the investors in our private placements sell their shares which have been registered under the Securities Act, the market price of our common stock may decline significantly.

The shares of common stock issued to the investors in our June 2006 and November 2005 private placements, as well as any shares issuable upon exercise of the warrants issued to the investors in those transactions, have been registered under the Securities Act of 1933, as amended, or Securities Act, and such shares are freely transferable without

restriction under the Securities Act (but may be subject to the short-swing profit rules and other restrictions on affiliates under the Securities Exchange Act of 1934, as amended). If a large number of shares are sold into the public market, the market price of our common stock may decline significantly.

43

# **Table of Contents**

#### Our ownership is concentrated among a small number of stockholders.

Our ownership is concentrated among a small number of stockholders, including Randal J. Kirk, our Chairman, and his affiliates. Mr. Kirk and his affiliates hold approximately 40.0% of our outstanding common stock as of June 8, 2007, after giving effect to the June 2006 private equity placement transaction and the subsequent exercise of his warrants. Mr. Kirk and his affiliates have a controlling block of our outstanding stock and are able to exert substantial control over various corporate matters including approvals of mergers, sales of assets, issuance of capital stock and similar transactions.

# The price of our common stock is volatile and could cause investors to lose a substantial part of their investment.

The stock market in general and the stock prices of life sciences companies in particular, experience volatility, which has often been unrelated to the operating performance of any particular company or companies. Our common stock is lightly traded and its price could decline regardless of our company s actual operating performance. Investors also could lose a substantial part of their investment as a result of industry or market-based fluctuations. If a more active public market for our common stock is not created, it may be difficult for stockholders to resell their shares. A number of additional factors also could cause the prevailing market prices of our common stock to fluctuate significantly and could adversely impact such prices and the ability of our company to raise additional equity capital. Such factors include but are not limited to the following:

the timing of our announcements or of our competitors announcements regarding significant products, clinical trials, NDA filings or product approvals, contracts or acquisitions;

variations in results of operations;

changes in earnings estimates or other comments by securities analysts;

general economic and market conditions; and

sales of substantial amounts of our common stock into the public market, or the perception that such sales might occur.

If the average closing price of our common stock were to decline significantly, we may be required to issue in excess of 20% of our outstanding capital stock upon conversion of the Series A Preferred Stock we issued to the preferred stockholder of Genaissance in our merger with that company.

In our recent merger with Genaissance, we issued 484,070 shares of our Series A Preferred Stock to the holder of all of the preferred stock of Genaissance. As of March 31, 2007, the holder of our Series A Preferred Stock has converted 300,000 shares of our Series A Preferred Stock into shares of our common stock, leaving 184,070 shares of our Series A Preferred Stock outstanding. Our outstanding preferred stock is initially convertible into 184,070 shares of our common stock, or approximately 1.8% of our outstanding capital stock as of March 31, 2007. However, if our preferred stock remains outstanding until October 6, 2008, then and thereafter, the conversion price of the preferred stock will begin to float based on the public market price of our common stock, subject to a minimum conversion factor of one share of preferred stock for one share of common stock. According to the terms of our Series A Preferred Stock, after October 6, 2008, on any given date of conversion, the conversion price will be equal to the average closing bid price of our common stock for the 10 consecutive trading days prior to such date of conversion. As a result, if the average closing bid price of the our common stock were to decline, the number of shares of our common stock into which our Series A Preferred Stock is then convertible would increase. If the average closing bid price of our common stock declines enough, it is possible that we would have to issue a number of shares of our common

stock upon conversion of our Series A Preferred Stock that would be greater than 20% of our then-outstanding capital stock. Such an event does not require additional stockholder approval, would have the effect of diluting your ownership interest in us and could result in the preferred stockholder exercising control over certain of our corporate decisions, which it previously did not have the ability to control or influence.

44

#### **Table of Contents**

We may issue preferred stock with rights that could affect your rights and prevent a takeover of the business.

Our board of directors has the authority, without further approval of our stockholders, to fix the rights and preferences, and to issue up to 1,500,000 shares of preferred stock (less any shares previously designated). In addition, Delaware corporate law imposes limitations on certain business combinations. These provisions could, under certain circumstances, delay or prevent a change in control of Clinical Data and, accordingly, could adversely affect the price of our common stock.

We currently do not intend to pay dividends on our common stock and consequently, your only opportunity to achieve a return on your investment is if the price of our common stock appreciates.

We currently do not plan to pay dividends on shares of our common stock in the near future. Consequently, your only opportunity to achieve a return on your investment in us will be if the market price of our common stock appreciates.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

#### ITEM 2. PROPERTIES

As of March 31, 2007, we leased or subleased a total of approximately 139,000 square feet of office and laboratory space. The leased and subleased properties, excluding those of our discontinuing businesses, are described below:

	Approximate		Expiration		
Location	Square Footage	Use	Date		
One Gateway Center, Suite 702 Newton, Massachusetts	6,700	Corporate office	7/31/2011		
5 Science Park	29,000	Office and laboratory	1/31/2010		
New Haven, Connecticut 100 Perimeter Park Drive,	37,000	Office and laboratory	2/28/2015		
Morrisville, North Carolina 9441 West Sam Houston Parkway,	15,000	Office and laboratory	12/31/2009		
Houston, Texas					
11 chemin des Pres Meylan, France	1,100	Office and laboratory	7/31/2009		
12 chemin des Pres Meylan, France	160	Laboratory	3/31/2011		
Via Balzilla 41/G/4 Forli, Italy	4,800	Office, manufacturing and warehousing	8/31/2007		
Van Rensselaerweg 4 Dieren,	35,000	Office, manufacturing	2/1/2008		
The Netherlands		and research and development			
Hope End, Takeley United Kingdom	10,000	Office and laboratory	6/30/2014		

We believe that these facilities are adequate to meet our current and planned needs. We believe that if additional space is needed in the future, such space will be available on commercially reasonable terms as needed.

### ITEM 3. LEGAL PROCEEDINGS

We are, from time to time, subject to disputes arising in the normal course of our business. While the ultimate results of any such disputes cannot be predicted with certainty, at March 31, 2007, there were no asserted claims against us which, in the opinion of management, if adversely decided, would have a material adverse effect on our financial position and cash flows.

45

#### **Table of Contents**

On June 6, 2007, the Company received \$2.8 million from the settlement of a breach of contract law suit filed against a third-party. The gain will be recognized when the cash is received.

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

No matter was submitted to a vote of our stockholders during the fourth quarter of the fiscal year covered by this report.

#### **PART II**

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

#### **Market Information**

Our common stock trades on the NASDAQ Global Market under the symbol CLDA. The following table sets forth the range of high and low sale prices per share of our common stock for each quarter in fiscal 2007 and 2006 as reported by the NASDAQ and the cash dividends paid with respect to the common stock.

	Sales 1	Dividends			
	High	Low	Paid		
Fiscal Year Ended March 31, 2007					
First Quarter	\$ 22.00	\$ 14.57	\$		
Second Quarter	\$ 16.00	\$ 11.45	\$		
Third Quarter	\$ 17.16	\$ 13.50	\$		
Fourth Quarter	\$ 22.89	\$ 15.96	\$		
Fiscal Year Ended March 31, 2006					
First Quarter	\$ 22.00	\$ 13.50	\$ 0.04		
Second Quarter	\$ 24.71	\$ 17.45	\$		
Third Quarter	\$ 23.73	\$ 16.64	\$		
Fourth Quarter	\$ 25.87	\$ 17.17	\$		

#### **Holders of Common Stock**

As of March 31, 2007, there were approximately 466 holders of record of our common stock.

#### **Dividends**

We paid a quarterly dividend of \$0.04 per share in the three months ended June 30, 2005. The payment of future dividends will be dependent upon financial results and other relevant factors to be considered by the Board of Directors.

46

#### **Table of Contents**

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

We have authorized common stock for issuance under equity compensation plans as follows as of March 31, 2007:

### **Equity Compensation Plan Information**

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance		
Equity compensation plans approved by security holders Equity compensation plans not approved by security holders	1,332,000 N/A	\$	18.51 N/A	832,000 N/A		
Total	1,332,000	\$	18.51	832,000		

The authorized plans are more fully described in Note 14 in the accompanying consolidated financial statements.

The following graph shows a comparison of the cumulative total stockholder returns on our common stock over the period from March 30, 2002 to March 31, 2007 as compared with that of the NASDAQ Global Market (U.S. and Foreign) Index and a peer group index that includes 74 active companies with SIC Code 382, Lab Apparatus and Analytical, Optical, Measuring, and Controlling Instruments. Total stockholder return is measured by dividing share price change plus dividends, if any, for each period by the share price at the beginning of the respective period, assuming reinvestment of any dividends.

#### **Table of Contents**

#### ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data have been derived from our audited historical consolidated financial statements, certain of which are included elsewhere in this Annual Report on Form 10-K. This data should be read in conjunction with our audited consolidated financial statements and related notes which are included elsewhere in this Annual Report on Form 10-K, and Management s Discussion and Analysis of Financial Condition and Results of Operations included in Item 7 below. Historical results are not necessarily indicative of operating results to be expected in the future.

# Recent Acquisitions Affect the Comparability of the Selected Consolidated Financial Data

As described in above in Item 1, we acquired the following four (4) businesses in the latter half of fiscal 2006:

Acquiree	Date of Acquisition
Genaissance Pharmaceuticals, Inc.	October 6, 2005
Electa Lab s.r.l	October 7, 2005
Icoria, Inc.	December 20, 2005
Genome Express, S.A.	March 7, 2006

All of the acquisitions were accounted for under the purchase method of accounting, and accordingly, their results of operations and balance sheet data have been included in our consolidated financial statements from the date of acquisition only. Accordingly, since the results of operations and balance sheet data of these businesses are included for a full year period in fiscal 2007 and a partial year in fiscal 2006, the acquisitions affect the comparability of our consolidated financial statements. These transactions are described in further detail in Note 4 to the Consolidated Financial Statements.

	Years Ended March 31,							
	2007	2006	2005	2004	2003			
	(In thousands, except share amounts)							
Consolidated Statements of Operations Data REVENUES	Ф 21.050	¢ 10.240	¢.	Ф	¢.			
Services	\$ 31,859	\$ 12,348	\$	\$	\$			
Products	31,873	25,415	24,216	21,853	13,037			
Total COST OF REVENUES	63,732	37,763	24,216	21,853	13,037			
Services	20,442	9,412						
Products	20,459	16,393	16,328	15,874	9,213			
Total	40,901	25,805	16,328	15,874	9,213			
Gross profit	22,831	11,958	7,888	5,979	3,824			

### **OPERATING EXPENSES**

Research and development Sales and marketing General and administrative Purchased in process research and development	13,663 7,924 28,540	5,196 3,255 12,693 39,700	1,729 1,681 2,540	1,493 1,294 2,170	1,074 1,181 1,447
Total operating expenses	50,127	60,844	5,950	4,957	3,702
	48				

# **Table of Contents**

		2007 2006				Ended March 31, 2005 2004 s, except share amounts)			2003		
Operating (loss) income		(2	27,296)		(48,886)	)	1,938		1,022		122
Interest expense			(627)		(341)	)	(33)	)	(50)		(28)
Interest income			475		183		60		65		43
Other income (expense), net			913		(47)	)	22		12		(32)
(Loss) income from continuing operations before	:										
taxes			26,535)		(49,091)		1,987		1,049		105
Provision for income taxes		(	(1,361)		(1,287)	)	(884)	)	(124)		(170)
(Loss) income from continuing operations (Loss) income from discontinued operations, net	of	(2	27,896)		(50,378)	)	1,103		925		(65)
taxes		(	(9,626)		(503)	)	2,292		1,246		181
Net (loss) income		(3	37,522)		(50,881)	)	3,395		2,171		116
Preferred stock dividend			(104)		(97)	)					
Preferred stock deemed dividend									(525)		
Net (loss) income applicable to common stockholders		\$ (3	37,626)	\$	(50,978)	) \$	3,395	\$	1,646	\$	116
(Loss) income per share from continuing operation	ons										
Basic		\$	(2.96)	\$	(8.46)	\$	0.25	\$	0.15	\$	(0.04)
Diluted			(2.96)		(8.46)	)	0.24		0.09		(0.03)
(Loss) income per share from discontinued											
operations		Ф	(1.00)	ф	(0.00)	Φ.	0.50	Ф	0.45	Ф	0.10
Basic Diluted		\$	(1.02) (1.02)	\$	(0.08) $(0.08)$		0.52 0.51	\$	0.45 0.29	\$	0.10 0.09
Net (loss) income per share			(1.02)		(0.08)	,	0.51		0.29		0.09
Basic		\$	(3.98)	\$	(8.54)	) \$	0.77	\$	0.60	\$	0.06
Diluted		Ψ	(3.98)	Ψ	(8.54)		0.75	Ψ	0.51	Ψ	0.06
Cash dividends paid per common share		\$	,	\$	0.04	\$	0.07	\$	0.04	\$	0.04
Weighted average shares:											
Basic			9,457		5,969		4,389		2,746		1,847
Diluted			9,457		5,969		4,507		4,266		1,913
	20	2007		2006		March 31, 2005		2004		2003	
						hous	ousands)				
Consolidated Balance Sheet Data:											
Cash and cash equivalents	\$ 13	,949	\$	7,	225 \$	4,	171	\$	1,800	\$	798
Total assets		,362		108,			146		8,318		11,198
	5	,785		5,	589				16		22

Long-term debt and capital leases, net of current portion

Shareholders equity 50,592 59,789 23,809 20,264 5,346

# ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of financial condition and results of operations together with the Selected Consolidated Financial Data included in Item 6 above and our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and within the meaning of Section 27A of the Securities Act of 1933, as amended, that reflect our plans, estimates and beliefs. Our actual

49

#### **Table of Contents**

results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this document, particularly in the section entitled Risk Factors.

Readers are cautioned that any forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements in this Annual Report on Form 10-K are subject to risks, uncertainties and assumptions including, among other things:

our ability to raise the necessary capital to fund our operations and to develop and commercialize our products;

our ability to successfully design and conduct our planned clinical trials;

our ability to achieve expected synergies and operating efficiencies in our acquisitions, and to successfully integrate the operations, business and technology obtained in our acquisitions;

general economic and business conditions in our markets;

the impact of current, pending or future legislation and regulation of our businesses in the U.S. and abroad;

our expectations and estimates concerning future financial performance, financing plans and the impact of competition; and

the impact of technological developments and competition.

In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this Annual Report on Form 10-K might not occur. We undertake no obligation to publicly update or revise any forward-looking statements made herein because of new information, future events or otherwise.

#### Overview

Our business activities are reported in three reporting segments: (i) Molecular Services, which is comprised of the operations of PGxHealth and Cogenics; (ii) Clinics and Small Hospitals, which represents sales of diagnostic equipment, consumables and services to small-to-medium-sized clinics, hospitals and laboratories through Vital Scientific and Electa Lab; and (iii) All Other, which includes corporate-related items and income and expense not allocated to reportable segments.

As a result of the integration and re-branding of the Genaissance, Icoria and Genome Express acquisitions into PGxHealth and Cogenics, we believe we are now a worldwide leader in providing molecular services, pharmacogenomics, genetic testing and clinical diagnostics to improve patient care. Our genomic services are marketed to the pharmaceutical, biotechnology, clinical, academic, government and agricultural marketplaces. We are utilizing pharmacogenomics to develop genetic-based tests and diagnostics and more efficacious therapeutics by finding genetic markers to guide drug development and utilization. Vilazodone, our therapeutic drug for depression, is in Phase III clinical development.

Our future success in molecular services will depend in large part on maintaining a competitive position in the genomics field, a field that has undergone, and is expected to continue to undergo, rapid and significant change.

Competition in the pharmacogenomics and molecular services market is intense and includes pharmaceutical, biotechnology and diagnostic companies, academic and research institutions and government and other publicly funded agencies, both in the U.S. and abroad. Our future success in this highly competitive market depends on our ability to demonstrate that our recently acquired technology platforms, know how, and informatics technologies and capabilities are superior to those of such competitors and our ability to advance technologies and genetic testing franchises. In addition, we must continue to contain costs and move toward profitability while growing revenues wherever possible.

50

#### **Table of Contents**

Funding the continued development of Vilazodone is another challenge that we face in our molecular services business. We currently do not have the cash reserves or the revenue from other sources to fund such development. In order to successfully commercialize this drug candidate, we will be required to either partner with a third party that has sufficient resources or raise capital through the sale of our equity and debt securities. Establishing a partnership with another company could have an impact on the future revenues we can expect to receive from Vilazodone if we have to share some portion of such revenues with a development partner. Additionally, fund raising could serve to dilute our stockholders.

We also face challenges with respect to our recent acquisitions. The continued integration of these operations has required significant efforts from each company, including the coordination of product development, sales and marketing efforts and administrative operations that will continue to be a time-consuming and complex process. Given that Genaissance, Icoria and Genome Express have a history of incurring significant net losses, we face the challenge of successfully integrating these businesses into companies that will generate sufficient revenue to become profitable and sustain profitability alleviating the need for external financing.

With respect to our diagnostic instrumentation operations, revenues from clinical laboratory testing are anticipated to grow as a result of the aging of the population, increased healthcare awareness and expanding insurance coverage. The present focus, however, on greater efficiency in disease management and on reducing health care costs exposes our customers to a constant pressure to contain costs. Consequently, in order to remain competitive and gain market share in these growing markets, it is essential for us to continue to provide cost-effective technologies.

Competition in the medical products industry, which includes our diagnostic instrumentation and reagent businesses, is intense and expected to increase as new products, technologies and services become available and new competitors enter the market. Our competitors in the United States, Europe and Asia-Pacific are numerous and include, among others, large, multi-national diagnostic testing and medical products companies. Our future success depends upon maintaining a competitive position in the development and distribution of products and other technologies for use in smaller clinical laboratories. In order to grow, gain market share and remain competitive, we must continue to introduce new products and technologies, and invest in research and development.

# **Financial Operations Overview**

*Revenues*. The most significant portion of our revenue from services relates to fee-for-service arrangements related to molecular services or diagnostic and genetic tests deliveries. Revenue for fee-for-service arrangements are recognized upon the later of service delivery or, if applicable, customer acceptance. We maintain relationships with certain healthcare providers as well as healthcare insurance companies; revenue from these arrangements is recognized net of contractual allowances.

Our revenues from the sale of diagnostic equipment and consumables are recognized at the time when persuasive evidence of an arrangement exists, delivery has occurred, the price to the buyer is fixed or determinable and collectibility is reasonably assured. Product revenues are generally recognized upon shipments.

Cost of Revenues. Cost of service revenues consist primarily of salaries and related expenses for personnel, including stock-based compensation expenses, laboratory expenses, depreciation, travel and facilities expenses, including rent, utilities and other facilities costs.

Cost of product revenues primarily represent costs to purchase or manufacture the diagnostic equipment, reagents and consumables, including equipment, parts and other materials, salaries and related expenses for personnel, including stock-based compensation expenses, and manufacturing overhead costs, such as depreciation, rent, utilities and other facilities costs.

*Research and Development Expense.* Research and development expense consists primarily of fees paid to professional service providers in conjunction with independently monitoring our clinical trials and acquiring and evaluating data in conjunction with our clinical trials, fees paid to independent researchers, costs of contract manufacturing, services expenses incurred in developing and testing products and product candidates,

51

#### **Table of Contents**

including salaries and related expenses for personnel, including stock-based compensation expenses, costs of materials, depreciation, rent, utilities and other facilities costs. During 2007, we recognized \$1.6 million of expense related to the acquisition of Vilazodone manufacturing and technology rights from Merck KGaA (Merck). We expense research and development costs as incurred.

Sales and Marketing Expense. Sales and marketing expense consists primarily of salaries, commissions and other related personnel costs, including stock-based compensation expenses, in our sales and marketing functions. Other costs primarily include advertising and promotion expenses, direct mailings, trade shows, facility costs and travel and related expenses.

General and Administrative Expense. General and administrative expense consists primarily of salaries and other related costs for personnel, including stock-based compensation expenses, in our executive, finance, accounting, information technology and human resource functions. Other costs primarily include facility costs and professional fees for accounting, consulting and legal services, including patent-related expenses.

Purchased Research and Development Expense. Purchased research and development expense represents the value of the in-process research and development projects at Genaissance and Icoria that had not yet reached technological feasibility and had no alternative use at their dates of acquisition in fiscal 2006. Such costs were expensed in accordance with Statement of Financial Accounting Standard (SFAS) No. 141, Business Combinations—see Note 4 to the consolidated financial statements for the method and assumptions used to value the in-process research and development.

Interest and Other Income (Expense), Net. Interest expense consists of interest incurred under notes payable and other debt financings and capital lease obligations. Interest income consists of interest earned on our cash and cash equivalents and short-term investments. Other income (expense), net consists primarily of foreign currency gains (losses).

*Preferred Stock Dividends.* Preferred stock dividends consists of dividends accrued on the outstanding shares of Series A Voting Convertible Preferred Stock (the Series A Preferred Stock) issued in connection with the acquisition of Genaissance on October 6, 2005. Dividends on outstanding shares are payable on January 5th and July 5th of each year, when and if declared by the Board of Directors. As of March 31, 2007, the cumulative dividends accrued on the Series A Preferred Stock totaled \$146,000.

A portion of our balance sheet is denominated in Euros, the functional currency of our Dutch operations. The effect of translation of these local currencies into U.S. dollars for reporting purposes is reflected as a separate component of stockholders equity. The gains or losses from foreign currency transactions are included in other income (expense) and have not been material to the financial statements. The Euro strengthened against the US dollar by 5.9% during fiscal 2007 and weakened against the US dollar by 6.6% during fiscal 2006 from the respective prior fiscal year s closing rates. The results of our European operations can be significantly impacted by changes in these foreign exchange rates.

Periodically we enter into foreign exchange forward contracts to reduce the exposure to currency fluctuations on customer accounts receivable denominated in foreign currency. The objective of these contracts is to minimize the impact of foreign currency exchange rate fluctuations on operating results. Derivative financial instruments are not used for speculative or trading purposes. There were foreign exchange forward contracts with a notional value of \$900,000 outstanding at March 31, 2007. The fair value of these instruments at March 31, 2007 was de minimis. Gains and losses related to these derivative instruments for fiscal 2007, 2006 and 2005 were not significant. We do not anticipate any material adverse effect on our consolidated financial position, results of operations, or cash flows resulting from the use of these instruments. However, there can be no assurance that these strategies will be effective

or that transaction losses can be minimized or forecasted accurately.

# Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements and notes, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make

52

#### **Table of Contents**

estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue, allowances for doubtful accounts, inventory, intangibles, goodwill, accrued expenses and income taxes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. A summary of our significant accounting policies is contained in Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition The most significant portion of our revenue from services relates to fee-for-service arrangements related to molecular services or diagnostic and genetic tests deliveries. Revenue for fee-for-service arrangements are recognized upon the later of service delivery or, if applicable, customer acceptance. We maintain relationships with certain healthcare providers as well as healthcare insurance companies; revenue from these arrangements is recognized net of contractual allowances.

Revenues from the molecular services segment are also derived from fees for licenses of intellectual property, commercial partnerships and government contracts and grants. Revenue from commercial contracts are generally related to service fees, milestone achievements and deliveries of molecular services data, diagnostic and genetic tests, and assays. Revenue for service fees and milestone achievements from commercial contracts are recognized as revenues based on the completed contract method. To the extent payments received exceed revenue recognized for each contract or grant, the excess portion of such payments is recorded as deferred revenues. To the extent revenues recognized exceed payments received for each contract, the excess revenues are recorded as accounts receivable. Revenue from government contracts and grants, which are typically cost plus arrangements, are recognized as revenues as related expenses are incurred over the term of each contract or grant.

Revenue from arrangement with multiple deliverables is divided into separate units of accounting when certain criteria are met. The consideration for the arrangement is then allocated to the separate units of accounting based on their relative fair values. Applicable revenue recognition criteria are then applied separately for each unit of accounting. We defer revenue of multiple element arrangements if the fair values of all deliverables are not known or if customer acceptance is contingent on delivery of specified items or performance conditions. Because we often lack evidence of fair value for commercial partnership contracts, revenue is deferred until the contract is completed and all elements have been delivered.

Our revenues from the sale of diagnostic equipment and consumables are recognized at the time when persuasive evidence of an arrangement exists, delivery has occurred, the price to the buyer is fixed or determinable and collectibility is reasonably assured. Product revenues are generally recognized upon shipments.

Generally, we receive a customer purchase order as evidence of an arrangement and product shipment terms are free on board (F.O.B.) shipping point. Returns and customer credits are infrequent and are recorded as a reduction to revenue. Rights of return or refund are generally not included in sales arrangements. Payments received under our commercial contracts and government contracts and grants are generally non-refundable regardless of the outcome of the future research and development activities to be performed by us.

Allowance for Doubtful Accounts Allowances for doubtful accounts are maintained for estimated losses resulting from the inability of our customers to make required payments. These estimated allowances of \$881,000, \$884,000 and \$381,000 at March 31, 2007, 2006 and 2005, respectively, are periodically reviewed, analyzing the customers payment history and information known to us regarding customers credit worthiness. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances

may be required.

*Inventory Valuation* Inventories are stated at the lower of cost (first-in, first-out) or market. Inventory quantities are periodically reviewed and, when necessary, provisions for excess and obsolete inventories are

53

#### **Table of Contents**

provided. On an ongoing basis, we review the carrying value of the inventory and record an inventory adjustment at such time as it is believed that the carrying value exceeds the inventory s net realizable value. Such assessments are based upon historical sales, forecasted sales, market conditions and information derived from our sales and marketing professionals.

In addition, certain of our products are perishable, and in the event that the product is not sold before the expiration date, such inventory is written off as soon as it is determined that the product is no longer marketable due to the expiration date. The product is then disposed.

Valuation of Intangibles — As discussed in Note 4 to the consolidated financial statements, we completed four business combinations during fiscal 2006. In accordance with SFAS No. 141, *Business Combinations*, the transactions have been accounted for based on fair value. As a result of the purchase price allocations, we recorded purchased intangibles totaling \$63.6 million and goodwill totaling \$20.0 million in the molecular services segment, and goodwill of \$1.2 million in the clinics and small hospitals segment. The fair value of the purchased intangibles was determined based on either discounted probable cash flows or replacement costs. The interest rates used to discount the net cash flows to their present value were based on our weighted-average cost of capital ranging between 16% and 27%. For a description of the purchased intangibles and their respective fair values, please see Note 4 to the consolidated financial statements.

In accordance with the requirements of SFAS No. 142, *Goodwill and Intangible Assets*, we perform an annual impairment test of the carrying value of goodwill using December 31 as our selected annual evaluation date. The fair value of our recorded intangibles can be impacted by economic conditions, market risks, and the volatility in the markets in which we and our customers operate. Changes in fair value could result in future impairment charges if the fair value of the reporting units or asset groups to which these long-lived assets are associated are determined to be less than the carrying value of such assets. As of December 31, 2006, the most recent evaluation date, there was no impairment of such goodwill.

In accordance with the requirements of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, when facts and circumstances suggest that there may be impairment, we will assess the carrying value of amortizing intangibles, including purchased intangibles. When a potential impairment has been identified, forecasted undiscounted net cash flows of the operations to which the asset relates are compared to the current carrying value of the assets present in that operations. If such cash flows are less than such carrying amounts, such intangibles are written down to their respective fair values. The results of these periodic impairment tests can be impacted by our future expected operating results and cash flows, economic conditions, market risks, and the volatility in the markets in which we and our customers operate. During the fourth quarter of fiscal 2007, we assessed the recoverability of certain intangible assets acquired in the Icoria transaction. This assessment was conducted in connection with the development of our fiscal 2008 budget. Based on the projections for fiscal 2008, we concluded that certain assets were impaired and we recorded a \$2.6 million impairment.

Accrued Expenses As part of the process of preparing consolidated financial statements we are required to estimate accrued expenses. This process involves identifying services which have been performed on our behalf and estimating the level of services performed and the associated cost incurred for such services as of each balance sheet date in our consolidated financial statements. Examples of estimated expenses for which we accrue include contract service fees, such as amounts paid to clinical monitors, data management organizations, clinical sites and investigators in conjunction with clinical trials, and fees paid to contract manufacturers in conjunction with the production of materials for clinical and non-clinical trials, and professional service fees. In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. In the event that we do not identify costs which have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for

such period would be too low or too high. The date, on which specified services commence, the level of services performed on or before a given date and the cost of such services is often judgmental. We attempt to mitigate the risk of inaccurate estimates, in part, by communicating with our service providers when other evidence of costs incurred is unavailable.

54

#### **Table of Contents**

Income Taxes As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatments of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. As of March 31, 2007, we had federal tax net operating loss carryforwards, after limitation for the change in ownership, of \$85.2 million, which expire starting in 2011, federal tax credit carryforwards of \$4.3 million and net deferred tax assets of \$151.4 million. We have recorded a valuation allowance of \$151.2 million as an offset against these otherwise recognizable net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that we determine in the future that we will be able to realize all or a portion of our net deferred tax asset, an adjustment to the deferred tax valuation allowance would increase net income in the period in which such a determination is made.

#### **Results of Operations**

## Fiscal Year Ended March 31, 2007 Compared to Fiscal Year Ended March 31, 2006

Fiscal 2007 includes the operations of PGxHealth, Cogenics and Electa Lab for a 12-month period while fiscal 2006 includes their operations since their dates of acquisition only. PGxHealth and Cogenics are the surviving operations of the Genaissance, Icoria and Genome Express acquisitions in October 2005, December 2005 and March 2006, respectively.

Revenues Consolidated revenues increased \$25.9 million, or 69%, from \$37.8 million in fiscal 2006 to \$63.7 million in fiscal 2007. Services revenue increased \$19.5 million, or 159%, from \$12.3 million in fiscal 2006 to \$31.8 million in fiscal 2007. Approximately \$19.3 million of the increase in services revenue was due to the inclusion of a full year of operations for PGxHealth and Cogenics in 2007.

Product revenues increased \$6.5 million, or 26%, from \$25.4 million in fiscal 2006 to \$31.9 million in fiscal 2007. The increase was due primarily to higher instruments sales within Vital Scientific and the inclusion of a full year of Electa Lab revenues. Vital Scientific s revenues grew by 15% due to increased unit sales and a sales mix more heavily weighted to higher-priced products.

*Gross Profit* Gross profit from services revenues increased from 24% in fiscal 2006 to 36% in fiscal 2007 due primarily to cost savings realized from integrating and streamlining the operations of Genaissance and Icoria.

Gross profit on product sales increased from 35% in fiscal 2006 to 36% in fiscal 2007 due to the more favorable sales mix within our Clinics and Small Hospitals segment specifically related to Vital Scientific s OEM sales.

Research and Development Expense Research and development expenses increased \$8.5 million, or 163%, from \$5.2 million in fiscal 2006 to \$13.7 million in fiscal 2007. The increase was due primarily to the inclusion a full year of operations for the acquired businesses in 2007, including approximately \$7.0 million related to the development of Vilazodone of which approximately \$1.6 million of the development costs relate to the fair value of 102,588 shares of common stock issued to Merck to acquire the manufacturing rights to Vilazodone. We expect our research and development expense to increase in fiscal 2008 due to costs associated with the Phase III clinical trials of Vilazodone.

Research and development expenses within the Clinics and Small Hospitals segment increased 24% due primarily to the inclusion of a full year of Electa Lab expense.

Sales and Marketing Expense Sales and marketing expenses increased \$4.6 million, or 139%, from \$3.3 million in fiscal 2006 to \$7.9 million in fiscal 2007. The increase was due primarily to the inclusion a full year of operations for the acquired businesses in 2007 as we integrate and build our sales and marketing function for molecular services. We

expect our sales and marketing expenses to continue to increase in fiscal 2008.

*General and Administrative Expense* General and administrative expenses increased \$15.8 million, or 125%, from \$12.7 million in fiscal 2006 to \$28.5 million in fiscal 2007. Approximately \$10.2 million of the

55

#### **Table of Contents**

increase was due to the inclusion of a full year of operations for the acquired businesses in 2007. Within these businesses, the 2007 general and administrative expenses included \$2.6 million for the impairment of purchased intangible assets associated with our acquisition of Icoria. General and administrative expense is expected to increase modestly in fiscal 2008.

General and administrative expense within the All Other segment increased by \$5.1 million primarily related to an increase in stock based compensation upon our adoption of FAS123R effective April 1, 2006 and higher compensation expense.

General and administrative expenses within the Clinics and Small Hospitals segment increased by approximately \$500,000 related to Vital Scientific s ERP software implementation and Sarbanes-Oxley implementation costs. The ERP software was successfully implemented on January 1, 2007.

Purchased Research and Development Expense Purchased research and development expenses of \$39.7 million in fiscal 2006 represents the fair value of the in-process research and development projects at Genaissance of \$36.3 million and at Icoria of \$3.4 million at their dates of acquisition. Since the costs relate to projects that had not yet reached technological feasibility and had no alternative use at their dates of acquisition, the costs were expensed in fiscal 2006. There were no such costs in fiscal 2007.

*Interest and Other Income (Expense), Net* Interest expense increased \$286,000 from \$341,000 in fiscal 2006 to \$627,000 in fiscal 2007 due primarily to the full year impact of the debt assumed in the acquisitions of Genaissance and Icoria.

Interest income increased \$292,000 from \$183,000 in fiscal 2006 to \$475,000 in fiscal 2007 due primarily to higher average investment balances, including net proceeds of \$16.9 million and \$11.9 million received from the private equity placements in June 2006 and November 2005, respectively.

Other income (expense), net of \$913,000 in fiscal 2007 and (\$47,000) in fiscal 2006 primarily represents a \$900,000 gain on the sale of an investment recognized in fiscal 2007.

*Provision For Income Taxes* The effective tax rate was (4.4)% in fiscal 2007 compared to (2.6)% in fiscal 2006. Although we incurred operating losses in fiscal 2007 and fiscal 2006, the in-process research and development expense is not tax deductible and no tax benefit was recorded on the operating losses in the United States as the deferred tax asset may not be realized. In addition, we recorded a tax provision for the income from our foreign operations. We expect that for the foreseeable future that we will not be able to benefit from our losses in the U.S.

*Preferred Stock Dividends* Preferred stock dividends of \$104,000 and \$97,000 in fiscal years 2007 and 2006, respectively, represent dividends accrued on the Series A Preferred Stock issued in connection with the acquisition of Genaissance.

# Fiscal Year Ended March 31, 2006 Compared to Fiscal Year Ended March 31, 2005

For fiscal 2005, the Clinics and Small Hospitals segment only includes the operating results of Vital Scientific as Vital Diagnostics has been recorded as discontinued operations and Electa Lab was acquired in fiscal 2006.

*Revenues* Consolidated revenues increased \$13.6 million, or 56%, from \$24.2 million in fiscal 2005 to \$37.8 million in fiscal 2006, of which approximately \$12.3 million of the increase was generated by PGxHealth and Cogenics since the dates of those acquisitions.

Services revenue increased \$12.3 million, or 100%, from zero in fiscal 2005 to \$12.3 million in fiscal 2006, due to the operations of Genaissance and Icoria.

Product revenues increased \$1.2 million, or 5%, from \$24.2 million in fiscal 2005 to \$25.4 million in fiscal 2006. The increase was due to increased sales in Clinics and Small Hospitals.

*Gross Profit* Gross profit on product sales increased from 33% in fiscal 2005 to 35% in fiscal 2006. The increase was primarily due to improved pricing and cost control.

56

#### **Table of Contents**

Research and Development Expense Research and development expenses increased \$3.5 million, or 206%, from \$1.7 million in fiscal 2005 to \$5.2 million in fiscal 2006. The increase was due primarily to the inclusion of approximately \$3.7 million of research and development expenses incurred by Genaissance and Icoria since their dates of acquisition.

Research and development expense within the Clinics and Small Hospitals segment decreased by \$0.2 million from \$1.7 million to \$1.5 million or 12%. Excluding the impact of foreign exchange, research and development expense remained essential flat year over year, as management focused on cost containment efforts.

Sales and Marketing Expense Sales and marketing expenses increased \$1.6 million, or 94%, from \$1.7 million in fiscal 2005 to \$3.3 million in fiscal 2006. The increase was due primarily to the inclusion of approximately \$1.4 million of sales and marketing expenses incurred by Genaissance and Icoria since their dates of acquisition.

Sales and marketing expense within Clinics and Small Hospitals segment increased by \$0.2 million from \$1.7 million to \$1.9 million or 12% and related primarily to higher personnel and commission expense.

General and Administrative Expense General and administrative expenses increased \$10.2 million, or 408%, from \$2.5 million in fiscal 2005 to \$12.7 million in fiscal 2006. The increase was due primarily to the inclusion of approximately \$8.6 million of general and administrative expenses incurred by our Molecular Services segment since the acquisition and integration of Genaissance and Icoria.

General and administrative expense within the Clinics and Small Hospitals segment increased by approximately \$0.1 million, from \$1.6 million to \$1.7 million or 6%. The increase was due primarily to increased personnel costs.

General and administrative expense within the All Other segment increased by approximately \$1.5 million, from approximately \$0.9 million to \$2.4 million or 166%. The increase was due primarily to costs associated with the merger and financing activities and increased professional fees.

Purchased Research and Development Expense Purchased research and development expenses of \$39.7 million in fiscal 2006 represents the fair value of the in-process research and development projects at Genaissance of \$36.3 million and at Icoria of \$3.4 million at their dates of acquisition as described above.

*Interest and Other Income (Expense), Net* Interest expense increased \$308,000 from \$33,000 in fiscal 2005 to \$341,000 in fiscal 2006 due primarily to debt assumed in the acquisition of Genaissance and Icoria.

Interest income increased \$123,000 from \$60,000 in fiscal 2005 to \$183,000 in fiscal 2006 due primarily to net proceeds of \$11.9 million received from the private equity placement in November 2005 and to higher average interest rates.

Other income (expense), net of (\$47,000) in fiscal 2006 and \$22,000 in fiscal 2005 primarily represents foreign currency (losses) and gains.

Provision For Income Taxes The effective tax rate was (2.6)% in fiscal 2006 compared to 44% in fiscal 2005. Although we incurred a loss in fiscal 2006, the in-process research and development expense is not tax deductible and no tax benefit was recorded on the operating losses in the United States as the deferred tax asset may not be realized. In addition, we recorded a tax provision for the income from our foreign operations. The fiscal 2005 effective rate represents the federal statutory rate with adjustments for the foreign tax rate differentials and state taxes payable in the United States. We expect that for the foreseeable future that we will not be able to benefit from our losses in the U.S.

*Preferred Stock Dividends* Preferred stock dividends of \$97,000 in fiscal 2006 represent dividends accrued on the Series A Preferred Stock issued in connection with the acquisition of Genaissance.

57

#### **Table of Contents**

# **Discontinued Operations**

During fiscal 2007, we determined that Vital Diagnostics, Pty. (Vital Diagnostics), our majority owned Australian subsidiary in the Clinics and Small Hospitals segment and Clinical Data Sales and Service, Inc. (CDSS) our wholly-owned U.S. subsidiary within our physician office laboratory segment (POL) did not fit with our strategic direction and the capital resources derived from the sale of the these two businesses could be better allocated to investments and growth opportunities in the pharmacogenomics and molecular services markets. Accordingly, we classified these two businesses as discontinued operations and their results of operations, financial position and cash flows are separately reported for all periods presented.

For more information, please see Discontinued Operations in Item 1 above and in Note 3 to the Consolidated Financial Statements.

## **Liquidity and Capital Resources**

Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table (in thousands):

	Year end December 31,						
(in thousands)	2007		2006		2005		
Cash (used in) provided by:							
Operating activities	\$ (12	2,874) \$	(6,182)	\$	4,388		
Investing activities		753	(1,444)		(930)		
Financing activities	13	3,447	11,597		(1,386)		
Effect of exchange rate		398	(917)		299		
Increase in cash and cash equivalents	\$	5,724 \$	3,054	\$	2,371		

We generated net cash flow of \$6.7 million during fiscal 2007, compared to \$3.0 million in fiscal 2006, and had cash and cash equivalents of \$13.9 million at March 31, 2007. The increased net cash flow in fiscal 2007 was primarily due to net proceeds of approximately \$20.6 million from the issuance of common stock and warrants related to private placements. Net cash flow in fiscal 2006 includes net proceeds of approximately \$11.9 million from the issuance of common stock and warrants in a private placement on November 17, 2005.

Our total debt obligations were \$6.9 million at March 31, 2007. In connection with the acquisitions of Genaissance, Icoria, Genome Express and Electa Lab in fiscal 2006, we assumed or incurred total debt obligations of approximately \$16.2 million, of which approximately \$6.7 million remain outstanding at March 31, 2007.

The terms of the convertible note payable with outstanding principal totaling \$2.6 million at March 31, 2007, assumed in the acquisition of Icoria were amended on August 31, 2006. The note is now due in semi-annual installments of \$334,070 with final maturity on October 19, 2010, and carries interest at prime plus 2.5% of which 6.0% is payable monthly in cash. The balance of the interest is payable quarterly in cash, common stock or a combination of cash and common stock at our option. If the market value of the common stock is equal to or greater than \$27.50 per share, the semi-annual payments may be paid in shares of common stock. The note is convertible into common stock at an initial price of \$25.00 per share at the option of the holder, and is mandatory convertible if the market value of the common stock is equal to or greater than \$27.50 per share for six consecutive trading days. The note is secured by all of Icoria s

assets and payments have been guaranteed by us up to \$760,000. The entire principal balance, plus any accrued and unpaid interest and fees could be accelerated in the event of default. The principal and interest outstanding on the note at March 31, 2007 was \$2.6 million.

58

#### **Table of Contents**

The following table summarizes our contractual obligations at March 31, 2007 and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

# **Payments Due by Period**

	Total	Fiscal T		TI 1	Fiscal 2009 nrough Fiscal 2010 thousand	Fiscal 2011 Through Fiscal 2012		After Fiscal 2012	
Contractual Obligations:									
Short and long-term debt(1)	\$ 7,948	\$	1,843	\$	3,659	\$	2,446	\$	
Capital lease obligations(1)	500		193		253		54		
Operating lease obligations	8,393		2,169		3,303		1,295		1,626
Total contractual cash obligations	\$ 16,841	\$	4,205	\$	7,215	\$	3,795	\$	1,626

# (1) Includes interest expense

Currently, we do not enter into financial instruments for trading or speculative purposes. We do not have any special purpose entities or other off-balance sheet arrangements.

In connection with the acquisitions completed in fiscal 2006, we recorded restructuring and integration reserves totaling approximately \$4.6 million, representing severance of \$3.1 million and lease termination of \$1.5 million. During fiscal 2007, we paid approximately \$2.3 million and \$1.1 million, relating to the severance and lease termination costs, respectively. During fiscal 2006, the respective payments were approximately \$748,000 and \$405,000. At March 31, 2007, the restructuring and integration reserves totaled approximately \$210,000, which is solely attributable to severance costs. We expect these costs will be fully paid during fiscal 2008.

On June 9, 2006, we issued convertible promissory notes to two affiliates of Randal J. Kirk, the Chairman of our Board of Directors. The lenders provided us with \$2.0 million to fund working capital needs until such time as we could complete a new private placement to certain institutional and accredited investors. The notes, which were payable thirty days from the date of issuance, accrued interest at a rate of 12% per annum and were convertible at the option of the holders into the same type of security sold by us to investors in the first financing following issuance, at a price per share equal to the last reported closing bid price of the our common stock as reported on the NASDAQ on the date of issuance. On June 14, 2006, we repaid the notes plus accrued interest of approximately \$4,000 using a portion of the proceeds from the private placement of common stock described below.

On June 13, 2006, we completed a private placement of common stock in which we sold 1,039,783 shares of common stock and warrants to purchase an additional 519,889 shares of common stock for net proceeds of approximately \$16.9 million, after transaction expenses of approximately \$63,000, to certain institutional investors, including certain members of our board of directors. The unit price was \$16.2725, which equaled the closing bid price of our common stock on the NASDAQ on the closing date, plus \$0.0625 per share. The exercise price of the warrants is \$19.45, equaling a twenty percent premium on the closing bid price of our common stock on the NASDAQ on the closing

date. The warrants are exercisable beginning December 14, 2006 through the close of business on June 13, 2011. In February 2007, Third Security, LLC and its affiliates, which are controlled by Mr. Kirk, exercised 190,505 of the warrants at a price of \$19.45 for net proceeds to us of approximately \$3.7 million.

We received offers from two groups to purchase Vital Diagnostics. During the second quarter of fiscal 2007, we accepted the most favorable offer which was to sell our 92.5% interest for net proceeds of \$1.0 million. The transaction, structured as a share purchase, closed on November 13, 2006. The buyers included Adrian Tennyenhuis, Vital Diagnostic s general manager and holder of the 7.5% minority interest, and New River Management IV, LP, an affiliate of Third Security, which is funded and controlled by Third

59

#### **Table of Contents**

Security, LLC which is controlled by Mr. Kirk. We recorded a loss on disposal in fiscal 2007 of approximately \$178,000 in connection with the sale.

We engaged Lazard to seek a buyer for the sale of CDSS. Lazard identified a list of potential buyers, who were contacted, and we received several letters of interest to purchase CDSS. We accepted the most favorable offer which was to sell CDSS to Adrian Tennyenhuis and New River Management IV, LP for net proceeds of approximately \$7.0 million. The transaction, structured as a share purchase, closed on June 18, 2007. Under the terms of the transaction, approximately \$3.3 million of the net proceeds from the sale will be required to retire a line-of-credit held by LaSalle bank. We recorded a loss on disposal in fiscal 2007 of approximately \$7.0 million in connection with the sale.

On June 6, 2007, we received \$2.8 million from the settlement of litigation we filed against a third-party for breach of contract.

During fiscal 2008, we expect to make capital expenditures of approximately \$3.1 million primarily to introduce new products, improve production processing of existing and planned product offerings and to upgrade our laboratory information systems. We expect to use our available cash and capital leases to fund these expenditures.

Our sources of cash as of June 18, 2007, include our cash and cash equivalents balance of approximately \$17.0 million, cash flows from our IVD operations, capital leases and possible future equity and/or debt financings. Our projected uses of cash include cash used in Molecular Services segment, capital expenditures, existing debt service costs and continued development of Vilazodone and other potential products through internal research, collaborations and, possibly through strategic acquisitions. As part of our strategy, we continually evaluate possible mergers, acquisitions and investments. The financing of such activities is evaluated as part of our review of any opportunity.

At currently projected rates of expenditure, we believe that additional funding will be required to operate our business beyond the second quarter of fiscal 2008, including the funding of Phase III clinical trials for our lead drug candidate, Vilazodone. We are considering several options for raising additional funds such as public or private offerings of equity or debt, or other financing arrangements. We cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain any required additional financing, we may be required to reduce the scope of our planned research, development and commercialization activities, including our efforts related to Vilazodone, HAP and other new technologies, which could harm our financial condition and operating results. Additional equity financing may be dilutive to the holders of our common stock and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

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

We are exposed to market risks, which include changes in interest rates, as well as changes in foreign currency exchange rates as measured against the U.S. dollar and each other. We attempt to minimize some of these risks by using foreign currency forward and swap contracts. These hedging activities provide only limited protection against interest rate and currency exchange risks. Factors that could influence the effectiveness of our programs include volatility of the interest rate and currency markets and availability of hedging instruments. All interest rate swap and currency contracts that we enter into are components of hedging programs and are entered into for the sole purpose of hedging an existing or anticipated interest rate and currency exposure, not for speculation.

#### **Interest Rate Risk**

We use a combination of fixed rate term loans, variable rate lines of credit and fixed rate leases to finance our activities. Our term loans and leases are all at fixed rates over their lives and carry no interest rate risk. As a result of our existing variable rate credit lines and loan agreements, we are exposed to risk from changes in interest rates. As of March 31, 2007, we had a convertible note with an outstanding balance of \$2.57 million

60

#### **Table of Contents**

carrying an interest rate of 2.5% over Prime (10.25%). A hypothetical 10% change in interest rates would not materially impact our annual interest expense.

#### **Foreign Exchange**

The value of certain foreign currencies as compared to the U.S. dollar may affect our financial results. Fluctuations in exchange rates may positively or negatively affect our revenues, gross margins, operating expenses, and retained earnings, all of which are expressed in U.S. dollars. Where we deem it prudent, we engage in hedging programs, using primarily foreign currency forward and swap contracts, aimed at limiting the impact of foreign currency exchange rate fluctuations on earnings. We purchase short-term foreign currency forward and swap contracts to protect against currency exchange risks associated with long-term intercompany loans due to our international subsidiaries and the payment of merchandise purchases to foreign vendors. We do not hedge the translation of foreign currency profits into U.S. dollars, as we regard this as an accounting and not an economic exposure.

As of March 31, 2007, we had outstanding foreign currency forward and swap contracts aggregating \$900,000, all of which related to intercompany debt. The fair value of the forward contracts and the related gains and losses were not material as of and for the year ended March 31, 2007.

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

The information required by this item is attached to this Annual Report on Form 10-K beginning on Page F-1.

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

None.

### ITEM 9A. CONTROLS AND PROCEDURES

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(b) under the Securities and Exchange Act) as of March 31, 2007. Based on its evaluation, our CEO and CFO concluded that, as of March 31, 2007, our disclosure controls and procedures were designed to ensure that material information relating to us is made known to our CEO and CFO by others within the Company, particularly during the period in which this report was being prepared; however, it was concluded that such controls were ineffective as of March 31, 2007, in that they do not provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities and Exchange Act is recorded, processed, summarized, and reported with in the time periods specified in the Securities and Exchange Commission s rules and forms.

During the quarter ended March 31, 2007, we concluded that the Company s internal controls related to the financial close and reporting process with regard to the Icoria business unit are not operating effectively as of March 31, 2007. Financial management within the Molecular Services segment is responsible for reviewing all significant account reconciliations and performing an overall financial statement review to assess the divisions application of the Company s accounting policies and reasonableness of the recorded balances within the Icoria business. Due to rapid changes in the Icoria division, including personnel turnover and the integration of the operations into other divisions within the Molecular Services segment, such reviews were not performed at March 31, 2007 or the reviews were not performed at a level of precision that would prevent a material error. The company expects to complete the integration

of Icoria s operations within the next year.

61

#### **Table of Contents**

#### **Changes in Internal Controls**

No change in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities and Exchange Act) occurred during the period covered by this report that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

#### ITEM 9B. OTHER INFORMATION

We engaged Lazard to seek a buyer for the sale of CDSS. Lazard identified a list of potential buyers, who were contacted, and we received several letters of interest to purchase CDSS. We accepted an offer to sell CDSS to Adrian Tennyenhuis and New River Management IV, LP for net proceeds of approximately \$7.0 million. The transaction, structured as a share purchase, closed on June 18, 2007. Under the terms of the transaction, approximately \$3.3 million of the net proceeds from the sale will be required to retire a line-of-credit held by a bank. We recorded a loss on disposal in fiscal 2007 of approximately \$7.0 million in connection with the sale. CDSS, is a seller of products and services from scientific instrumentation, equipment and reagents to lab management and consulting services and previously comprised the Company s Physician s Office Laboratories (POL) segment. Please see Note 3, Discontinued Operations.

62

#### **Table of Contents**

#### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

#### **DIRECTORS**

# **Business Experience During Past Five Years Director** and Other Directorships Since Name and Age Randal J. Kirk Randal J. Kirk has been a director of Clinical Data since 2002 and 2002 Chairman of the Board of Directors since December 2004. Additionally, Age: 53 Mr. Kirk has served as a director of New River Pharmaceuticals Inc., a publicly-traded specialty pharmaceutical company focused on developing novel pharmaceuticals and improved versions of widely-prescribed drugs, since August 1996, as Chairman of its Board since 1996, and as its President and Chief Executive Officer since October 2001. Mr. Kirk has over 20 years of experience in the healthcare industry. Mr. Kirk began his professional career in the private practice of law. Mr. Kirk co-founded General Injectables & Vaccines, Inc., a pharmaceutical distributor (GIV), in 1983 and served as Chairman of the Board of GIV prior to the sale of that company in 1998. Previously, Mr. Kirk served as a member of the Board of Directors of Scios, Inc. (previously traded on the NASDAQ prior to its acquisition by Johnson & Johnson) between February 2000 and May 2002. He has served on the Board of Directors of Harvest Pharmaceuticals Inc., a pharmaceutical company and an affiliate of New River, since December 2002, and on the Virginia Bioinformatics Institute Policy Advisory Board since March 2004. Mr. Kirk also currently serves in a number of additional capacities with the following entities, each of which is an affiliate of New River: Senior Managing Director of Third Security, LLC, an investment management firm founded by Mr. Kirk, since 1999; Chairman of Biological & Popular Culture LLC, an automated proactive notification software and service company, since September 2002; and member of the Board of Directors of Howe and Rusling, Inc., a registered investment advisory firm, since December 2001. Mr. Kirk has also served on the Board of Visitors of Radford University since July 2003 and on the Board of Directors of the Radford University Foundation, Inc. since September 1998. Mr. Kirk received a B.A. in Business from Radford University and a J.D. from the University of Virginia. Andrew J. Fromkin Andrew J. Fromkin joined Clinical Data on October 12, 2005, as our 2006 Executive Vice President and Chief Marketing Officer, and was elected Age: 40 President and Chief Executive Officer on May 12, 2006. Mr. Fromkin has more than 17 years of senior leadership experience in the health care industry in the areas of corporate development, strategic planning, and sales and marketing management. He was most recently president and CEO of DoctorQuality, Inc., a leading provider of patient safety products and information services that was acquired by Quantros, Inc. Prior to that, Mr. Fromkin held several senior management roles at emerging healthcare

Table of Contents 125

companies, including executive appointments as President and Chief

Executive Officer of Endo Surgical Devices, Inc., where his achievements included developing a line of innovative surgical devices, securing funding for the company, and guiding the company to its first FDA approval. Mr. Fromkin also was Vice President, Business Development and before that, Vice President, Sales for Merck-Medco Managed Care, LLC, a wholly owned subsidiary of Merck & Co., Inc. In all of these roles, Mr. Fromkin successfully developed and negotiated complex transactions including major account sales, strategic alliances, joint ventures and acquisitions. Mr. Fromkin began his career in healthcare at Health Information Technologies.

63

# **Table of Contents**

Name and Age	Business Experience During Past Five Years and Other Directorships	Director Since
Larry D. Horner Age: 73	Larry D. Horner has also served as a member of the Board of Directors of New River Pharmaceuticals Inc., a publicly-traded specialty pharmaceutical company focused on developing novel pharmaceuticals and improved versions of widely-prescribed drugs, since 1999. From 1994 to 2001, Mr. Horner served as Chairman of the Board of Pacific USA Holdings Corporation, a holding company of companies in real estate and financial services. From 1997 to 2001, Mr. Horner served as Chairman of the Board of Asia Pacific Wire & Cable, Ltd., a publicly-traded manufacturer of wire and cable products for the telecommunications and power industries in the Asia Pacific Region. From 1991 to 1994, he served as Managing Director of Arnhold & S. Bleichroeder, Inc., an equity market trading and corporate finance firm. Prior to that, he served as Chairman and Chief Executive Officer of the accounting firm KPMG Peat Marwick. Mr. Horner is on the Board of Directors of Atlantis Plastics, Inc., Technical Olympics USA, Inc., and UTStarcom, Inc., all public companies; Mr. Horner serves on the audit committee of all three of these companies and as the audit committee financial expert for Atlantis Plastics, Inc. and UTStarcom, Inc.	2002
Arthur B. Malman Age: 65	Arthur B. Malman is a partner of the law firm of Malman & Goldman, LLP and a principal of the Urban Group, a real-estate investment company. Mr. Malman is also Chairman of Dimex Holdings Corporation, a telecom venture company and a director of PS America, Inc. a floor covering chain. Mr. Malman received a B.A. from Princeton University and a J.D. from the Yale University School of Law, and attended Columbia University School of Business Administration.	1975
Burton E. Sobel, M.D. Age: 69	Burton E. Sobel, M.D. has been at the University of Vermont since 1994 where he is currently E.L. Amidon Professor of Medicine, Director of the Cardiovascular Research Institute, and Professor of Biochemistry. Dr. Sobel has been a trustee of Fletcher Allen Health Care Center in Burlington, Vermont. Previously, he held senior academic and administrative positions at Washington University School of Medicine and Barnes Hospital from 1973 to 1994, and at the University of California, San Diego, from 1968 to 1973. Dr. Sobel completed postgraduate training at the Peter Bent Brigham Hospital, Boston and the National Institutes of Health, Bethesda and received his M.D., magna cum laude, from Harvard University and his A.B. from Cornell University. Dr. Sobel is President-elect for the Society for Experimental Biology and Medicine and also serves as a member of the Board of Directors of Nuvelo, Inc., Ariad Pharmaceuticals, Inc., and New River Pharmaceuticals Inc., all publicly-traded life science companies	2005
Kevin L. Rakin Age: 46	Kevin L. Rakin is an Executive-In-Residence at Canaan Partners and Interim CEO of Advanced BioHealing, Inc. He co-founded Genaissance Pharmaceuticals, Inc. (acquired by Clinical Data in October 2005) and served as its President and Chief Executive Officer from August 2002 until October 2005 and its President from October 2000. Mr. Rakin holds a B.S.	2005

in business and a M.S. in finance from the University of Cape Town and a M.B.A. from Columbia University.

# **Board and Committee Matters**

*Independence*. Our Board of Directors has determined that each of the current directors is independent as defined by applicable NASDAQ standards governing the independence of directors, other than Kevin L. Rakin and Andrew J. Fromkin.

64

# **Table of Contents**

Code of Ethics We have adopted a code of ethics that applies to our Chief Executive Officer and senior financial officers, in addition to a code of business conduct and ethics that applies to the executive officers and all other employees of the Company. Both codes are filed as exhibits to this report and are posted on our website at http://investor.clda.com/gov.cfm. We will provide a copy of our codes of conduct and ethics to any person without charge upon written request to Caesar J. Belbel, Executive Vice President, Chief Legal Officer and Secretary, Clinical Data, Inc., One Gateway Center, Suite 702, Newton, MA 02458.

Audit Committee. The members of the Audit Committee are Larry D. Horner (Chair), Arthur B. Malman, and Burton E. Sobel, M.D. Our Board of Directors has concluded that each of the members of the Audit Committee satisfies the independence and financial literacy and expertise requirements defined by applicable NASDAQ standards governing the qualifications of Audit Committee members. Additionally, our Board of Directors has determined that Mr. Horner qualifies as an audit committee financial expert under the rules of the SEC.

#### **EXECUTIVE OFFICERS**

The following contains certain information as of March 31, 2007 about our executive officers and significant employee:

Name	Age	Position
Andrew J. Fromkin	40	President and Chief Executive Officer
C. Evan Ballantyne	47	Senior Vice President and Chief Financial Officer
Caesar J. Belbel	47	Executive Vice President, Chief Legal Officer and
		Secretary
Carol Reed, M.D.*	54	Senior Vice President and Chief Medical Officer

#### \* Significant employee

Andrew J. Fromkin, joined Clinical Data on October 12, 2005, as our Executive Vice President and Chief Marketing Officer, and was elected President and Chief Executive Officer on May 12, 2006. Mr. Fromkin has more than 17 years of senior leadership experience in the health care industry in the areas of corporate development, strategic planning, and sales and marketing management. He was most recently president and CEO of DoctorQuality, Inc., a leading provider of patient safety products and information services that was acquired by Quantros, Inc. Prior to that, Mr. Fromkin held several senior management roles at emerging healthcare companies, including executive appointments as President and Chief Executive Officer of Endo Surgical Devices, Inc., where his achievements included developing a line of innovative surgical devices, securing funding for the company, and guiding the company to its first FDA approval. Mr. Fromkin also was Vice President, Business Development and before that, Vice President, Sales for Merck-Medco Managed Care, LLC, a wholly owned subsidiary of Merck & Co., Inc. In all of these roles, Mr. Fromkin successfully developed and negotiated complex transactions including major account sales, strategic alliances, joint ventures and acquisitions. Mr. Fromkin began his career in healthcare at Health Information Technologies.

C. Evan Ballantyne joined Clinical Data as Chief Financial Officer and Senior Vice President on August 7, 2006. He was most recently Senior Vice President and Chief Financial Officer of ZymeQuest, Inc., a medical technology company based in Beverly, Massachusetts, and previously was the Chief Financial Officer of Knowledge Impact, of Wayland, Massachusetts. Earlier, Mr. Ballantyne was a vice president and chief operating officer for ACNielsen Corporation and held the chief financial officer position as well for 2 years. There, he was responsible for all aspects

of operations, strategic planning and finance in more than 45 countries for a corporation with 9,700 employees and annual revenue exceeding \$650 million. At ACNielsen, he drove productivity gains and cost savings activities totaling \$27.5 million while holding expenses flat with the prior year and helped develop new revenue opportunities while implementing a cross-border sales tracking system. He also helped lead the company s successful ISO certification in three countries. Mr. Ballantyne also held an audit position for Dun & Bradstreet, earned a B.A. from the University of Western Ontario, and took a post-graduate degree in Business Administration with Honors from the University of Windsor.

65

#### **Table of Contents**

Caesar J. Belbel joined Clinical Data as Vice President and General Counsel on May 7, 2003, and was elected Secretary of Clinical Data on June 25, 2003. Mr. Belbel was subsequently elected Senior Vice President in May 2005 and Executive Vice President of Clinical Data in October 2005. Prior to joining Clinical Data, Mr. Belbel served from 2000 to 2002 as Senior Vice President, General Counsel and Secretary of Xpedior Incorporated, a publicly-held Internet consulting services and e-commerce software development company. Previously, from 1997 to 2000, Mr. Belbel served as General Counsel of Programart Corporation, a developer of application performance management software. Mr. Belbel holds a Bachelor of Arts degree from Columbia University and a Juris Doctor degree from Boston College Law School.

Carol Reed, M.D. joined Clinical Data in October 2005 following the completion of its merger with Genaissance Pharmaceuticals, Inc., where Dr. Reed had served as Vice President, Medical Affairs since 2003. Dr. Reed joined Genaissance from Bayer Pharmaceuticals, Inc., where she was an Associate Medical Director in Pulmonary Medical Research. Previously, she was the Associate Director, Section of Pulmonary and Critical Care Medicine, at the Hospital of St. Raphael and directed its Medical Intensive Care Unit. Dr. Reed received a M.S. in biology from the University of Illinois and a M.D. from Rush Medical College in Chicago.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Our executive officers and directors and persons who own beneficially more than ten percent of our equity securities are required under Section 16(a) of the Securities Exchange Act of 1934 to file reports of ownership and changes in their ownership of our securities with the Securities and Exchange Commission. They must also furnish copies of these reports to us. Based solely on a review of the copies of reports furnished to us and written representations that no other reports were required, we believe that for the fiscal year ended March 31, 2007 our executive officers, directors and ten percent beneficial owners complied with all applicable Section 16(a) filing requirements.

#### ITEM 11. EXECUTIVE COMPENSATION

### COMPENSATION DISCUSSION AND ANALYSIS

The Compensation Committee of the Board (or the Committee ) assists the Board in fulfilling its oversight responsibilities with respect to the compensation of the Company s officers. The Committee is responsible for (i) establishing and administering the base salaries and cash bonuses of Clinical Data s executive officers, and (ii) administering and making recommendations and awards under Clinical Data s 2002 Stock Option Plan and 2005 Equity Incentive Plan. Base salaries, cash bonuses and equity awards for the senior management are recommended by the Committee subject to Board approval. The Committee monitors whether the compensation paid to the Company s senior management is fair, reasonable and competitive and is substantially tied to Company performance. Clinical Data s Compensation Committee evaluates, both subjectively and objectively, Clinical Data s financial performance, competitive position, future potential, and the individual and group performance of the members of senior management. In such evaluation, the Compensation Committee reviews data prepared by Clinical Data and employs the business experience of the individual members of the Compensation Committee.

#### **Compensation Objectives**

Our executive compensation program is designed to attract, retain, motivate and reward talented individuals who will execute our business plan so that Clinical Data can succeed in the competitive business environment in which the Company operates.

# **Elements of Executive Compensation**

The Company s executive compensation program consists of the following elements:

base salary;

annual cash bonus award;

66

#### **Table of Contents**

equity compensation; and

post-termination compensation.

The Company does not provide its executives with perquisites. The Company does not have any deferred compensation programs or retirement programs other than our 401(k) plan that is generally available to all employees. Clinical Data enrolls all salaried employees in its health, dental and life and disability insurance programs.

Each of these elements of executive compensation is addressed separately below.

## **Base Salary**

Base salary is provided in order to retain executives consistent with the Company s achievement of its financial and strategic goals. Officers and other key employees are compensated within salary ranges that are generally based on similar positions in companies of comparable size and complexity to that of Clinical Data based on information gathered by members of our Compensation Committee and our human resources staff. The annual compensation for each officer is based on Company and individual performance as well as achievement of Company and individual goals including, but not limited to, growth in the market capitalization of Clinical Data; establishment and consolidation of Clinical Data s leadership position in the pharmacogenetic field; and completion of strategic initiatives including acquisitions and divestitures of operating assets, and completion of key collaboration agreements. The Compensation Committee also takes into account prevailing general economic conditions, marketplace trends, and other factors deemed important by them and the Board, including the fact that Clinical Data does not offer a defined benefit retirement or other similar plans and perquisites to its senior management employees.

The base salaries for Mr. Fromkin and Mr. Belbel are set forth in their employments agreements described below. The base salaries of other senior management are established upon the commencement of their employment with the Company and are adjusted annually by the Compensation Committee. All base salaries paid to executive officers were fully deductible in the fiscal year ending March 31, 2007.

## **Annual Bonus**

Clinical Data pays discretionary bonuses that are recommended by the Committee and approved by the Board. Target cash bonus compensation of two times Mr. Fromkin s base salary, and one time Mr. Belbel s base salary are specified in their respective employment agreements. The Committee considers the bonus targets set forth in the executives employment agreements as a maximum payment that would be made based on outstanding company and individual performance. The Compensation Committee historically has recommended to the Board that the level of bonuses to be awarded to senior management be based, in the case of the chief executive officer, primarily upon the financial and strategic performance of Clinical Data, and for other executives primarily on the performance of the operating units for which they are directly responsible. For fiscal 2006, the Committee took into consideration, for those employees who will be playing critical roles in the company going forward, several factors, including the ongoing efforts of the named executive officers with respect to the successful restructuring and integration of the businesses including Genaissance Pharmaceuticals, Icoria and Genome Express recently acquired by the Company. Accordingly, in 2006, we made bonus payments of \$70,000 each to both Messrs. Fromkin and Belbel. Mr. Fromkin took \$35,000 of his bonus in cash and the remaining \$35,000 in a stock option. Mr. Belbel took \$50,000 of his total bonus payment in cash and the remaining \$20,000 in a stock option. Bonus payments were in recognition of Mr. Belbel successfully completing a number of important restructuring initiatives and, in the case of Mr. Fromkin, as a result of his assumption of greater responsibilities when he was appointed President and Chief Executive Officer of the Company in May 2006. All bonus payments were fully deductible in 2006. Bonuses for 2006 paid to the named executive

officers are reported in the Bonus column of the Summary Compensation Table.

For fiscal 2007, the Compensation Committee recommended and the Board approved cash bonus payments for senior management based upon the achievement by Clinical Data of an increase in the market

67

#### **Table of Contents**

capitalization of the company and certain other strategic and financial goals. The senior management group for fiscal 2007 included seven individuals. The total amount of the cash bonus pool awarded to these individuals was \$725,000, of which Mr. Fromkin received \$315,000; Mr. Belbel received \$130,000, Dr. Reed received \$90,000, Mr. Ballantyne received \$90,000, and three other members of the company senior management received a total of \$100,000. The Committee will consider for 2008 similar bonus programs based upon the achievement by Clinical Data and its operating units of continued improvement of the company senior management and certain other strategic and financial goals.

#### **Equity Compensation**

Currently, stock options are Clinical Data's primary method for providing long-term incentive compensation to its senior management. The size of the awards has historically been based on guidelines that take growth in market capitalization, individual performance, salary level and tenure into account. The Committee believes that broad and significant employee ownership of Clinical Data's stock effectively motivates the building of stockholder wealth. We also use stock options because we believe that equity compensation in this form aligns the interests of stockholders with senior management to ensure the Company's long-term success as reflected in increases to the Company's market capitalization. Accordingly, in May 2006, upon his appointment to the position of President and Chief Executive Officer of Clinical Data, Mr. Fromkin received a stock option grant of 304,515 shares at an exercise price of \$18.55 per share, which was equal to the closing price of Clinical Data's common stock quoted by the NASDAQ on the day immediately preceding the grant. The number of options granted to Mr. Fromkin reflected the level of responsibility he assumed, particularly with respect to the on-going integration of the Company's operations and in ensuring the success of the Company's strategic repositioning in the molecular diagnostics field. Further details regarding the terms of outstanding stock options held by our named executive officers are set forth in the Outstanding Equity Awards at 2007 Fiscal Year End' table. None of the named executives received restricted stock grants in 2007.

For fiscal 2008, the Committee recommended and the Board approved as equity incentive the grant of an additional 180,000 stock options to the senior management of the company. These stock options were granted on June 14, 2007, at an exercise price of \$22.48 per share, which was equal to the closing price of Clinical Data s common stock quoted by the NASDAQ on the day of grant. Of these stock options, Mr. Fromkin received 80,000 options; Messrs. Belbel and Ballantyne, and Dr. Reed each received 30,000 options; and one other member of senior management received 10,000 options.

### **Fringe Benefits**

Under the terms of Mr. Fromkin s employment agreement, for an annual premium not to exceed \$2,000 per year (which premium is fully taxable to Mr. Fromkin), the Company maintains a term life insurance policy on Mr. Fromkin s life, the proceeds of which are payable to Mr. Fromkin s beneficiaries. Otherwise, we provide our corporate officers the same benefits as those provided to all our other salaried employees, such as health and dental insurance, life insurance, short- and long-term disability, and opportunities to participate in our 401(k) plan with company match.

## **Post-Termination Compensation**

Messrs. Fromkin, Belbel, and Ballantyne, and Dr. Reed, are all entitled to receive post-termination compensation under their employment arrangements with the Company. In the cases of Messrs. Fromkin and Belbel, and Dr. Reed, these benefits were established under the terms of their employment agreements entered into by the Company during the 2007 fiscal year. Mr. Ballantyne s post-termination compensation benefits arise under the terms of his offer of employment, which commenced in August 2006. The terms of all these arrangements remain in effect generally unless any of the executive employees is terminated by the Company with cause or any of the executive employees

resign voluntarily from the Company other than for good reason. In addition, the agreements provide accelerated equity vesting, to be provided upon a change of control. The Company s agreements with Messrs. Fromkin and Belbel also provide for tax gross-up payments in connection with a change in control of the company. The amount of benefits that each executive would potentially earn

68

#### **Table of Contents**

under these contracts upon a covered termination of employment and a change in control is described and quantified below under Potential Payments upon Termination of Employment or Change in Control .

### **Stock Option Granting Practices**

The Committee s practice when granting stock options had been to use the closing price of the Company s common stock on the day of the grant. As a matter of formal written policy, the Company has not and does not time the grant of stock options around the disclosure of non-public information or back date stock options. On two occasions in the 2007 fiscal year, the Committee delegated to Mr. Fromkin its authority to grant up to a fixed number of stock options to enable him to provide equity incentive awards to key personnel throughout the organization below the senior management level. Accordingly, on July 31, 2006 and December 20, 2006, Mr. Fromkin granted 231,000 and 180,893, respectively, to such personnel at an exercise price equal to the closing price of the Company s Common Stock on the date of grant as quoted by the NASDAQ.

# **Deduction Limit for Executive Compensation**

Section 162(m) of the Internal Revenue Code limits the tax deductibility by a public company of compensation in excess of one million dollars paid to any of its five most highly compensated executive officers. Outstanding stock options granted under Clinical Data s 2002 Stock Option Plan and 2005 Equity Incentive Plan will not be subject to the limitation under applicable regulations. Clinical Data s Compensation Committee intends to use its best efforts to structure future compensation so that executive compensation paid by it is fully deductible in accordance with Section 162(m) of the Code. Clinical Data s Compensation Committee may, however, in a particular case, approve compensation that may not be deductible under Section 162(m).

#### **COMPENSATION COMMITTEE REPORT:**

We, the Compensation Committee of the Board of Directors of Clinical Data, Inc. have reviewed and discussed the Compensation Discussion and Analysis set forth above with the management of the Company, and, based on such review and discussion, have recommended to the Board of Directors inclusion of the Compensation Discussion and Analysis in this Annual Report on Form 10-K for the year ended March 31, 2007.

By the Compensation Committee:

Arthur B. Malman (Chair) Larry D. Horner

69

#### **Table of Contents**

### **Summary Compensation Table**

The following table sets forth the information required by SEC Regulation S-K Item 402 as to the compensation paid or accrued by us for the year ended March 31, 2007 for services rendered in all capacities, by all person who served as our Chief Executive Officer or Chief Financial Officer and the other most highly compensated executive officer during the fiscal year ended March 31, 2007 (the named executive officers).

# **Summary Compensation Table for Fiscal Year 2007**

Name and Principal Position	Year(1)	Salary (\$)	Bonus (\$)	Option Awards (\$)(2)	All Other Compensation (\$)(3)	Total (\$)
Andrew J. Fromkin,  Chief Executive Officer,	2007	388,846	350,000	804,928	4,938	1,548,712
President,(4)						
C. Evan Ballantyne,	2007	143,846	90,000	84,626	1,523	319,995
Chief Financial Officer,						
Senior Vice President(5)						
Caesar J. Belbel,	2007	256,096	180,000	391,588		827,684
Executive Vice President,						
Secretary, General Counsel						
Israel M. Stein, MD,	2007	368,217		73,173	29,872	471,265
former Chief Executive Officer and former Acting						
Chief Financial Officer(6)						
Mark D. Shooman,	2007	38,702			774	39,476
former Chief Financial Officer(7)						

- (1) Our fiscal year ends on March 31.
- (2) This column represents the dollar amount recognized for financial statement reporting purposes with respect to the 2007 fiscal year for the fair value of stock options granted to the named executive officers, in 2007 as well as prior years, in accordance with SFAS 123R. Portions of awards granted over several years are included. To see the value of awards made to named executive officers in fiscal 2007, see the Grants of Plan-Based Awards in 2007 Fiscal Year table. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeiture related to service-based vesting conditions. For additional information on the valuation assumptions used by the Company in calculating these amounts refer to Note 14 to Consolidated Financial Statements included in this report. The amounts reported in the Summary Compensation Table for these awards may not represent the named executive officers will actually realize from the awards. Whether and to what extent, a named executive officer realizes value will depend on stock price fluctuations and the named executive officer s continued employment. Additional information on all outstanding awards is reflected in the Outstanding Equity Awards at 2007 Fiscal Year-End table.
- (3) The amounts set forth in the All Other Compensation column for the named executive officers consist of Company contributions to the Clinical Data 401(k) Plan. Of the amount shown for Dr. Stein, \$5,125 constituted

a car allowance and approximately \$14,600 constituted term life insurance premiums and \$8,300 was related to reimbursement for legal expenses.

- (4) Mr. Fromkin became President and Chief Executive Officer on May 12, 2006.
- (5) Mr. Ballantyne joined the Company on August 7, 2006.
- (6) Dr. Stein voluntarily resigned as President and Chief Executive Officer and became Executive Vice Chairman on May 12, 2006. Following the resignation of Mr. Shooman, he served as Acting Chief Financial Officer from May 30 until August 7, 2006. Subsequently, Dr. Stein voluntarily resigned as an officer and director of the Company effective as of August 30, 2006. Under the terms of Dr. Stein s amended employment agreement with the Company, Dr. Stein was scheduled to receive salary continuation through October 28, 2007, of his then current base annual salary of \$350,000 per year, as well as

70

#### **Table of Contents**

continuation of the payment by the Company of the premiums for his health and dental plans, and in respect of certain life insurance policies maintained by the Company, together with the continuation his fringe benefits, including his car allowance for this period. On March 30, 2007, the Company terminated Dr. Stein s amended employment agreement payment of all benefits payable thereunder, as a result of Dr. Stein s alleged breach of his continuing covenants under the amended employment agreement. As of the date of this filing, no further action has been taken with respect to this matter by Dr. Stein or the Company.

(7) Mr. Shooman voluntarily resigned his employment with the Company effective as of May 30, 2006. Mr. Shooman was not entitled to any post-termination benefits.

#### Grants of Plan-Based Awards in 2007 Fiscal Year

All stock options have been granted at exercise prices equal to the closing price of the Company s Common Stock as quoted by the NASDAQ Global Market (the NASDAQ) on the date of grant or on the date immediately preceding the date of grant. The exercise price for stock options granted to new hires is equal to the closing price of the Company s Common Stock as quoted by the NASDAQ on the date of hire. In general, stock options become cumulatively exercisable in three equal annual installments on the first, second and third anniversaries of the date of grant. For those grants still outstanding under Clinical Data s 1991 Stock Option Plan, the expiration dates are between five and six years. For those grants issued under Clinical Data s 2002 Stock Option Plan and 2005 Equity Incentive Plan, the expiration date is ten years from the date of grant. All stock options granted to directors, executive officers and certain of our senior management personnel pursuant to the 2005 Equity Incentive Plan contain provisions accelerating vesting upon a change of control of Clinical Data.

All Other

			Option Awards: Number of			
			Securities	Exercise or Base Price of	Grant Date Fair Value of Stock	
Name	Grant Date	Ratification Date	Underlying Options (#)	Option Awards (\$/Sh)	and Options Awards (\$)(3)	
Andrew J. Fromkin	5/12/06 5/12/06 6/22/06	9/21/06(1) 9/21/06(2)	150,000 154,515 5,303	18.55 18.55 16.10	2,045,415 2,106,982 62,943	
C. Evan Ballantyne	8/7/06		50,000	12.98	392,080	
Caesar J. Belbel	5/12/06		60,000	18.55	818,166	
1 11/10/11/10	6/22/06		3,030	16.10	35,964	
Israel M. Stein, MD Mark D. Shooman						
Mark D. Shooman						

(1) Options issued and granted as of May 12, 2006 and ratified at the annual meeting of shareholders on September 21, 2006, vest in 36 equal monthly installments beginning on the first month following of the date of grant.

- (2) Options issued and granted as of June 22, 2006 and ratified at the annual meeting of shareholders on September 21, 2006, vest equally over a three-year period beginning on the one-year anniversary of the date of grant.
- (3) This column shows the full grant date fair value of the stock options awarded this year under SFAS 123R. Generally, the full grant date fair value is the amount that the Company would expense in its financial statements over the award s vesting schedule. For stock options, fair value is calculated using the Black Scholes value on the grant date. The fair value shown is accounted for in accordance with SFAS 123R. For additional information on the valuation assumptions see Note 14 of the Consolidated Financial Statements filed as part of this report.

71

#### **Table of Contents**

### **Executive Employment Agreements**

Effective May 12, 2006, Mr. Fromkin and Mr. Belbel are parties to employment agreements with the Company that provide the following:

Positions Mr. Fromkin serves as the Company s President and Chief Executive Officer. Mr. Fromkin is

also serving as a director of the Company.

Mr. Belbel serves as Executive Vice President, Chief Legal Officer and Secretary of the

Company.

Salary and Bonus Mr. Fromkin s agreement provides for an annual base salary of \$400,000 and a potential

annual cash bonus equal to up to 200% of Mr. Fromkin s then current annual base salary, based on whether Mr. Fromkin and the Company achieve certain goals, as determined by the board of

directors in their sole discretion.

Mr. Belbel s agreement provides for an annual base salary of \$260,000 and a potential annual

bonus equal to up to 100% of Mr. Belbel s then current annual base salary, based on whether Mr. Belbel and the Company achieve certain goals, as determined by the board of directors in

their sole discretion.

Term The initial terms of both employment agreements commenced on May 12, 2006 and end on

June 30, 2007, and automatically extend thereafter for successive one (1) year periods unless, at least ninety (90) days prior to the end of the initial terms or the then-current terms of the

Agreements, the Company or the executive has notified the other that the term shall terminate

upon its expiration date.

Termination Both agreements provide that employment may be terminated with or without cause at any time

by the Company, or by the executive with or without good reason (as defined in the

agreements). The payments due to the executives upon termination by the Company without cause or by the executives for good reason, include continuation of the executives salaries for one year; continuation for one year of the payment of the Company s portion of the premiums for health and dental insurance plans; payment of pro-rata bonuses; and payment of accrued

portions of the Company s contributions to any 401(k) or similar benefit plan.

Benefits Both executives are entitled to participate in all employee benefit plans of the Company and are

entitled to four weeks vacation per year, with the ability to roll over up to three weeks of unused vacation from any prior year. The Company has agreed to provide and maintain a life insurance policy for Mr. Fromkin, payable to his beneficiary or beneficiaries, with annual

premiums not to exceed \$2,000.

Covenants The agreements contain confidentiality covenants applicable during the period of the executives

employment and thereafter, as well as non-solicitation and non-competition covenants applicable to the executives both during and for a period of six (6) months following their

employment with the Company.

72

#### **Table of Contents**

#### **Outstanding Equity Awards at 2007 Fiscal Year-End**

	Option Awards						
N	Number of Securities Underlying Unexercised Options (in # s)	Number of Securities Underlying Unexercised Options (in # s)	Option Exercise	Option Expiration			
Name	Exercisable	Unexercisable	Price (\$)	Date			
Andrew J. Fromkin	1,333(1)		22.50	9/6/08			
	50,000(2)		17.89	10/17/15			
	84,586(3)	219,929(3)	18.55	5/12/16			
		5,303(4)	16.10	6/22/16			
C. Evan Ballantyne		50,000(5)	12.98	8/7/16			
Caesar J. Belbel	7,500(6)		4.82	5/7/13			
	8,000(7)		21.34	9/23/15			
	50,000(2)		17.89	10/17/15			
		60,000(8)	18.55	5/12/16			
		3,030(9)	16.10	6/22/16			
Israel Stein, MD							

Mark D. Shooman

- (1) Fully exercisable on the date of grant.
- (2) Granted on October 17, 2005, and amended to become fully exercisable on and after May 12, 2006.
- (3) Granted on May 12, 2006, and, as to 154,515 options, ratified on September 21, 2006, with all options vesting in 36 equal monthly installments beginning one month after the date of grant. These options become fully exercisable on a change of control of the Company, or as a result of the termination of Mr. Fromkin s employment by the Company without cause or by Mr. Fromkin for good reason.
- (4) Granted on June 22, 2006, and ratified on September 21, 2006, with one third of the options vesting cumulatively on each of the first three anniversaries of the date of grant. These options become fully exercisable on a change of control of the Company, or as a result of the termination of Mr. Fromkin s employment by the Company without cause or by Mr. Fromkin for good reason.
- (5) Granted on August 7, 2006, with one third of the options vesting cumulatively on each of the first three anniversaries of the date of grant. These options become fully exercisable on a change of control of the Company.
- (6) 15,000 stock options granted on May 7, 2003, with one third of the options vested cumulatively on each of the first three anniversaries of the date of grant. In fiscal 2006, Mr. Belbel exercised 7,500 options, leaving the balance shown above.

- (7) Granted on September 23, 2005, and amended to become fully exercisable on and after May 12, 2006.
- (8) Granted on May 12, 2006, with one third of the options vesting cumulatively on each of the first three anniversaries of the date of grant. These options become fully exercisable on a change of control of the Company, or as a result of the termination of Mr. Belbel s employment by the Company without cause or by Mr. Belbel for good reason.
- (9) Granted on June 22, 2006, with one third of the options vesting cumulatively on each of the first three anniversaries of the date of grant. These options become fully exercisable on a change of control of the Company, or as a result of the termination of Mr. Belbel s employment by the Company without cause or by Mr. Belbel for good reason.

73

### Option Exercises and Stock Vested in Fiscal Year 2007

	Option Awards								
	<b>Number of Shares</b>								
	Acquired		Value						
Name	on Exercise (#)	Realize	d on Exercise (\$)						
Andrew J. Fromkin									
C. Evan Ballantyne									
Caesar J. Belbel									
Israel Stein, MD	62,000	\$	683,760						
Mark D. Shooman	17,000	\$	237,150						

### TERMINATION OF EMPLOYMENT AND CHANGE OF CONTROL ARRANGEMENTS

Under the terms of their respective employment agreements with the Company, if the Company terminates Mr. Fromkin's or Mr. Belbel's employment without cause, or if the executive terminates his employment for good reason, the Company must pay him: (1) all unpaid salary up to the date of termination, any earned but unpaid bonuses, any unreimbursed expenses and any other payments and benefits to which the executive may be entitled under the Company's benefit plans; (2) a pro-rated bonus amount for the year of his termination;, (3) his then current base salary on a continuous basis for the twelve months following the date of termination; and (4) all premiums for health and other benefits during the twelve month period following the date of termination. Additionally, if the executive s employment is terminated without cause or by him for good reason, or if a change of control of the Company occurs during his employment, all of his outstanding unvested options become fully vested and the post-termination exercise period will be extended for a period equal to the shorter of (i) ten years, or (ii) the remaining term of the options.

To the extent that any payments due to Mr. Fromkin or Mr. Belbel on the termination of their employment with the Company (the Post-termination Payments ) are subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, and to the extent that the Post-termination Payments exceed four times the base amount (as such term is defined in Section 280G(d)(2) of the Code), then the Company will make an additional (gross-up) payment to the executive so that, the net amount retained by the executive shall be equal to the original amount of the Post-termination Payments after deduction of the excise tax, any federal, state and local income and employment tax and excise tax on the gross-up payment, but before deduction for any federal, state or local income and employment tax on the Post-termination Payments. However, to the extent that the Post-termination Payments do not exceed four times the base amount, then the Post-termination Payments will be reduced to the extent necessary to avoid imposition of the Excise Tax. Any amounts reduced shall be irrevocably forfeited by the executive and he shall have no further rights to receive them.

The agreements contain a confidentiality covenant applicable during the period of the executive s employment or at any time thereafter, as well as non-solicitation and non-competition covenants applicable to the executive both during and for a period of six months following his employment with the Company.

The amounts (in addition to those shown in the Summary Compensation Table) that would have been payable to Mr. Fromkin or Mr. Belbel under the agreements described above if a termination or change in control had occurred on March 31, 2007 are as follows:

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	Andre	w J. Fromkin	Caesar J. Belbel	
Twelve months salary Twelve months health and other benefits Acceleration of options Tax gross-up	\$	400,000 12,793 3,061,917 N/A	\$	260,000 5,261 854,130 N/A
74				

### **DIRECTOR COMPENSATION IN FISCAL YEAR 2007**

Our directors who are not our employees or consultants receive compensation for their services as directors as follows:

Title	Cash	n Compensation	Equity Compensation (See below)
Chairman	\$	60,000 per year	20,000 stock options 10,000 stock options
Director	\$	30,000 per year	

The portion of fees paid in cash is paid quarterly in arrears (approximately at the end of each fiscal quarter). The portion of fees paid in equity was granted on September 21, 2006, the date of the annual meeting of stockholders, with an exercise price of \$14.80, which was the closing price of our common stock on the date of grant. One-half of the equity portion is fully vested upon grant, with the remainder to vest on the date of the 2007 annual meeting of the Company s stockholders. In addition, we pay a \$1,000 per meeting cash compensation fee for members of the Audit Committee, to be paid quarterly in arrears with all other cash compensation.

Outside directors are given a choice of the method for receipt of their Board compensation. For the portion of fees paid in cash, instead of cash payments, directors may choose to receive all or any part of their cash compensation to be paid in a calendar year in the form of deferred stock units, so long as they make a deferral election prior to December 31 of the prior year. Deferred stock units allow directors to defer payment of their cash compensation (and taxes on such compensation) until the earlier date that is at least two years from the date of grant, their retirement from the Board, or their death or disability. At the time of payment, the director will receive shares of our common stock in an amount equal to the number of shares that would have been purchased on the date of grant of the deferred stock units. We grant deferred stock units to directors who have chosen this method of compensation on the date that we otherwise make cash payments for director fees (approximately the end of each fiscal quarter). No director elected to receive deferred stock units in the fiscal year ending March 31, 2007.

For the portion of fees paid in equity, directors may choose to receive all or any part of such compensation in the form of stock options, restricted stock or restricted stock units. Such equity portion of the directors compensation was granted on September 21, 2006, the date of the annual meeting of stockholders, with one-half of such awards being fully-vested on the date of grant the remainder vesting upon the date of the 2007 annual meeting of the Company s stockholders. If a director chose to receive such equity compensation in the form of stock options, such options are granted at an exercise price equal \$14.80 per share, the fair market value of our common stock quoted by the NASDAQ on the date of grant. If a director chose to receive such equity compensation in the form of restricted stock or restricted stock units, we used the Black-Scholes method of valuation to grant to the director that number of shares of restricted stock or restricted stock units that was equal to the value of 10,000 stock options (or 20,000 stock options in the case of the Chairman) on such date. Like deferred stock units, restricted stock units allow a director to defer the payment of shares of our common stock (and taxes on such compensation) until the earlier of a date that is a least two years from the date of grant, their retirement from the Board, or their death or disability. With restricted stock units, the award must vest prior to the director having any right to have the underlying shares issued, and, if a director were to terminate his or her Board service prior to full vesting, we would not be obligated to issue any shares under a restricted stock unit to the extent that the restricted stock unit had not vested at such time. The vesting of all equity compensation will accelerate upon a change in control of Clinical Data. In fiscal 2007, Messrs. Kirk and Malman chose to receive their equity compensation in the form of 10,800 shares of restricted stock for Mr. Kirk, and 5,400 shares of restricted stock for Mr. Malman. Messrs. Horner and Rakin and Dr. Sobel, each chose to receive his equity compensation in fiscal 2007 in the form of 10,000 stock options.

The following table shows the amounts paid to non-employee directors in fiscal 2007:

Name	Fees Earned or Paid in Cash (\$)	Restricted Stock Awards (\$)(1)	Option Awards (\$)(2)	Total (\$)
Randal J. Kirk, Chair	60,000	168,892		228,892
Larry D. Horner	34,000		139,181	142581
Arthur B. Malman	34,000	84,446		118,446
Burton E. Sobel MD	34,000		139,181	142,581
Kevin L. Rakin(4)	28,080		1,015,649	1,043,729
Joseph Klein III(3)			40,576	40,576

- (1) This column represents the dollar amount recognized for financial statement reporting purposes with respect to the 2007 fiscal year for the fair value of restricted stock units (RSU s) granted to directors in 2007 as well as prior years. In fiscal 2007, Messrs. Kirk and Malman received RSU s totaling 10,800 and 5,400, respectively.
- (2) This column represents the dollar amount recognized for financial statement reporting purposes with respect to the 2007 fiscal year for the fair value of stock options granted to directors, in 2007 as well as prior years, in accordance with SFAS 123R. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeiture related to service-based vesting conditions. For additional information on the valuation assumptions used by the Company in calculating these amounts refer to Note 14 to Consolidated Financial Statements included in this report. For fiscal 2007, Mr. Horner, Dr. Sobel and Mr. Rakin each elected to receive options to purchase 10,000 shares, for which the grant date fair value was \$14.80.
- (3) Mr. Klein was a director through September 21, 2006. Because Mr. Klein elected in fiscal 2006 to receive his cash and equity compensation for his service as a director during that fiscal year, in the form of deferred stock units for his cash compensation and restricted stock units for his equity compensation, Mr. Klein received 1,518 shares of unrestricted Common Stock on March 28, 2007 in respect of his deferred stock units.
- (4) In May 2006, the Company granted 70,000 options to Kevin Rakin, a member of the Company s Board of Directors, in connection with the settlement of an employment agreement. The options were exercisable immediately and had a fair value of approximately \$896,000, which was expensed on the date of grant. On September 21, 2007, Mr. Rakin received 4,360 options related to his duties as a Board member in fiscal 2006, which were immediately exercisable. On the same day, Mr. Rakin received an additional 10,000 options in connection with his duties as a member of the Board of Directors for fiscal 2007.

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

## **EQUITY COMPENSATION PLAN INFORMATION**

Clinical Data had authorized common stock for issuance under equity compensation plans as follows as of March 31, 2007.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options (a)		eighted-Average Exercise ce of Outstanding Options (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 Equity compensation plans	1,332,000	\$	18.51	832,000		
not approved by security holders	N/A		N/A	N/A		
Total	1,332,000	\$	18.51	832,000		
		76				

### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

As of June 8, 2007, we had a total of 10,011,872 shares of common stock, \$0.01 par value per share, issued and outstanding.

The following table and footnotes set forth certain information regarding the beneficial ownership of our common stock as of June 8, 2007 by (i) persons known by us to be beneficial owners of more than 5% of our common stock, (ii) our current executive officers, significant employee and our named executive officers, (iii) our current directors, and (iv) our current executive officers, significant employee and directors as a group.

	Stock and Nature of	Percent of Common
Name and Address of Beneficial Owner(1)	Ownership	Stock
5% Stockholder		
Third Security, LLC and affiliates	4,028,656(2)	40.00%
The Governor Tyler		
1881 Grove Avenue		
Radford, VA 24141		
Directors, Executive Officers and Significant Employee		
Randal J. Kirk	4,028,656(2)	40.00%
Arthur B. Malman	43,325(3)	*
Larry D. Horner	91,279(4)	*
Burton E. Sobel, M.D.	15,000(5)	*
Kevin L. Rakin	117,036(6)	1.15%
Andrew J. Fromkin	172,672(7)	1.69%
Caesar J. Belbel	86,510(8)	*
Carol Reed, M.D.	81,434(9)	*
C. Evan Ballantyne	1,000	*
Israel M. Stein, M.D.	421,836(10)	4.19%
Mark D. Shooman	3,000	*
All Directors, Current Executive Officers and Significant Employee as a		
Group (9 persons)	4,636,912(11)	43.80%

- \* Indicates ownership of less than 1%
- (1) The address of each of the directors, named executive officers and executive officers is: c/o Clinical Data, Inc., One Gateway Center, Suite 702, Newton, MA 02458, other than Dr. Stein, whose address is 17 Edge Hill Road, Chestnut Hill, Massachusetts 02467; and Mr. Shooman, whose address is 1460 Beacon Street, Waban, Massachusetts 02468.
- (2) Includes 1,066,991 shares owned by Mr. Kirk; 680,504 shares owned by Kirkfield, LLC; 731,083 shares owned by RJK, LLC; 41,719 shares owned by Zhong Mei, LLC; 699,918 shares owned by New River Management, II, LP; 193,343 shares owned by New River Management, III, LP; 153,353 shares owned by Radford Investment LP; and 461,745 shares owned by Third Security Staff 2001 LLC. Mr. Kirk is deemed to have beneficial ownership of all shares owned by Kirkfield, LLC, RJK, LLC, Zhong Mei, LLC, New River Management, II, LP, New River Management, III, LP, Radford Investment LP and Third Security Staff 2001,

LLC.

- (3) Includes 24,000 shares issuable upon the exercise of stock options exercisable within 60 days after June 8, 2007 and 2,500 shares issuable upon the exercise of warrants for shares of common stock.
- (4) Includes 14,218 shares held by Mr. Horner s wife as to which Mr. Horner disclaims beneficial ownership. Also includes 39,000 shares issuable upon the exercise of stock options exercisable within 60 days after June 8, 2007 and 9,609 shares issuable upon the exercise of warrants for shares of common stock by Mr. Horner and 7,109 shares issuable upon the exercise of warrants for shares of common stock by Mr. Horner s wife.
- (5) Consists of 15,000 shares issuable upon the exercise of stock options exercisable within 60 days after June 8, 2007.

77

### **Table of Contents**

- (6) Includes 6,175 shares held in trust and 325 shares held jointly with Mr. Rakin s wife. Also includes 79,360 shares issuable upon the exercise of stock options exercisable within 60 days after June 8, 2007 and 1,250 shares issuable upon the exercise of warrants for shares of common stock.
- (7) Includes 163,063 shares issuable upon the exercise of stock options exercisable within 60 days after June 8, 2007.
- (8) Consists of 86,510 shares issuable upon the exercise of stock options exercisable within 60 days after June 8, 2007.
- (9) Includes 79,809 shares issuable upon the exercise of stock options exercisable within 60 days after June 8, 2007.
- (10) Based on the latest data available to us. Dr. Stein is no longer serving as our Chief Executive Officer and has no reporting responsibility.
- (11) See footnotes (2) through (9), including Mr. Ballantyne s shares.

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND INDEPENDENT DIRECTORS

Randal J. Kirk, the Chairman of our Board of Directors, controls Third Security, LLC and its affiliates. Directly and through Third Security and its affiliates, Mr. Kirk controls approximately 40.0% of our outstanding stock. During the years ended March 31, 2007 and 2006, we were billed for sales commissions by Third Security in the amount of \$89,000 and \$85,000, respectively. In fiscal 2005 the Company was billed for sales commissions and consulting services by Third Security in the amount of \$169,000. The commissions payable to Third Security arise from an agreement we entered into with Third Security in 2005 for the sale of our IVD products in the People s Republic of China that are arranged for us through an affiliate of Third Security.

On June 9, 2006, we issued convertible promissory notes to two affiliates of Mr. Kirk. Under these promissory notes, the lenders provided us with \$2.0 million to fund working capital needs until such time as we could complete a private placement of our common stock and warrants. The promissory notes, which were payable thirty days from the date of issuance, accrued interest at a rate of 12% per annum and were convertible at the option of the holders into the same type of security sold by us to investors in the first financing following issuance, at a price per share equal to the last reported closing bid price of our common stock quoted by the NASDAQ Global Market on the date of issuance. On June 14, 2006, we repaid the notes plus accrued interest of approximately \$4,000 using a portion of the proceeds from the private placement of our common stock and warrants discussed below.

On June 13, 2006, we closed a private placement of common stock in which we sold 1,039,783 shares of common stock and warrants to purchase an additional 519,889 shares of common stock for net proceeds of approximately \$17.0 million, to certain institutional investors, including 403,873 shares and 201,936 warrants to affiliates of Third Security and certain members of our Board of Directors. The unit price was \$16.27, which equaled the closing bid price of our common stock quoted by the NASDAQ Global Market on the closing date, plus \$0.06 per share. The exercise price of the warrants is \$19.45, equaling a twenty percent premium on the closing bid price of our common stock on the closing date. The warrants are exercisable beginning December 14, 2006 through the close of business on June 13, 2011. In February 2007, Third Security and its affiliates, exercised warrants issued in connection with the private placement to purchase 190,505 shares of common stock at a price of \$19.45 per share, resulting in net proceeds to us of approximately \$3.7 million.

We received offers from two groups to purchase Vital Diagnostics, and during the second quarter of fiscal 2007, the Board of Directors accepted the most favorable offer which was to sell the Company s 92.5% interest for net proceeds of \$1.0 million. The transaction closed on November 13, 2006. The buyers included Adrian Tennyenhuis, Vital Diagnostic s general manager and holder of the 7.5% minority interest, and New River Management IV, LP, which is an affiliate of Third Security. The Company recorded a loss on disposal of approximately \$178,000 in connection with the sale of Vital Diagnostics during the year ended March 31, 2007.

During the second fiscal quarter we engaged Lazard Freres & Co., an investment bank, to seek a buyer for CDSS. Lazard identified and contacted a list of potential buyers, and the Board of Directors accepted the

78

### **Table of Contents**

most favorable offer which was to sell CDSS to Adrian Tennyenhuis and New River Management IV, LP for net proceeds of approximately \$7.0 million. The transaction closed on June 18, 2007. The Company recorded a loss on disposal of approximately \$7.0 million in connection with the sale.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Deloitte & Touche LLP, the member firms of Deloitte Touche Tohmatsu, and their respective affiliates (collectively, Deloitte & Touche) an independent registered public accounting firm, audited our financial statements for the year ended March 31, 2007. The Board of Directors has appointed Deloitte & Touche to serve as our independent registered public accounting firm for the fiscal year ending March 31, 2008. Representatives of Deloitte & Touche are expected to attend the annual meeting to respond to appropriate questions, and will have the opportunity to make a statement if they desire.

The aggregate fees for the audit and other services provided by Deloitte & Touche for the fiscal years 2007 and 2006 are as follows:

	2007	2006
Audit Fees(1)	\$ 656,689	\$ 688,907
Audit-Related Fees(2)	52,782	108,458
Tax Fees(3)	116,453	107,142
Total	\$ 825,924	\$ 904,508

- (1) Audit fees represent fees for professional services provided in connection with the audit of our financial statements and review of our quarterly financial statements and audit services provided in connection with other statutory or regulatory filings.
- (2) Audit-related fees represent payments for due diligence services provided in connection with certain business combinations.
- (3) Tax fees represent fees for services rendered to us for tax compliance services and related consultations.

Our Audit Committee has adopted procedures requiring the pre-approval of all non-audit (including tax) services performed by the independent registered public accounting firm in order to assure that these services do not impair the auditor s independence. These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is to be reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the Audit Committee for each engagement of the independent registered public accounting firm to perform other audit-related or other non-audit services. The Audit Committee does not delegate its responsibility to approve services performed by the independent registered public accounting firm to any member of management.

The standard applied by the Audit Committee in determining whether to grant approval of any type of non-audit service, or of any specific engagement to perform a non-audit service, is whether the services to be performed, the compensation to be paid therefore and other related factors are consistent with the independent registered public accounting firm s independence under guidelines of the Securities and Exchange Commission and applicable

professional standards. Relevant considerations include whether the work product is likely to be subject to, or implicated in, audit procedures during the audit of our financial statements, whether the independent registered public accounting firm would be functioning in the role of management or in an advocacy role, whether the independent registered public accounting firm s performance of the service would enhance our ability to manage or control risk or improve audit quality, whether such performance would increase efficiency because of the independent registered public accounting firm s familiarity with our business, personnel, culture, systems, risk profile and other factors, and whether the amount of fees involved, or the non-audit services portion of the total fees payable to the independent registered public accounting firm in the period would tend to reduce the independent registered public accounting firm s ability to exercise independent judgment in performing the audit.

All of the non-audit services rendered by Deloitte & Touche with respect to the 2007 fiscal year were pre-approved by the Audit Committee in accordance with this policy.

79

## **PART IV**

## ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) 1. Consolidated Financial Statements

The Consolidated Financial Statements are filed as part of this report.

2. Consolidated Financial Statement Schedules

All schedules are omitted because of the absence of conditions under which they are required or because the required information is included in the Consolidated Financial Statements or notes thereto.

3. Exhibits

80

## **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on June 19, 2007.

### CLINICAL DATA, INC.

/s/ Andrew J. Fromkin Andrew J. Fromkin President and Chief Executive Officer Principal Executive Officer

Dated: June 19, 2007

/s/ C. Evan Ballantyne C. Evan Ballantyne Senior Vice President and Chief Financial Officer Principal Financial and Accounting Officer

Dated: June 19, 2007

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

/s/ Randal J. Kirk Randal J. Kirk Chairman of the Board

Dated: June 19, 2007

/s/ Andrew J. Fromkin Andrew J. Fromkin President and Chief Executive Officer, Director

Dated: June 19, 2007

/s/ Larry D. Horner Larry D. Horner Director

Dated: June 19, 2007

81

## **Table of Contents**

/s/ Arthur B. Malman Arthur B. Malman Director

Dated: June 19, 2007

/s/ Burton E. Sobel Burton E. Sobel Director

Dated: June 19, 2007

/s/ Kevin Rakin Kevin Rakin Director

Dated: June 19, 2007

82

## **Table of Contents**

## CLINICAL DATA, INC. AND SUBSIDIARIES

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements	Page
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets at March 31, 2007 and 2006	F-3
Consolidated Statements of Operations for the Years Ended March 31, 2007, 2006 and 2005	F-4
Consolidated Statements of Stockholders Equity for the Years Ended March 31, 2007, 2006 and 2005	F-5
Consolidated Statements of Cash Flows for the Years Ended March 31, 2007, 2006 and 2005	F-6
Notes to Consolidated Financial Statements	F-8
F-1	

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Clinical Data, Inc. Newton, Massachusetts

We have audited the accompanying consolidated balance sheets of Clinical Data, Inc. and subsidiaries (the Company) as of March 31, 2007 and 2006, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended March 31, 2007. 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 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 the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123(R), *Share Based Payment*, effective April 1, 2006.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company s accumulated deficit, negative cash flows from operations and the expectation that the Company will continue to incur losses in the future raise substantial doubt about its ability to continue as a going concern. Management s plans concerning these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Deloitte & Touche LLP

Boston, Massachusetts June 18, 2007

F-2

## CLINICAL DATA, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

	In thousands, excesshare and per share amounts)  13,949 \$ 7,11,053 11,7,910 7,2,625 4,9,466 12  45,003 43  6,791 8,20,126 21,12,636 22,126 21,2,636 22,210 11  87,490 \$ 108  1,404 \$ 3,171 6,787 8,881 13,1921 22,10 11  27,985 38  5,506 5,506 5,506 279 2,032 968 1		2006 except share
ASSETS	2007 (In thousands, eshare and per shamounts)  5 13,949 \$ 11,053 7,910 2,625 9,466  45,003  6,791 20,126 12,636 724 2,210  5 87,490 \$ 1  6 1,404 \$ 171 6,787 8,081 1,921 1,503 8,118  27,985  5,506 279 2,032 968		
Current Assets:			
Cash and cash equivalents	\$ 	\$	7,225
Accounts receivable, net			11,566
Inventories			7,843
Prepaid expenses and other current assets			4,693
Assets of discontinued operations	9,466		12,467
Total current assets	45,003		43,794
Property, plant and equipment, net	6,791		8,250
Goodwill			21,197
Intangible assets, net			22,595
Other assets, net	724		1,268
Assets of discontinued operations	2,210		11,123
TOTAL ASSETS	\$ 87,490	\$	108,227
LIABILITIES AND STOCKHOLDERS EQUITY			
Current Liabilities:			
Current portion of long-term debt	\$	\$	3,155
Current portion of capital leases			226
Accounts payable			8,660
Accrued expenses			13,132
Customer advances and deferred revenue			2,147
Other current liabilities			1,971
Liabilities of discontinued operations	8,118		9,655
Total current liabilities	27,985		38,946
Long-Term Liabilities:			
Long-term debt, net of current portion	5,506		5,518
Capital lease obligations, net of current portion	279		71
Other long-term liabilities	2,032		2,186
Liabilities of discontinued operations	968		1,717
Total long-term liabilities	8,785		9,492

Commitments and contingencies (Note 10)

Stockholders Equity:

Preferred Stock, \$.01 par value, 1,500,000 shares authorized, 484,070 authorized Series A voting, convertible preferred stock, 184,000 and 234,000 shares issued and outstanding at March 31, 2007 and 2006, liquidation preference of \$4,343 at March 31, 2 2 2007 Common stock, \$.01 par value, 14,000,000 shares authorized; 10,022,000 and 8,520,000 shares issued at March 31, 2007 and 2006, respectively; 10,012,000 shares and 8,510,000 shares outstanding at March 31, 2007 and 2006, respectively 85 100 Additional paid-in capital 105,145 132,435 Accumulated deficit (83,436)(45,810)Treasury stock, 10,000 shares at cost (47)(47)Deferred compensation (318)Accumulated other comprehensive income 1,666 732 50,720 59,789 Total stockholders equity

TOTAL LIABILITIES AND STOCKHOLDERS EQUITY \$ 87,490 \$ 108,227

See notes to the consolidated financial statements.

F-3

**Table of Contents** 

## CLINICAL DATA, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS

		2007	2006	except per share		
REVENUES Services Products	\$	31,859 31,873	\$	12,348 25,415	\$	24,216
Total COST OF REVENUES Services		63,732 20,442		37,763 9,412		24,216
Products  Total		20,459 40,901		16,393 25,805		16,328 16,328
Gross profit OPERATING EXPENSES:		22,831		11,958		7,888
Research and development Sales and marketing General and administrative		13,663 7,924 28,540		5,196 3,255 12,693		1,729 1,681 2,540
Purchased in process research and development  Total operating expenses		50,127		39,700 60,844		5,950
Operating (loss) income Interest expense Interest income Other income (expense), net		(27,296) (627) 475 913		(48,886) (341) 183 (47)		1,938 (33) 60 22
(Loss) income from continuing operations before taxes Provision for income taxes		(26,535) (1,361)		(49,091) (1,287)		1,987 (884)
(Loss) income from continuing operations (Loss) income from discontinued operations, net of taxes		(27,896) (9,626)		(50,378) (503)		1,103 2,292
Net (loss) income Preferred stock dividend		(37,522) (104)		(50,881) (97)		3,395
Net (loss) income applicable to common stockholders	\$	(37,626)	\$	(50,978)	\$	3,395
(Loss) income per share from continuing operations Basic Diluted	\$ \$	(2.96) (2.96)	\$ \$	(8.46) (8.46)	\$ \$	0.25 0.24

164

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(Loss) income per share from discontinued operations			
Basic	\$ (1.02)	\$ (0.08)	\$ 0.52
Diluted	\$ (1.02)	\$ (0.08)	\$ 0.51
Net (loss) income per share			
Basic	\$ (3.98)	\$ (8.54)	\$ 0.77
Diluted	\$ (3.98)	\$ (8.54)	\$ 0.75
Weighted average shares basic	9,457	5,969	4,389
Weighted average shares diluted	9,457	5,969	4,507

See notes to the consolidated financial statements.

F-4

**Table of Contents** 

## CLINICAL DATA, INC. AND SUBSIDIARIES

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY FOR THE YEARS ENDED MARCH 31, 2007, 2006 AND 2005

]	Preferre <b>l</b>	lCommon		nmon ock		lditional		umulated eficit)	d				ımulate Other	ed			
	Stock	Stock Par	Stock	P	Par	F	Paid-In	Re	etained	Tre	easury	Deferr <b>6</b>	domp	rehens	ive	C	Comp
	Shares	Value	Shares	Va	alue	(	Capital		rnings n thousan			ompensat	tiorIr	icome		Total	(. Ir
CE at April 1,			4,405	\$	44	\$	16,995	\$	2,303	\$	(56)		\$	978	\$	20,264	
of stock			.,	+	• •	7	-,	₹′	,= 00	+			7	2.0	*	·	
ls paid on adjustment									(354)		9			495		9 (354) 495	\$
me									3,395					-		3,395	
nprehensive																	\$
CE at 1, 2005 preferred stock			4,405		44		16,995		5,344		(47)			1,473		23,809	
connection uisitions on of Series A stock into	484	5					9,512									9,517	
stock into stock sued in on with	(250)	(3)	250		3												
on with ons of stock			3,040		30		62,504					(572)	)			61,962	
lacement of et of			42				331									331	
on costs of \$83 of stock			614		6		11,930									11,936	
			153		2		3,587									3,589	
of restricted			16				286					(143)	)			143	
ls paid on stock									(176) (97)			. ,				(176) (97)	

166

ls accrued on I stock											
ation of											
compensation								397		397	
on adjustment									(741)	(741)	\$
3						(50,881)			, ,	(50,881)	·
						(00,001)				(00,001)	
mprehensive											\$
CE at											
1, 2006	234	2	8,520	85	105,145	(45,810)	(47)	(318)	732	59,789	
on of Series A	25 .	_	0,520	00	105,115	(15,010)	(.,)	(310)	,32	55,705	
stock into	(50)		50								
stock	(50)		50								
n of FAS 123R					(318)			318			
of stock											
			102	1	574					575	
lacement of											
et of											
on costs of \$63			1,040	10	16,846					16,856	
of stock			-,		,					,	
or stock			191	2	3,703					3,705	
ls accrued on			171	2	3,703					3,703	
l stock						(104)				(104)	
						(104)				(104)	
of common											
the purchase											
odone rights			103	1	1,622					1,623	
of treasury											
							(234)			(234)	
ent of treasury											
			(16)		(234)		234				
of warrants					120					120	
sued in											
on with the											
Express											
			15		347					347	
on 1			13		347					347	
sed			1.7		4.620					1.601	
ation			17	1	4,630					4,631	
on adjustment									934	934	
						(37,522)				(37,522)	
mprehensive											
											\$

See notes to the consolidated financial statements.

(47)

1,666

50,720

\$ 100 \$ 132,435 \$ (83,436)

CE at 1, 2007

184 \$ 2

10,022

**Table of Contents** 

## CLINICAL DATA, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

		2007	Ended March 2006 In thousands)	31, 2005
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net (loss) income	\$	(37,522)	\$ (50,881)	\$ 3,395
Less (loss) income from discontinued operations	Ψ	(9,626)	(503)	2,292
Not (loss) income from continuing energtions		(27,896)	(50,378)	1,103
Net (loss) income from continuing operations Adjustments to reconcile net (loss) income from continuing operations to		(27,090)	(30,378)	1,103
net cash (used in) provided by operating activities:				
Depreciation and amortization		10,266	4,984	376
•		10,200	·	370
Purchased research and development		2 502	39,700	
Impairment of intangible assets		2,583	<b>5</b> 40	
Stock-based compensation including Merck license		6,120	540	
Gain on sale of investment		(890)	26	(10)
(Gain) loss on sales of equipment		(41)	26	(10)
Deferred taxes		(218)	(18)	178
Changes in current assets and liabilities:		1.060	(400)	1.064
Accounts receivable		1,063	(498)	1,364
Inventories		510	(2,163)	281
Prepaid expenses and other current assets		2,152	943	229
Other assets		616	(218)	(32)
Accounts payable and accrued liabilities		(5,981)	4,456	162
Customer advances and deferred revenue		(460)	891	(45)
Other current liabilities		(1,774)	(2,944)	360
Cash (used in) provided by continuing operations		(13,950)	(4,676)	3,966
Cash provided by (used in) discontinued operations		1,076	(1,503)	422
Net cash (used in) provided by operating activities		(12,874)	(6,182)	4,388
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of equipment		(1,230)	(1,023)	(410)
Proceeds from sale of investment		1,000	(1,020)	(.10)
Proceeds from sales of equipment		393	78	26
Cash used in business combinations		(222)	(322)	20
Capitalization of software development costs		(222)	(175)	(247)
Capitalization of software development costs			(173)	(247)
Cash used in investing activities continuing operations		(59)	(1,442)	(631)
Cash provided by (used in) investing activities discontinued operations		812	(2)	(299)
Net cash used in investing activities		753	(1,444)	(930)

169

	2007	ded March 2006 housands)	, 2005
CASH FLOWS FROM FINANCING ACTIVITIES: Borrowings under other debt arrangements Payment on debt and capital leases Proceeds from the sale of common stock and warrants, net of transaction	121 (2,233)	121 (7,291)	(22)
costs Purchase of treasury shares Exercise of stock options	20,561 (234) 575	15,525 331	9
Stockholder dividends		(231)	(354)
Cash provided by financing activities continuing operations Cash (used in) provided by financing activities discontinued operations	18,790 (343)	8,455 3,142	(367) (1,019)
Net cash provided by financing activities	18,447	11,597	(1,386)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS NET INCREASE IN CASH AND CASH EQUIVALENTS CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	398 6,724 7,225	(917) 3,054 4,171	299 2,371 1,800
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 13,949	\$ 7,225	\$ 4,171
Supplemental disclosure of cash flow information: Cash paid during the year for: Interest	\$ 916	\$ 341	\$ 33
Income taxes	\$ 865	\$ 1,331	\$ 2,028
Non-cash transactions: Accrued acquisition costs	\$	\$ 60	\$
Equity issued in business acquisitions	\$ 219	\$ 71,479	\$
Debt issued in business acquisitions	\$	\$ 607	\$
Equipment acquired through capital leases and long-term debt	\$ 279	\$	\$
Equity issued to acquired technology rights	\$ 1,623	\$	\$
Warrants issued in connection with amendment of convertible note payable	\$ 120	\$	\$
Accrued preferred stock dividends	\$ 146	\$ 42	\$

See notes to consolidated financial statements.

Concluded F-7

## CLINICAL DATA, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED MARCH 31, 2007, 2006 AND 2005

### (1) Nature of Business and Basis of Presentation

### Nature of Business

Clinical Data, Inc. (the Company) is a Delaware corporation headquartered in Newton, Massachusetts. The Company manages its businesses in three segments (i) Molecular Services which includes PGxHealth LLC (PGxHealth), Cogenics, Inc. (Cogenics) and Cogenics Icoria, Inc. (Icoria), (ii) Clinics & Small Hospitals which includes Vital Scientific BV (Vital Scientific) and Electa Lab s.r.l. (Electa Lab) and (iii) All Other, which is primarily comprised of the corporate entity.

Under the PGxHealth<sup>TM</sup> brand name and division, the Company focuses on biomarkers and related test development, validation and commercialization activities designed to improve the efficacy and safety of drugs for patients. These genetic tests are marketed to providers, payers and consumers. PGxHealth is also seeking to develop and commercialize Vilazodone, a novel dual-serotonergic antidepressant compound being studied for treatment of depression along with a potential companion pharmacogenetic test.

Under the Cogenics<sup>TM</sup> brand name and division, the Company offers a wide range of molecular and pharmacogenomics services which are marketed and provided to pharmaceutical, biotechnology, academic, agricultural and government clients to assist them in endeavors relating to human, animal and plant genomes. The Cogenics unit offers various services including sequencing, genotyping, gene expression, bio-banking and others. Furthermore, these services are offered in both regulated and unregulated environments.

Within the Clinics & Small Hospitals segment, the Company operates Vital Scientific and Electa Lab. These companies participate in the *in vitro* diagnostic (IVD) testing markets and are leading manufacturers and distributors of clinical laboratory instrumentation and related assays. The instruments are marketed worldwide through distributions and original equipment manufacturers partnerships. Worldwide, the Company has an installed base of over 15,000 units and provides IVD products and services in Europe, Asia and the U.S.

As part of its decision to focus on Molecular Services, the Company entered into plans to discontinue the operations of its Clinical Data Sales & Service (CDSS) and Vital Diagnostics Pty. (Vital Diagnostics) subsidiaries and has presented these operating units in the financial statements as discontinued operations. These transactions are described in more detail in Note 3 - Discontinued Operations.

### **Basis of Presentation**

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

The Company s sources of cash as of March 31, 2007, include cash balances, cash flows from operations of the Clinics and Small Hospitals segment, net proceeds from the sale of our discontinued operations, capital leases and possible future equity and/or debt financings. The Company s projected uses of cash include cash to be used in the Molecular Services segment, capital expenditures, existing debt service costs and continued development of potential products through internal research, collaborations and, possibly through strategic acquisitions. Subsequent to March 31, 2007,

the Company received \$2.8 million from the settlement of a claim the Company had filed against a third-party for breach of contract—see Note 18 to the consolidated financial statements. At currently projected rates of expenditure, management believes that additional funding will be required to operate the Company beyond the second quarter of fiscal 2008, including the funding of Phase III clinical trials for the Company—s lead drug candidate, Vilazodone. The Company will seek such financing from public or private issuances of equity or debt securities, or from collaborations with third parties or government grants. There is no assurance that such financing will be available. If the Company is unable to

F-8

### CLINICAL DATA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

obtain any required additional financing, it may be required to reduce the scope of its planned research, development and commercialization activities, including those efforts related to Vilazodone, which could harm the Company s long-term financial condition and operating results.

## (2) Significant Accounting Policies

## **Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

### Use of Estimates

The preparation of the Company s consolidated financial statements in conformity with accounting principles generally accepted in the United States of America necessarily requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Accounting estimates are based on historical experience and other factors that are considered reasonable under the circumstances. Actual results could differ from those estimates.

## Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid instruments with remaining maturities of 90 days or less when purchased and consist of operating and savings accounts.

### Accounts Receivable

The Company carries its accounts receivable net of an allowance for doubtful accounts. Accounts receivable balances are evaluated on a regular basis and allowances are provided for potentially uncollectible accounts based on management s estimate of the collectibility of customer accounts. Allowance adjustments are charged to operations in the period in which the facts that give rise to the adjustments become known.

A summary of the activity in the allowance for uncollectible accounts for the years ended March 31 is as follows:

		2	2007 (I	2006 In thousan	2005 ds)
Allowance for uncollectible accounts Provisions Less: deductions	beginning of year	\$	884 130 (133)	\$ 381 752 (249)	\$ 165 216
Allowance for uncollectible accounts	end of year	\$	881	\$ 884	\$ 381

### **Inventories**

Inventories consist of analyzers, reagents and consumables, purchased materials in connection with the performance of molecular services, and certain deferred contracts costs. Deferred contract costs represent accumulated costs on commercial contracts accounted for under the completed contract method. These balances are not material.

Inventories are stated at the lower of cost (first-in, first-out) or market. Inventory quantities are periodically reviewed and, when necessary, provisions for excess and obsolete inventories are provided. On a regular basis, the Company reviews the carrying value of its inventory and records an inventory impairment charge at such time as it is believed that the carrying value exceeds the inventory s net realizable value. Such

F-9

### CLINICAL DATA, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

assessments are based upon historical sales, forecasted sales, market conditions and information derived from the Company s sales and marketing professionals.

In addition, certain of the Company s products are perishable and carry expiration dates. Customers require a minimum useful life before expiration of these products. In the event that the product will not be sold before this minimum useful life, the product is disposed and written off.

No significant inventory charges have been recorded in the years presented. Inventories consist of the following at March 31:

	2007 (In th	2006 ousands)
Raw materials Work-in-process Finished goods	\$ 4,680 1,486 1,744	\$ 5,131 1,457 1,255
	\$ 7,910	\$ 7,843

### **Depreciation and Amortization**

The Company provides for depreciation and amortization using the straight-line method by charges to operations in amounts that depreciate the cost of equipment over their estimated useful lives. The estimated useful lives, by asset classification, are as follows:

Asset Classification Useful Lives

Manufacturing and computer equipment	3-7 years
Laboratory equipment	2-7 years
Leasehold improvements	Lesser of useful life or lease term
Furniture and fixtures	2-7 years
Vehicles	3-5 years

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to their carrying amount. If an impairment is indicated, the assets are written down to fair value. Fair value is determined based on discounted cash flows or appraised values, depending on the nature of the assets. No impairments have been recorded in the years presented.

## **Goodwill and Intangibles**

The Company s intangible assets consist of (i) goodwill which is not being amortized, (ii) purchased amortizing intangibles which primarily include customer relationships and completed technology which are being amortized over their useful lives, and (iii) capitalized software development costs which are also being amortized over their useful lives.

The Company completes its annual impairment test of goodwill, as required by Statement of Financial Standards (SFAS) No. 142, *Goodwill and other Intangible Assets*, as of December 31, 2006 and concluded that as of December 31, 2006, there was no impairment of goodwill. In performing the annual goodwill assessment, the Company has identified its reporting units as its reporting segments. This same impairment test will be performed at other times during the course of the year should an event occur which suggests that the goodwill should be evaluated.

F-10

### CLINICAL DATA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Purchased intangibles are currently evaluated for impairment using the methodology set forth in SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Recoverability of these assets is assessed only when events have occurred that may give rise to an impairment. When a potential impairment has been identified, forecasted undiscounted net cash flows of the operations to which the asset relates are compared to the current carrying value of the long-lived assets present in that operation. If such cash flows are less than such carrying amounts, long-lived assets, including such intangibles are written down to their respective fair values. Please see Note 6 for more detail.

## Software Development Costs

The Company has capitalized certain software development costs incurred in connection with the software embedded in an analysis product in accordance with the provisions of SFAS No. 86, *Accounting for the Costs of Computer Software to be Sold, Leased or Otherwise Marketed.* SFAS No. 86 requires the Company to capitalize those costs incurred for the software development once technological feasibility has been established. Capitalization ends and amortization begins when the product is available for sale to the customer. During fiscal 2007, the Company did not capitalize any software development costs. In fiscal 2006 and 2005, the Company capitalized approximately \$175,000 and \$247,000, respectively, which are included as a component of intangible assets in the accompanying consolidated balance sheet.

Amortization has been recognized based on the greater of the ratio that current gross revenues for a product line bear to the total of current and anticipated future gross revenues for that product, or the straight-line basis over the estimated useful life of the product. The estimated useful life for the straight-line method is generally 4 years. Unamortized capitalized software development costs determined to be in excess of net realizable value of the product are expensed immediately. Of the total amortization of intangible assets, amortization related to capitalized software recorded during fiscal 2007, 2006 and 2005 was approximately \$388,000, \$160,000 and \$105,000, respectively, and is included in the costs of products revenue in the accompanying consolidated statements of operations.

Amortization with regard to the software development costs as of March 31, 2007 is expected to total \$344,000 in 2008, \$322,000 in 2009, and \$214,000 in 2010.

## **Warranties**

The Company provides for warranties based on historical claims experience; warranties are provided within the Clinics and Small Hospitals segment. The Company provides a one-year product warranty for the sale of certain products. A provision is made at the time the related revenue is recognized for the estimated costs of product warranties. Extended warranties are available to customers at an additional cost. Revenues from the sale of extended warranties are deferred and recognized over the term of the extended warranty period.

A summary of warranty reserve activity for the years ended March 31 is as follows:

		2007	(In thousands)	2005
Accrued warranty	beginning of year	\$ 290	\$ 227	\$ 240

Assumed during the purchase of Electa Lab		25	
Provisions	163	104	12
Less: warranty claims	(54)	(66)	(25)
Accrued warranty end of year	\$ 399	\$ 290	\$ 227

F-11

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### **Derivatives**

The Company records its foreign currency exchange contracts at fair value in its consolidated balance sheets. The Company enters into foreign exchange forward contracts to reduce the exposure to currency fluctuations on customer accounts receivable denominated in foreign currency. The objective of these contracts is to minimize the impact of foreign currency exchange rate fluctuations on operating results. Derivative financial instruments are not used for speculative or trading purposes. There were foreign exchange forward contracts with a notional amount of \$900,000 outstanding at March 31, 2007 and 2006. The fair value of derivative instruments and the related gains and losses on derivative instruments were not material as of and for the years ended March 31, 2007, 2006 and 2005.

## Revenue Recognition

The most significant portion of the Company s revenue from services relates to fee-for-service arrangements related to molecular services or diagnostic and genetic tests deliveries. Revenue for fee-for-service arrangements are recognized upon the later of service delivery or, if applicable, customer acceptance. The Company maintains relationships with certain healthcare providers as well as healthcare insurance companies; revenue from these arrangements is recognized net of contractual allowances.

Revenues from the molecular services segment are also derived from fees for licenses of intellectual property, commercial partnerships and government contracts and grants. Revenue from commercial contracts are generally related to service fees, milestone achievements and deliveries of molecular services data, diagnostic and genetic tests, and assays. Revenue for service fees and milestone achievements from commercial contracts are recognized as revenues based on the completed contract method. To the extent payments received exceed revenue recognized for each contract or grant, the excess portion of such payments is recorded as deferred revenues. To the extent revenues recognized exceed payments received for each contract, the excess revenues are recorded as accounts receivable. Revenue from government contracts and grants, which are typically cost plus arrangements, are recognized as revenues as related expenses are incurred over the term of each contract or grant.

Revenue from arrangement with multiple deliverables is divided into separate units of accounting when certain criteria are met. The consideration for the arrangement is then allocated to the separate units of accounting based on their relative fair values. Applicable revenue recognition criteria are then applied separately for each unit of accounting. The Company defers revenue of multiple element arrangements if the fair values of all deliverables are not known or if customer acceptance is contingent on delivery of specified items or performance conditions. Because the Company often lacks evidence of fair value for commercial partnership contracts, revenue is deferred until the contract is completed and all elements have been delivered.

The Company s revenues from the sale of diagnostic equipment and consumables are recognized at the time when persuasive evidence of an arrangement exists, delivery has occurred, the price to the buyer is fixed or determinable and collectibility is reasonably assured. Product revenues are generally recognized upon shipments.

Generally, the Company receives a customer purchase order as evidence of an arrangement and product shipment terms are free on board (F.O.B.) shipping point. Returns and customer credits are infrequent and are recorded as a reduction to revenue. Rights of return or refund are generally not included in sales arrangements. Payments received under the Company s commercial contracts and government contracts and grants are generally non-refundable regardless of the outcome of the future research and development activities to be performed by the Company.

## Research and Development Costs

The Company charges research and development costs to operations as incurred.

F-12

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### **Income Taxes**

Deferred tax assets and liabilities are recognized for the future tax consequences of differences between the carrying amounts and tax bases of assets and liabilities and operating loss carryforwards using enacted rates expected to be in effect when those differences reverse. Valuation allowances are provided against deferred tax assets that are not expected to be realized.

## Comprehensive (Loss) Income

Comprehensive (loss) income includes charges and credits to equity that are not the result of transactions with stockholders. Included in other comprehensive (loss) income for the Company are the cumulative translation adjustments related to the net assets of the foreign operations. These adjustments are accumulated within the consolidated statements of stockholders equity under the caption accumulated other comprehensive (loss) income.

#### Foreign Currency

Assets and liabilities of the Company s foreign subsidiaries denominated in foreign currency are translated to U.S. dollars at year-end exchange rates and income statement accounts are translated at weighted-average rates in effect during the year. For those subsidiaries whose functional currency is other than the United States dollar, the translation adjustment into U.S. dollars is credited or charged to accumulate other comprehensive income, included as a separate component of stockholders—equity in the accompanying consolidated balance sheets. Gains and losses from foreign currency transactions are included in other income (expense), net in the consolidated statements of operations. For fiscal 2007, 2006, and 2005 the net foreign exchange gains and (losses) were \$26,000, \$(35,000) and \$26,000 respectively.

## Net (Loss) Income per Share

Basic net (loss) income per share is determined by dividing net (loss) income applicable to common stockholders by the weighted average shares of common stock outstanding during the period. Diluted earnings per share are determined by dividing net (loss) income applicable to common stockholders by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as common stock options calculated using the treasury stock method and convertible preferred stock using the if-converted method.

The numbers of basic and diluted weighted average shares outstanding are as follows at March 31:

	2007	2006 (In thousands)	2005
Basic weighted average common shares outstanding Dilutive effect of common stock options	9,457	5,969	4,389 118
Dilutive weighted average common shares outstanding	9,457	5,969	4,507

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following dilutive securities were not included in the diluted earnings per share calculations as at March 31, 2007 and 2006 because the inclusion of these amounts would have been anti-dilutive because the Company has a net loss.

	2007 (In thousa			
Common stock options	1,340	612		
Common stock warrants	789	452		
Convertible note payable	89	95		
Restricted common stock	8	16		
Convertible Series A preferred stock	184	234		
Total	2,410	1,409		

#### **Equity-Based Compensation**

The Company adopted the provisions of SFAS No. 123(R), *Share-Based Payment* (SFAS 123R), using the modified prospective application method effective April 1, 2006. SFAS 123R establishes accounting for stock-based awards exchanged for employee services and other stock-based transactions. Stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as compensation cost over the requisite service period. The Company previously applied Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and its interpretations and provided the required pro forma disclosures of SFAS No. 123, *Accounting for Stock-Based Compensation*. The effect of adopting SFAS 123R was to increase the net loss for the year ended March 31, 2007 by \$3.2 million reflecting the compensation expense of employee stock options recorded at fair value; \$134,000 of this amount is recorded in net loss from discontinued operations.

#### Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company maintains substantially all of its cash in financial institutions, believed to be of high-credit quality. The Company grants credit to customers in the ordinary course of business and provides a reserve for potential credit losses. See discussion related to significant customers in Note 11 to the consolidated financial statements.

#### Fair Value of Financial Instruments

The estimated fair value of the Company s financial instruments, which include cash equivalents, accounts receivable, accounts payable, long-term debt and capital leases, approximates their carrying value due to the current maturities of these instruments or the competitive interest rates that are applicable to the instruments.

## **Recent Accounting Pronouncements**

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, *an interpretation of FAS 109* (FIN 48) which clarifies the accounting for uncertainty in income taxes recognized in accordance with FAS 109, *Accounting for Income Taxes*. FIN 48 is a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. If an income tax position exceeds a more likely than not (greater than 50%) probability of success upon tax audit, the company will recognize an income tax benefit in its financial statements. Additionally, companies are required to accrue interest and related penalties,

F-14

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

if applicable, on all tax exposures consistent with jurisdictional tax laws. This interpretation is effective from April 1, 2007. The Company is evaluating the impact, if any, that this interpretation will have on its financial statements

In September 2006, FASB Statement No. 157, *Fair Value Measurements* (SFAS 157), was issued. This statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, or GAAP, and expands disclosures about fair value measurements. This statement applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this statement does not require any new fair value measurements. However, for some entities, the application of this Statement will change current practice. The statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is evaluating the impact, if any, that this standard will have on its financial statements.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Iincluding an amendment of FASB Statement No. 115*, (SFAS 159) which expanded SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 159 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 159 is effective for fiscal years beginning after November 15, 2007. Earlier adoption is permitted, provided the company has not yet issued financial statements, including for interim periods, for that fiscal year. The Company is evaluating the impact of SFAS 159, but does not expect the adoption of SFAS 159 to have a material impact on our financial statements.

#### (3) Discontinued Operations

During fiscal 2007, the Company determined that Vital Diagnostics and CDSS did not fit with the Company s strategic direction and the capital resources derived from the sale of the these two businesses could be better allocated to investments and growth opportunities to increase its presence in the pharmacogenomics and molecular services markets. Accordingly, the Company has classified these two businesses as discontinued operations and their results of operations, financial position and cash flows are separately reported for all periods presented.

## **Vital Diagnostics**

The Company received offers from two groups to purchase Vital Diagnostics, a distributor focused on selling scientific instrumentation, equipment and reagents in Australia and New Zealand and component of the Company s Small Clinics and Hospitals reporting segment. During the second quarter of fiscal 2007, the Board of Directors accepted an offer to sell the Company s 92.5% interest for net proceeds of \$1.0 million. The transaction closed on November 13, 2006. The buyers included Adrian Tennyenhuis, Vital Diagnostic s general manager and holder of the 7.5% minority interest, and New River Management IV, LP, an affiliate of Third Security, which is funded and controlled by Third Security, LLC which is controlled by Randal J. Kirk (Mr. Kirk), the Company s Chairman of the Board. The Company recorded a loss on disposal of approximately \$178,000, net of taxes in connection with the sale in the second fiscal quarter of the year ended March 31, 2007.

#### **CDSS**

During the second fiscal quarter, the Company engaged advisors to seek a buyer for the sale of CDSS, a seller of products and services from scientific instrumentation, equipment and reagents to lab management and consulting services and previously comprised the Company s Physician s Office Laboratories (POL) segment.

F-15

## CLINICAL DATA, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A list of potential buyers was contacted, and the Company received several letters of interest to purchase CDSS. The Board of Directors accepted an offer which was to sell CDSS to Adrian Tennyenhuis and New River Management IV, LP for net proceeds of approximately \$7.0 million. The transaction closed on June 18, 2007. During the fourth quarter, CDSS was reclassified to discontinued operations and in connection therewith the Company recorded a loss of approximately \$7.0 million to adjust the net assets of CDSS to fair value.

Summarized statement of operations data for Vital Diagnostics and CDSS for the years ended March 31, 2007, 2006 and 2005 is set forth below.

	2007	(In	2006 thousands)	2005
Revenues	\$ 24,761	\$	30,985	\$ 32,184
(Loss) income From Operations Before Disposal: (Loss) income before taxes and minority interest Minority interest	\$ (2,348) (9)	\$	461 (19)	\$ 3,542 (16)
(Loss) income before taxes Income taxes	(2,357) (91)		442 (945)	3,526 (1,234)
(Loss) income from discontinued operations before disposal, net of taxes <i>Disposal</i> :  Loss on disposal before taxes	(2,448) (7,178)		(503)	2,292
Income tax benefit  Loss on disposal, net of taxes	(7,178)			
(Loss) income from discontinued operations, net of tax	\$ (9,626)	\$	(503)	\$ 2,292

F-16

#### CLINICAL DATA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Summarized balance sheet information for the discontinued operations at March 31, 2007 and 2006 is set forth below.

	2007 (In tho	2006 usands)
Cash and equivalents	\$ 122	\$
Accounts receivable, net	4,007	5,725
Inventory, net	5,188	6,246
Prepaid expenses and other current assets	149	496
Property, plant and equipment, net	1,906	2,656
Other assets	304	8,467
Assets of discontinued operations	\$ 11,676	\$ 23,590
Revolving credit facility	\$ 3,970	3,980
Current portion of capital leases and long-term debt	496	548
Accounts payable	1,716	2,178
Customer advances	1,000	269
Other accrued expenses	936	2,680
Capital leases and long-term debt, net of current portion	814	1,474
Other long-term liabilities	154	243
Liabilities of discontinued operations	\$ 9,086	\$ 11,372

#### (4) Business Combinations

#### Genaissance Pharmaceuticals, Inc.

On October 6, 2005, the Company acquired all of the outstanding shares of Genaissance in exchange for 484,070 shares of a newly designated voting, convertible Series A preferred stock (Series A Preferred Stock) and approximately 2.3 million shares of the Company s common stock. The Series A Preferred Stock was valued at its common stock equivalent, \$19.66 per share, and the common stock was valued at \$19.66 per share, the average of the trading price two days before and two days after June 20, 2005, the date of the announced acquisition.

The Company also issued warrants to purchase 386,000 shares of common stock with an aggregate fair value of approximately \$1.2 million. The warrants were immediately exercisable and have exercise prices ranging from approximately \$26.00 per share to approximately \$64.15 per share and expire on dates ranging from April 30, 2006 through April 21, 2010.

The Company has reserved 349,000 shares of common stock for issuance pursuant to the options assumed in connection with the acquisition. The options have a weighted average exercise price of \$49.10 per share and a remaining contractual term of 6.7 years. The aggregate fair value, measured using the Black-Scholes model, totaled

F-17

#### CLINICAL DATA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The cost of the transaction is comprised of:

(In	thousand	S)
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Value of the Company s common stock	\$	45,570
Value of the Company s Series A preferred stock		9,517
Fair value of stock options and warrants		2,846
Transaction costs		1,248
Less: cash acquired		(978)
	¢	58,203
	Þ	30,203

Genaissance develops products based on its proprietary pharmacogenomic technology and has a revenue-generating business in DNA and pharmacogenomic products and services. The product development strategy is focused on drug candidates with promising clinical profiles and finding genetic markers to identify a responsive patient population. The Company believes that Genaissance is a strong strategic fit, enabling the Company to enter the molecular diagnostics market in a meaningful way. Genaissance has two clinically relevant molecular diagnostic tests available commercially and additional developmental opportunities in the central nervous system and cardiovascular area. The Company believes that the acquisition will allow the Company to leverage its market knowledge and experience with Genaissance s platform to become a leading pharmacogenomics company with high margin, proprietary tests and services serving broad markets.

The purchase price has been allocated to the tangible and identifiable intangible assets of Genaissance acquired and the liabilities assumed based on the fair values on the acquisition date as follows:

#### **Purchase Price Allocation (In thousands)**

Accounts receivable	\$ 4,717
Inventories	517
Other current assets	1,269
Equipment	6,040
Intangible assets	53,150
Long-term assets	373
Accounts payable	(1,621)
Current portion of long-term debt and capital lease obligations	(5,104)
Accrued expenses and other current liabilities	(8,217)
Long-term debt and capital lease obligations	(3,338)
Long-term liabililties	(1,593)
Deferred compensation for unvested options, restricted common stock and warrants	521
Goodwill	11,489

Total purchase price \$ 58,203

F-18

#### CLINICAL DATA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The allocation of the fair value of Genaissance s identifiable intangible assets is as follows:

	Increase in Value (In thousands)		Weighted Average Useful Life
Completed technology	\$	9,000	4.6 years
In-process research and development		36,300	
Customer relationships		7,500	7.9 years
Other		350	3.9 years
	\$	53,150	

#### Electa Lab s.r.l.

On October 7, 2005, the Company acquired all the outstanding stock of Electa Lab s.r.l. based in Forli, Italy, in exchange for 1.5 million (approximately \$1.8 million) plus transaction costs totaling \$103,000. The purchase of Electa Lab was financed, in part, by the issuance of a note payable with principal totaling 500,000 (approximately \$607,000). The note bears interest at 5.5% and matures in September 2007. A bank guarantee has been provided to secure the note.

Electa Lab is a manufacturer of equipment and supplies used to perform blood sedimentation rate analysis. Electa Lab sells its products through a number of distributors throughout the world. The merger provides vertical integration of the blood sedimentation rate analysis products sold by the Company in addition to providing access to other distributors.

The purchase price has been allocated to the tangible and identifiable intangible assets of Electa Lab acquired and the liabilities assumed based on the fair values on the acquisition date as follows:

#### **Purchase Price Allocation (In thousands)**

Cash	\$ 214
Accounts receivable	217
Inventories	554
Other current assets	10
Equipment	310
Long-term assets	2
Accounts payable	(260)
Accrued expenses and other current liabilities	(275)
Goodwill	1,153

Total purchase price \$ 1,925

#### Icoria, Inc.

On December 20, 2005, the Company acquired all of the outstanding stock of Icoria in exchange for 614,000 shares of the Company s common stock with an aggregate fair value of approximately \$11.3 million. The common stock was valued at \$18.46 per share, the average of the trading price two days before December 20, 2005, the date of the acquisition and deemed measurement date.

The Company issued warrants to purchase 42,000 shares of the company s common stock with an aggregate fair value of approximately \$81,000 in exchange for the outstanding warrants of Icoria. The

F-19

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

warrants were immediately exercisable and have exercise prices ranging from approximately \$34.15 per share to \$756.36 per share and expire on dates ranging from July 20, 2006 though October 19, 2009.

The Company has reserved 43,000 shares of its common stock for issuance pursuant to the options assumed in connection with the acquisition. The options have a weighted average exercise price of \$97.04 per share and a remaining contractual term of 4.2 years. The aggregate fair value, measured using the Black-Scholes model, was approximately \$227,000.

The cost of the transaction is comprised of:

	(111 11	iousurus)
Value of the Company s common stock	\$	11,329
Fair value of stock options and warrants		308
Transaction costs		367
Less: cash acquired		(1,901)
	\$	10,103

(In thousands)

Icoria is a biotechnology company dedicated to finding new ways of detecting and treating human disease. Icoria uses its ability to analyze biological function at the level of gene expression, biochemical pathways and tissue structure to discover and validate biomarkers, drugs and drug targets. Icoria works with pharmaceutical, biotechnology, government and academic laboratories on a fee-for-service or collaborative basis, while it develops its own sets of products for internal development, or eventual out-licensing. The internal programs focus on metabolic disorders (diabetes, obesity, among others) and the liver as a site of disease progression and drug action. The Company believes that this acquisition will add additional immediate revenue, expand service offerings and will enhance the intellectual property estate including proprietary markers for future diagnostics.

The purchase price has been allocated to the tangible and identifiable intangible assets of Icoria acquired and the liabilities assumed based on the fair values on the date of acquisition as follows:

#### **Purchase Price Allocation (In thousands)**

Accounts receivable	\$ 2,603
Inventories	329
Other current assets	2,360
Equipment	1,715
Intangible assets	10,500
Long-term assets	667
Accounts payable	(780)
Current portion of long-term debt and capital lease obligations	(3,010)

Accrued expenses and other current liabilities	(5,705)
Long-term debt and capital lease obligations	(2,531)
Deferred compensation for unvested options, restricted common stock and warrants	52
Goodwill	3,903
Total purchase price	\$ 10,103

F-20

#### CLINICAL DATA, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The allocation of the fair value of Icoria s identifiable intangible assets is as follows:

	Increase in Value (In thousands)	
Completed technology	\$ 3,400	7.6 years
In-process research and development	3,400	
Customer relationships	3,300	5.3 years
Other	400	3.0 years
	\$ 10,500	

## Genome Express S.A.

On March 7, 2006, the Company acquired all of the outstanding stock of Genome Express in exchange for 108,000 shares of the Company s common stock with an aggregate fair value of approximately \$2.5 million and a contingent issuance of 15,000 shares of common stock with a value of 300,000 (approximately \$361,000); the total purchase price was approximately \$3.3 million. The common stock was valued at \$22.99 per share, the average of the trading price two days before and after March 2, 2006, the deemed measurement date. Transaction costs approximate \$490,000. Effective March 7, 2007, the Company issued 15,000 shares of common stock to the sellers of Genome Express in satisfaction of the acquisition contingency.

The cost of the transaction is comprised of:

	(In the	ousands)
Value of the Company s common stock	\$	2,485
Value of the Company s contingently issuable common stock		361
Transaction costs		490
Less: cash acquired		(9)
	\$	3,327

Genome Express is a biotechnology company dedicated to accelerating the discovery of new products for the advancement of human and animal health, and for the agri-food industry. Genome Express offers a team of experts, proprietary technologies, and an optimized process that together form a unique molecular biology and bioinformatics platform. Using its DNA sequencing core business expertise, Genome Express has developed services and high value added solutions that allow its customers to interpret the data generated quickly and efficiently. The Company believes

that this acquisition will add additional immediate revenue, expand service offerings and will enhance the intellectual property estate including proprietary markers for future diagnostics.

F-21

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The purchase price has been allocated to the assets of Genome Express acquired and the liabilities assumed based on the fair values on the date of acquisition as follows:

## **Purchase Price Allocation (In thousands)**

Accounts receivable	\$ 599
Inventories	146
Other current assets	887
Equipment	726
Long-term assets	18
Accounts payable	(438)
Current portion of long-term debt and capital lease obligations	(629)
Accrued expenses and other current liabilities	(1,618)
Long-term debt	(1,016)
Goodwill	4,652
Total purchase price	\$ 3,327

Goodwill arising from all of the acquisitions described above is not deductible for tax purposes.

#### Restructuring and Integration Reserves

Included in the purchase price allocation of the Genaissance, Icoria and Genome Express transactions are restructuring and integration reserves totaling approximately \$4.6 million. The Company expects the severance costs will be fully paid during fiscal 2008. A summary of the activity for the years ended March 31, 2007 and 2006 are as follows:

	Rest	ructuring and			В	alance					Ba	lance
	Inte	egration			Ma	arch 31,		Fisc	al 20	007	Mar	rch 31,
	Re	eserves	Pa	yments		2006	Ac	crual	Pa	yments	2	007
Severance Lease termination costs	\$	3,098 1,495	\$	(748) (405)	\$	2,350 1,090	\$	125	\$	(2,265) (1,090)	\$	210
	\$	4,593	\$	(1,153)	\$	3,440	\$	125	\$	(3,355)	\$	210

### **In-Process Research and Development**

For the year ended March 31, 2006, of the total purchase price of Genaissance and Icoria, approximately \$39.7 million has been allocated to acquired in-process research and development (IPRD) projects and was expensed in the third

quarter of fiscal 2006. Projects that qualify as IPRD represent those that have not yet reached technological feasibility and have no alternative use. Technological feasibility is defined as being equivalent to the U.S. Food and Drug Administration s approval.

These projects were valued based on discounted probable future cash flows on a project-by-project basis. The Company prepared revenue and expense projections as well as technology assumptions through 2025 for two projects and 2014 for the other projects. The revenue estimates for each project were based on estimates of the relevant market sizes and growth factors, expected trends in technology and the nature and expected timing of the introduction of the new products. The estimated expenses were based upon the remaining costs to complete each project.

The Company discounted the projected cash flows using risk adjusted interest rates and considered the probability of success, where appropriate. The rates utilized to discount the net cash flows to their present values were based on the Company s weighted-average cost of capital. The weighted-average cost of capital

F-22

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

was adjusted to reflect the difficulties and uncertainties in completing each project and thereby achieving technological feasibility, the percentage of completion of each project, anticipated market acceptance and penetration, market growth rates and risks related to the impact of potential changes in future target markets. Based on these factors, discount rates that range from 18% 30% were deemed appropriate for valuing the IPRD.

The projects for which the IPRD charge relates were as follows:

Clozapine: In December 2004, Genaissance reported the discovery of genetic markers that are believed to predict who is at risk of developing Clozapine-induced agranulocytosis, a life threatening decrease of white blood cells that requires frequent blood testing of patients. Genaissance is in the process of organizing another clinical trial to further support its findings. This IPRD project was estimated to be 60% complete as of the acquisition date. The estimated fair value of this IPRD project was \$17.9 million as of October 6, 2005.

*Vilazodone:* In September 2004, Genaissance acquired an exclusive license from Merck KGaA (Merck) to develop and commercialize Vilazodone, which is under development for the treatment of depression. Genaissance is attempting to identify the genetic marker that defines patients who are more likely to respond to Vilazodone and develop a genetic test. This project was estimated to be 25% complete as of the acquisition date. The estimated fair value of this IPRD project was \$18.4 million as of October 6, 2005.

Acute liver injury and liver-disease-related research projects: Icoria had several research projects underway to identify biomarkers. These projects were estimated to be 75% complete relative to Icoria s role. The estimated fair value of these IPRD projects was \$3.4 million as of December 20, 2005.

The estimates used in valuing IPRD were based upon assumptions believed to be reasonable but which are inherently uncertain and unpredictable. Assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. Accordingly, actual results may differ from the projected results. The development efforts subsequent to acquisition and the revenue projections related to the primary drug candidate, Vilazodone, have not varied materially from the original estimates. The failure of Vilazodone to reach commercial success could have a material impact on the Company s expected results.

In February 2006, the Company initiated a Phase III clinical trial of Vilazodone for the treatment of major depressive disorder at ten U.S. centers and enrollment of 410 subjects was completed in March 2007. This study includes pharmacogenetic analyses for biomarkers of response to Vilazodone. We are applying our expertise in genetic biomarkers to identify biomarkers of response with the intention of developing a companion genetic test for Vilazodone response. Results this clinical trial are expected in September 2007.

During the year ended March 31, 2007, the Company incurred research and development costs of approximately \$7.0 million related to the clinical trials and the development of Vilazodone. There were no material variances associated with the underlying projections established in connection with the Vilazodone project and reported results.

F-23

#### CLINICAL DATA, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## (5) Property, Plant and Equipment

Property, plant and equipment consist of the following at March 31:

	2007		2006	
		(In tho	usan	ds)
Manufacturing, computer equipment and software	\$	7,503	\$	5,940
Leasehold improvements		3,836		3,398
Laboratory equipment		3,413		3,506
Furniture and fixtures		797		1,157
Vehicles		8		7
		15,557		14,008
Less: accumulated depreciation and amortization		8,766		5,758
	\$	6,791	\$	8,250

Manufacturing and computer equipment includes capital leases with a principal value of \$526,000 and \$243,000 at March 31, 2007 and 2006, respectively. Amortization of assets under capital leases totaled \$84,000 and \$27,000 during fiscal 2007 and 2006, respectively. There was no amortization expense in fiscal 2005.

## (6) Goodwill and Intangible Assets

Goodwill balances, by segment, are as follows at March 31:

	Clinics & Small Hospitals	Molecular Services In thousands)	Total
Balance at March 31, 2005	\$	\$	\$
Additions:	1.170		1 150
Electa Lab	1,153		1,153
Genaissance		11,489	11,489
Icoria		3,903	3,903
Genome Express		4,652	4,652
Balance at March 31, 2006	1,153	20,044	21,197
Adjustments			

Adjustments:

Genaissance		(1,210)	(1,210)
Icoria		(238)	(238)
Genome Express		377	377
Balance at March 31, 2007	\$ 1,153	\$ 18,973	\$ 20,126

During the year ended March 31, 2007, the reduction in Genaissance s goodwill was related to a reduction in accrued expenses recorded for the favorable resolution of a pre-acquisition contingency, the increase in Genome Express goodwill was primarily related to the payment for the remaining Genome Express stock, and the reduction in Icoria s goodwill was related to an adjustment to the fair value of fixed assets.

F-24

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The company completed its annual impairment test of goodwill as required by SFAS No. 142, *Goodwill and Other Intangible Assets*, as of December 31, 2006, and concluded that as of December 31, 2006, there was no impairment of goodwill.

The intangible asset balances are as follows at March 31:

	2007 (In thou	<b>2006</b> (sands)
Purchased intangibles: Completed technology Customer relationships Other	\$ 9,210 10,800 570	\$ 12,400 10,800 769
Less: accumulated amortization	20,580 (8,854)	23,969 (2,921)
Purchased intangibles, net	11,726	21,048
Capitalized software Less: accumulated amortization	1,761 (851)	1,609 (443)
Capitalized software, net	910	1,166
ERP implementation and software		381
Intangible assets, net	\$ 12,636	\$ 22,595

During fiscal 2007, 2006 and 2005, amortization of intangible assets totaled \$6.9 million, \$2.9 million and \$154,000, respectively. During the year ending March 31, 2007, management assessed a \$2.6 million impairment of the value primarily attributed to completed technology associated with our acquisition of Icoria, Inc., which is part of the Molecular Services segment which was charged to general and administrative expense. The impairment reflects declining metabolic service revenues and the value of certain Icoria license options within the agricultural business which was significantly reduced in fiscal 2007. Fair value used in the impairment assessment was based on an analysis of discounted cash flows. See Note 4 for the estimate useful life of purchased intangibles.

Amortization with regard to the intangible assets at March 31, 2007 is expected to total, \$4.2 million in 2008, \$1.7 million in 2009, \$1.6 million in 2010, \$1.2 million in 2011, \$1.0 million in 2012 and \$2.9 million in 2013 and beyond.

#### (7) Other Assets

Other assets consist of the following at March 31:

	2007 (In th	2006 nousands)
Restricted cash	\$ 224	\$ 785
Deposits	301	231
Other	199	252
	\$ 724	\$ 1,268

The restricted cash balances represent security deposits on leased facilities. Approximately \$561,000 of the restricted cash balances at March 31, 2006 were retained by the landlord in connection with the termination of the lease of certain laboratory space during fiscal 2007.

F-25

## CLINICAL DATA, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## (8) Accrued Expenses

Accrued expenses consist of the following at March 31:

	2007 (In tho	2006 ousands)	
Payroll and payroll-related expenses	\$ 3,812	\$ 2,721	
Commissions, royalties and license fees	1,002	1,002	
Accrued professional fees	621	644	
Unvouchered invoices	419	439	
Accrued severance and other acquisition costs	348	4,180	
Accrued dividends assumed in acquisition		1,211	
Warranty reserve	239	290	
Accrued facilities costs	307	1,138	
Accrued VAT and sales taxes	189	236	
Other	1,144	1,271	
	\$ 8,081	\$ 13,132	

## **(9) Debt**

## Long-term Debt

**Table of Contents** 

The Company s long-term debt obligations are as follows at March 31:

	2007 (In tho	2006 usands)
Notes payable, bearing interest at 6.5%, with maturities between February 2009 and May 2011 and secured by certain of Cogenics leasehold improvements	\$ 3,033	\$ 3,520
Convertible note payable, bearing interest at 10.75% at March 31, 2007 with maturity on	,	,
October 19, 2010; secured by all of Icoria s assets  Advances from French government under a program to stimulate national innovation, with	2,570	3,227
maturities between September 2007 and September 2008 Euro note payable, bearing interest at 5.5%, with maturity on September 2007 and	1,123	1,134
quarterly payments of \$76 and secured by a bank guarantee	166	452
Other note payable	18	340
	6,910	8,673
Less: current portion	(1,404)	(3,155)

207

\$ 5,506 \$ 5,518

On August 31, 2006, the Company amended the terms of the convertible note payable assumed as part of the acquisition of Icoria in December 2005. The note is now due in semi-annual installments of \$334,070 with final maturity on October 19, 2010, and carries interest at prime plus 2.5% of which 6.0% is payable monthly in cash. The balance of the interest is payable quarterly in cash, common stock or a combination of cash and common stock at our option. If the market value of the common stock is equal to or greater than \$27.50 per share, the semi-annual payments may be paid in shares of common stock. The note is convertible into common stock at an initial price of \$25.00 per share at the option of the holder, and is mandatorily convertible if the market value of the common stock is equal to or greater than \$27.50 per share for six consecutive trading days. The note is secured by all of Icoria s assets.

F-26

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In connection with the terms of the amendment, the Company issued warrants to the holders of the note. The warrants consist of the right to purchase 25,622 shares of the Company s common stock at an exercise price of \$30.00 per share. Of the 25,622 warrants, 12,811 terminate in August 2008 and 12,811 will terminate in August 2011. The fair value of the warrants at the date of issuance totaled approximately \$120,000, which has been recorded as an increase to unamortized discount on the note and an increase to additional paid-in capital. The discount is amortized and recorded as additional interest expense.

The maturities of the long-term debt as of March 31, 2007 are as follows:

2008 2009 2010 2011 2012 After	\$ 1,404 1,611 1,522 2,156 217
Total	\$ 6,910

The Company maintains a line of credit agreement with a financial institution which provides for 1.8 million (approximately \$2.4 million) of available credit. The line of credit bears interest at 1.25% above the base rate as reported by the Netherlands Central Bank with a minimum base rate of 3.25%. At March 31, 2007 the base rate as reported by the Netherlands Central Bank was 4.75%; therefore the rate on borrowings would be 6.00%. Trade receivables and inventories are provided as collateral for this facility. The line of credit requires the Company to comply with certain financial covenants relating to solvency, which are not considered restrictive to the Company s operations. As of March 31, 2007, no amounts were outstanding under the agreement.

#### (10) Commitments and Contingencies

The Company is, from time to time, subject to disputes arising in the normal course of business. While the ultimate results of any disputes cannot be predicted with certainty, at March 31, 2007, there were no asserted claims against the Company, which in the opinion of management, if adversely decided would have a material adverse effect on the statements of financial position and cash flows.

F-27

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## **Contractual Commitments and Commercial Obligations**

The Company leases facilities, vehicles and computer equipment under capitalized and operating leases. Future minimum lease payments under these leases as of March 31, 2007 are approximately as follows (in thousands):

Year Ending March 31,		Operating Leases		Capitalized Leases	
2008	\$	2,169	\$	193	
2009		1,800		165	
2010		1,503		88	
2011		698		33	
2012		597		21	
Thereafter		1,626			
Total	\$	8,393		500	
Less: amount representing interest				(50)	
Total principal obligations				450	
Less: current portion				(171)	
Long-term capital lease			\$	279	

Rent expense was approximately \$2.9 million, \$1.5 million and \$.4 million during fiscal 2007, 2006 and 2005, respectively.

During fiscal 2007, the Company financed equipment purchased under capitalized leases with a principal value of \$279,000. No equipment purchases in fiscal 2006 or 2005 were financed with capitalized leases.

#### (11) Significant Customers

During fiscal 2007, 2006 and 2005, the Company had sales of scientific and blood analysis equipment and reagents to one significant customer amounting to approximately 15%, 24% and 37% of consolidated revenues, respectively. Approximately 8% and 5% of accounts receivable at March 31, 2007 and 2006, respectively, were receivable from this customer.

## (12) Equity

#### Preferred Stock

In connection with the Genaissance acquisition, the Company authorized and issued 484,070 shares of Series A Preferred Stock. The Series A Preferred Stock has a par value of \$0.01 per share. The Series A Preferred Stock is senior in right of payment of dividends and on liquidation to the common stock. At March 31, 2007 and 2006, 184,070 and 234,070 shares remained outstanding, respectively.

**Dividends** The holders of Series A Preferred Stock are entitled to receive, when, as and if declared by the Board of Directors, cash dividends at the rate of 2% of the accretive value of such share of Series A Preferred Stock, in preference to cash dividends on any other class of capital stock. Dividends on outstanding shares of the Series A Preferred Stock are payable on January 5th and July 5th of each year, when and if declared by the Board of Directors. Dividends on the Series A Preferred Stock are cumulative and will not be accrued or payable until each dividend payment date. Accrued but unpaid dividends with respect to each share of Series A Preferred Stock shall, upon conversion of such share into common stock, be forfeited. During the

F-28

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

years ended March 31, 2007 and 2006 the Company accrued dividends of \$104,000 and \$94,000, respectively, of which \$55,000 were paid in January 2006.

**Voting** The holders of the Series A Preferred Stock shall be entitled to vote on all matters submitted to the stockholders of the Company for a vote, voting as a single class with the common stock, with the holders of the Series A Preferred Stock entitled to one vote for each share of preferred stock they hold, without regard to the number of shares of common stock into which such shares would then be convertible.

Conversions At any time, a holder of the Series A Preferred Stock shall have the right to convert any shares of the Series A Preferred Stock into the number of shares of common stock computed by dividing (X) the original issue price of \$22.80 by (Y) the conversion price then in effect for such share of the Series A Preferred Stock, currently set at \$22.80 (such quotient being the ordinary conversion amount ); provided, however, that after the third anniversary of the date of filing of the certificate of merger relating to Genaissance, any share(s) of the Series A Preferred Stock shall be convertible into a number of shares of common stock computed by dividing (A) the original issue price of \$22.80 by (B) the average market price for the ten consecutive trading days before the delivery to the office of the Company or any transfer agent of the written notice of election to convert if such amount is greater than the ordinary conversion amount.

If the market price of the common stock exceeds the original issue price per share plus \$5.00 per share for ten consecutive trading days, the Company may elect, beginning on the first business day following such ten trading day period, and at any time thereafter while any shares of the Series A Preferred Stock remain outstanding, to require the holders of all outstanding shares of the Series A Preferred Stock to convert such shares into common stock.

**Redemption** If the Company is liquidated, dissolved, or wound-up, or transfers all or substantially all of its assets, or is a party to a merger or other change in control transaction in which its stockholders do not own a majority of its outstanding voting securities after such transaction prior to the fifth anniversary of the completion of the Genaissance merger, then, regardless of whether any dividend payments are in arrears, and unless the holders of 662/3% of the shares of the Series A Preferred Stock then outstanding elect otherwise to receive the as converted value, the Company shall redeem each then outstanding share of the Series A Preferred Stock at a per share purchase price equal to the sum of (i) the accreted value of such shares of the Series A Preferred Stock on the date of redemption, plus (ii) all dividends (whether or not declared) accrued since the end of the previous dividend period on such share of the Series A Preferred Stock, plus (iii) the sum of the remaining dividends that would have accrued and/or been payable on one share of the Series A Preferred Stock from the date of redemption through the fifth anniversary of the date of filing of the certificate of merger had such share of the Series A Preferred Stock not been so redeemed.

#### Common Stock

On June 13, 2006, the Company closed a private placement of common stock in which it sold 1,039,783 shares of common stock and warrants to purchase an additional 519,889 shares of common stock for net proceeds of approximately \$16.9 million, after transaction expenses of approximately \$63,000, to certain institutional investors, including certain members of our board of directors. The unit price was \$16.27 per share. The exercise price of the warrants is \$19.45. The warrants are exercisable between December 14, 2006 and June 13, 2011. In February 2007, Third Security, LLC and its affiliates, which are controlled by Randal J. Kirk, the Chairman of the Board of Directors, exercised warrants issued in connection with the private placement to purchase 190,505 shares of common stock at a price of \$19.45 for net proceeds to the Company of approximately \$3.7 million.

In the fourth quarter of fiscal 2007, the holder of Series A Preferred shares converted 50,000 shares into the Company s common stock.

F-29

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On August 16, 2006, the Company issued 24,947 shares of common stock to Merck to acquire a license to manufacture Vilazodone in connection with the on-going Phase III pivotal clinical trials. On December 20, 2006, the Company issued an additional 77,641 shares of common stock to Merck to complete acquisition of the manufacturing rights. The total value of the shares issued to Merck of approximately \$1.6 million (based on the quoted price of our common stock on the dates of issuance) was recorded as a research and development expense in fiscal 2007.

On September 22, 2006, in connection with the exercise of common stock options, the Company s former Chief Executive Officer sold 15,600 shares of common stock with a current value of \$234,000 to the Company. Simultaneously, the Board or Directors voted to retire the shares from treasury.

On November 17, 2005, the Company entered into a securities purchase agreement to sell to certain qualified institutional buyers and accredited investors, including certain members of the Company s board of directors, an aggregate of 614,405 shares of the Company s common stock and warrants to purchase an additional 307,203 shares of common stock, for an aggregate purchase price, net of associated costs, of approximately \$11.9 million. The sale of securities was consummated on November 17, 2005. The exercise price of the warrants is \$23.40 per share. The warrants are exercisable at any time after May 17, 2006 and expire on May 17, 2011.

On April 26, 2007, the Company increased the authorized common stock from 14,000,000 shares to 60,000,000 shares.

## (13) Income Taxes

The components for (loss) income before income taxes were as follows at March 31:

	2007	2006 (In thousands)	2005
United States Foreign	\$ (30,848) 4,313	\$ (52,958) 3,867	\$ (668) 2,655
	\$ (26,535)	\$ (49,091)	\$ 1,987

The provision for (benefit from) income taxes shown in the accompanying consolidated statements of operations consists of the following for fiscal 2007, 2006 and 2005:

	2007		2006 nousands)	2005
Current:				
Federal	\$	\$	(73)	\$ (143)
State	1	39	33	(4)

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Foreign	1,390	1,345	853
Total Current	1,579	1,305	706
Deferred:			
Federal	(492)	9	(56)
State	(28)	18	
Foreign	(116)	(48)	103
Change in valuation allowance	418	3	131
Total Deferred	(218)	(18)	178
	\$ 1,361	\$ 1,287	\$ 884

F-30

**Table of Contents** 

## CLINICAL DATA, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The provision for (benefit from) income taxes differs from the amount computed by applying the statutory Federal income tax rate to income before taxes due to the following for fiscal 2007, 2006 and 2005:

	2007	2006 (In thousands)	2005
(Benefits from) provision for taxes at statutory rate	\$ (9,022)	\$ (16,524)	\$ 869
Losses not benefited	9,849	3,898	
Prior losses utilized	(224)		
State taxes	116	33	(4)
Non-US rate differential, net	(136)	(128)	(13)
Change in valuation reserves	418	3	132
Write-off of purchased research and development		13,498	
Other	360	507	(100)
	\$ 1,361	\$ 1,287	\$ 884

The approximate income tax effect of each type of temporary difference comprising the net deferred tax (liability) asset at March 31, 2007 and 2006 is as follows:

	2007 (In thousa		ısano	<b>2006</b> sands)	
Deferred tax assets:					
Net operating losses	\$	135,115	\$	128,404	
Capitalized research costs		9,933		9,738	
Tax credits		4,322		2,413	
Fixed assets		2,113		1,916	
Severance and accrued payroll		1,725		740	
Other reserves and accrued liabilities		2,586		720	
Total assets		155,794		143,931	
Deferred tax liabilities:					
Purchased intangibles		(4,400)		(7,750)	
Capitalized software		(328)		(448)	
Other				(22)	
Total liabilities		(4,728)		(8,220)	
Net deferred tax asset		151,066		135,711	

216

Less: valuation allowance (151,318) (136,015)

\$ (252) \$ (304)

SFAS No. 109, *Accounting for Income Taxes*, requires the Company to assess whether it is more likely than not that the Company will realize its deferred tax assets. Upon the completion of the fiscal 2006 business combinations, the Company incurred taxable losses in the United States. The Company determined that it was more likely than not that the net operating losses and the deferred tax assets would not be realized in future periods and a valuation allowance was provided.

The Company has United States federal net operating loss carryforwards, after limitation for a change in ownership, of approximately \$85.2 million; these carryforwards will expire from 2011 through 2027. In addition, the Company has available United States federal tax credit carryforwards of approximately

F-31

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

\$4.3 million. These carryforwards which will expire between 2009 and 2021 may be used to offset future taxable income, if any, and are subject to review and possible review by the Internal Revenue Service. The Company has net operating loss carryforwards of approximately \$284.6 million for state purposes which expire from 2008 through 2027.

The Company has foreign net operating loss carryforwards of approximately \$17.9 million of which \$241,000 are not subject to expiration and \$17.7 million that expire between 2008 and 2017. A full valuation allowance has been provided on these losses for all periods presented as the amounts are not deemed recoverable.

#### (14) Stock Incentive Plans and Equity Based Compensation

The Company established a 1991 Stock Option Plan (the 1991 Plan ) and a 1991 Directors Stock Option Plan (the Directors Plan ) under which an aggregate of 150,000 shares and 75,000 shares of common stock were reserved, respectively, for the purpose of granting incentive and non-statutory stock options. In September 2002, the stockholders approved the establishment of the 2002 Incentive and Stock Option Plan (the 2002 Plan ) under which an aggregate of 250,000 shares of common stock were reserved.

In October 2005, the stockholders approved the establishment of the 2005 Equity Incentive Plan (the 2005 Plan ) under which an aggregate of 1.0 million shares of common stock were reserved. On September 21, 2006, the stockholders approved an amendment to the 2005 Plan which (a) increased the aggregate number of shares issuable from 1.0 million to 2.0 million and (b) increased the maximum number of shares that may be awarded to any participant in any tax year from 150,000 to 500,000 shares. All options are granted at not less than the fair market value of the stock on the date of grant.

Under the terms of the 1991 Plan and the Directors Plan, options are exercisable over various periods not exceeding four years; the options under the 1991 Plan expire no later than seven years after the date of grant whereas the options granted under the Directors Plan expire no later than ten years after the date of grant.

Under the terms of the 2002 Plan and 2005 Plan, options are exercisable at various periods and expire as set forth in the grant document. In the case where an incentive stock option is granted, the maximum expiration date is not later than 10 years from the date of grant unless made to a more than 10% stockholder; those incentive stock options expire no later than 5 years from the date of grant.

F-32

#### CLINICAL DATA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes stock option activity.

			eighted verage	Weighted Average Remaining	Ag	gregate
	Number of Shares (In th	]	xercise Price nds, excep	Contractual Term ot for per share a	•	trinsic Value nts)
Outstanding April 1, 2004 Exercised	199 (11)	\$	5.58 1.63			
Outstanding March 31, 2005 Granted Issued in connection with business combinations Forfeited Exercised	188 304 392 (230) (42)		5.82 18.54 62.82 55.14 7.93			
Outstanding March 31, 2006 Granted Forfeited Exercised	612 1,084 (254) (102)		30.17 16.77 23.65 5.24			
Outstanding March 31, 2007	1,340	\$	18.27	8.7 years	\$	5,476
Exercisable March 31, 2007	427	\$	21.33	7.5 years	\$	1,762
Exercisable March 31, 2006	242	\$	26.25			
Available for future grants March 31, 2007	904					

The intrinsic value of options exercised during fiscal 2007 was \$1.2 million.

Stock-based compensation expense including options and restricted stock totaled approximately \$4.6 million and \$540,000 during the years ended March 31, 2007 and 2006, respectively; \$134,000 of the expense in fiscal 2007 is expensed in net loss from discontinued operations. There was no restricted stock issued by the Company until 2006. In May 2006, the Company granted 70,000 options to Kevin Rakin, a member of the Company s Board of Directors, in connection with the settlement of an employment agreement. The options were exercisable immediately and had a fair value of approximately \$896,000, which was expensed on the date of grant. In August 2006, the Company modified the terms of 62,000 options granted to Dr. Israel Stein in 2005 to accelerate the vesting; additional expense of \$250,000 was recorded pursuant to the modification.

During fiscal 2007 and 2006, the Company granted 16,000 shares of restricted common stock in each year to certain members of the Board of Directors; one-half vested immediately and the remainder to vest one year after grant. The fair value of these shares totaled \$239,000 or \$14.80 per share in fiscal 2007 and \$286,000 or \$17.90 per share in fiscal 2006. Total compensation expense recognized with respect to these shares during fiscal 2007 and 2006 totaled \$277,000 and \$192,000, respectively. During fiscal 2006, in connection with the acquisitions of Genaissance and Icoria, the Company issued 42,000 shares of restricted stock with a fair value of \$236,000 and 392,000 options to purchase common stock with a fair value of \$336,000 to employees and consultants of the acquired businesses to replace previously issued awards. Total compensation expense recognized with respect to the assumed restricted stock and stock options during fiscal 2007 and 2006 totaled \$120,000 and \$348,000, respectively.

F-33

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table presents the stock-based compensation expense for the period ended March 31, 2007:

	2007 (In thousands, ex per share amoun				
Cost of revenues Sale and marketing Research and development General and administrative	\$	146 533 99 3,719			
Pre-tax stock based compensation expense Income tax benefits	\$	4,497			
Stock based compensation expense, net	\$	4,497			
Basic and diluted net loss per share	\$	0.48			

In addition, the Company expensed \$134,000 in net loss from discontinued operations.

Since the Company realized no tax benefits related to the stock-based compensation expense, the adoption of SFAS 123R had no impact on the reported net cash flows provided from operating or financing activities during fiscal 2007.

As of March 31, 2007, there was \$7.9 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements granted under our stock plans. That cost is expected to be recognized over a weighted average remaining period of 2.0 years.

The fair value of options on the date of grant was estimated using the Black-Scholes option pricing model. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Expected stock price volatility was calculated based on the historical volatility of the Company s common stock over the expected life of the option. The average expected life in 2007 was based on an average of the vesting period and the contractual term of the option in accordance with the simplified method described in SEC Staff Accounting Bulletin No. 107. The risk-free interest rate is based on zero-coupon U.S. Treasury securities with a maturity term approximating the expected life of the option at the date of grant. No dividend yield has been assumed as the Company does not currently pay dividends on its common stock. Exclusive of the options assumed in connection with the recent business combinations, forfeitures have historically been minimal and are estimated to be 0% per annum.

For 2007 and 2006 the Company used the following assumptions to estimate the fair value of share-based payment awards:

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	2007	2006
Risk-free interest rate	4.00-5.18%	3.88-4.75%
Expected dividend yield	0.00%	0.00%
Expected lives	5-6 years	3-5 years
Expected volatility	73-82%	32-43%
Weighted average grant date fair value	\$10.33	\$30.17

There were no stock options granted in 2005.

F-34

### CLINICAL DATA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table illustrates the effect on net (loss) income and the per share amounts if the Company had applied the fair value recognition provisions of SFAS 123R to stock-based employee awards for the years ended March 31, 2006 and 2005:

	,	2006 In thousand per share a	ds, e	-
Net (loss) income applicable to common stockholders, as reported Add: Stock-based employee compensation expense included in reported net loss Deduct: Total stock-based compensation expense determined under the fair value method	\$	(50,978) 540 (889)	\$	3,395 (108)
Pro forma net (loss) income applicable to common stockholders	\$	(51,327)	\$	3,287
As reported Basic loss per share Diluted loss per share Pro-forma	\$ \$	(8.54) (8.54)	\$ \$	0.77 0.75
Basic loss per share Diluted loss per share	\$ \$	(8.60) (8.60)	\$ \$	0.75 0.73

The range of exercise prices for options outstanding and options exercisable at March 31, 2007 is as follows:

Price Range	Number of Shares (Thousands)	Outstanding Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Exercisable Number of Shares (Thousands)	Weighted Average Exercise Price
\$ 4.82 - 6.31	38	2.43	\$ 4.98	38	\$ 4.98
\$ 7.85 - 9.20	16	6.61	9.08	16	9.08
\$11.00 - 13.23	66	7.92	12.58	15	11.27
\$13.85 - 15.46	293	9.34	14.77	20	14.81
\$16.00 - 18.55	852	9.17	17.93	287	18.24
\$18.92 - 22.50	35	8.34	21.70	23	21.88
\$23.84 - 28.99	6	7.38	25.70	4	25.76
\$30.46 - 35.43	9	7.68	33.80	4	33.77
\$39.30 - 41.23	13	6.64	39.41	10	39.41
\$46.15 - 190.77	12	5.61	74.93	10	81.68

1,340 8.72 \$ 18.27

427

\$

21.33

(15) Defined Contribution and Pension Plans

The Company sponsors defined contribution plans for its employees. Contributions and expenses incurred by the Company amounted to approximately \$682,000, \$342,000 and \$220,000 during fiscal 2007, 2006 and 2005, respectively. In the United States, the plan contributions represent the employer s matching contributions to the Company s 401k plan. Outside the United States, the plans are defined contribution plans.

F-35

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### (16) Segment Information

The Company s chief decision-maker, as defined under SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, is the Chief Executive Officer, who evaluates the Company s performance based on the revenues, cost of revenues and operating expenses and net income. The accounting policies of the segments are the same as those policies discussed in Note 2. The Company manages its business as three reporting segments: Molecular Services, Clinics and Small Hospitals and All Other. All Other includes corporate related items and expense not allocated to reportable segments. The Molecular Services segment was formed during the quarter ended December 31, 2005 as a result of the acquisitions of Genaissance and Icoria. The Molecular Services segment also includes the operations of Genome Express from the date of its acquisition during the quarter ended March 31, 2006.

The Clinics and Small Hospitals segment includes the operations of the Company s Dutch subsidiary Vital Scientific BV and from the date of its acquisition during the quarter ended December 31, 2005, the operations of Electa Lab.

Segment information for the years ended March 31, 2007, 2006 and 2005 is as follows:

	Aolecular Services	9	nics and Small ospitals (In thou	ll Other	Total
Revenues					
2007	\$ 31,557	\$ 3	32,175	\$	\$ 63,732
2006	12,332	2	25,407	24	37,763
2005		2	24,135	81	24,216
Cost of revenues and operating expenses					
2007	\$ 55,652	\$ 2	27,967	\$ 7,409	\$ 91,028
2006	62,322(a)	2	21,730	2,597	86,649
2005		2	21,275	1,003	22,278
Interest expense					
2007	\$ 539	\$	31	\$ 57	\$ 627
2006	256		32	53	341
2005			7	26	33
Interest income					
2007	\$ 85	\$	68	\$ 322	\$ 475
2006	29		91	63	183
2005			60		60
Income tax (benefit) provision					
2007	\$ 126	\$	(1,168)	\$ (319)	\$ (1,361)
2006	199		(1,435)	(51)	(1,287)
2005			(859)	(25)	(884)
(Loss) income from continuing operations					
2007	\$ (24,636)	\$	3,202	\$ (6,462)	\$ (27,896)

2006	(50,520)	2,596	(2,454)	(50,378)
2005		1,872	(769)	1,103

(a) Includes \$39,700 of purchased research and development costs written off after the acquisitions of Genaissance on October 6, 2005 and Icoria on December 21, 2005.

F-36

### CLINICAL DATA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	olecular ervices	Clinics and Small ospitals	l Other thousand	Or	continued perations	Total
Capital expenditures						
2007	\$ 914	\$ 276	\$ 40		n/a	\$ 1,230
2006	104	915	4		n/a	1,023
2005		404	6		n/a	410
Total assets						
2007	\$ 47,280	\$ 20,373	\$ 8,033	\$	12,232	\$ 87,918
2006	63,127	18,108	3,403		23,590	108,228

Geographic information for the years ended March 31, 2007, 2006 and 2005 is as follows:

		erth erica	E	urope	Asia thousan	Other	Con	solidated
Revenues								
2007	\$ 24	4,486	\$	23,635	\$ 7,645	\$ 7,966	\$	63,732
2006	10	0,767		16,365	6,345	4,286		37,763
2005		867		13,217	6,469	3,663		24,216
Property Plant & Equipment, net								
2007	\$ 4	4,396	\$	2,395	\$	\$	\$	6,791
2006	4	5,698		2,552				8,250
Goodwill & Intangibles, net								
2007	\$ 24	4,922	\$	7,840	\$	\$	\$	32,762
2006	35	5,656		8,136				43,792

#### (17) Related Party Transactions

The Company was billed for sales commissions by Third Security in the amount of \$89,000 and \$85,000 in fiscal 2007 and 2006, respectively.

On June 9, 2006, the Company issued convertible promissory notes to two affiliates of Mr. Kirk. The lenders provided us with \$2.0 million to fund working capital needs until such time as we could complete a new private offering, structured as a private placement to certain institutional and accredited investors exempt from registration under Section 4(2) of the Securities Act of 1933. The notes, which were payable thirty days from the date of issuance, accrued interest at a rate of 12% per annum and were convertible at the option of the holders into the same type of security sold by us to investors in the first financing following issuance, at a price per share equal to the last reported closing bid price of the our common stock as reported on the NASDAQ on the date of issuance. On June 14, 2006, the

Company repaid the notes plus accrued interest of approximately \$4,000 using a portion of the proceeds from the private placement of common stock discussed below.

On June 13, 2006, the Company closed a private placement of common stock in which the Company sold 1,039,783 shares of common stock and warrants to purchase an additional 519,889 shares of common stock for net proceeds of approximately \$17.0 million, after transaction expenses of approximately \$63,000, to

F-37

#### CLINICAL DATA, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

certain institutional investors, including certain members of the Board of Directors. The unit price was \$16.27, which equaled the closing bid price of our common stock on the NASDAQ on the closing date, plus \$0.06 per share. The exercise price of the warrants is \$19.45, equaling a twenty percent premium on the closing bid price of the Company s common stock on the NASDAQ on the closing date. The warrants are exercisable between December 14, 2006 and June 13, 2011. In February 2007, Third Security, LLC and its affiliates, which are controlled by Mr. Kirk, exercised warrants issued in connection with the private placement to purchase 190,505 shares of common stock at a price of \$19.45 for net proceeds to the Company of approximately \$3.7 million.

The Company received offers from two groups to purchase Vital Diagnostics, and during the second quarter of fiscal 2007, the Board of Directors accepted an offer to sell the Company s 92.5% interest for net proceeds of \$1.0 million. The transaction, structured as a share purchase, closed on November 13, 2006. The buyers included Adrian Tennyenhuis, Vital Diagnostic s general manager and holder of the 7.5% minority interest, and New River Management IV, LP, an affiliate of Third Security, which is funded and controlled by Third Security, LLC which is controlled by Mr. Kirk. The Company recorded a loss on disposal of approximately \$178,000, net of taxes in connection with the sale during the year ended March 31, 2007. Please see Note 3 of the consolidated financial statements for additional information

The Company engaged Lazard Freres & Co. LLC (Lazard) to seek a buyer for the sale of CDSS. Lazard identified a list of potential buyers, who were contacted, and the Company received several letters of interest to purchase CDSS. The Board of Directors accepted an offer to sell CDSS to Adrian Tennyenhuis and New River Management IV, LP for net proceeds of approximately \$7.0 million. The transaction, structured as a share purchase, closed on June 18, 2007. The Company recorded a loss on disposal of approximately \$7.0 million in connection with the sale during the year ended March 31, 2007. Please see Note 3 of the consolidated financial statements for additional information.

### (18) Subsequent Events

On June 6, 2007, the Company received \$2.8 million from the settlement of a breach of contract law suit filed against a third-party. The gain was recognized in the first quarter of fiscal 2008.

On June 18, 2007 the Company completed its sale of CDSS for net proceeds of \$7.0 million. Please see Notes 3 and 17 of the consolidated financial statements for additional information.

#### (19) Quarterly Summarized Financial Information (Unaudited)

	First	Second	Third	Fourth Quarter
	Quarter 2007	Quarter 2007	Quarter 2007 ot per share amount	2007(1,2)
	(	in thousands excep	ot per share amount	.5)
Total revenues	\$ 17,649	\$ 13,993	\$ 16,181	\$ 15,909
Gross profit	2,750	4,903	5,631	9,547
Operating loss	(5,260))	(7,552)	(5,943)	(8,541)
Loss from continuing operations	(5,707)	(7,789)	(5,363)	(9,037)

Loss from discontinued operations	(478)	(331)	(909)	(7,908)
Net loss	(6,185)	(8,120)	(6,272)	(16,945)
Net loss per share:				
Basic and diluted	\$ (0.71)	\$ (0.85)	\$ (0.65)	\$ (1.76)

(1) Loss from continuing operations includes a \$2.6 million impairment charge relating to intangible assets at Icoria.

F-38

### CLINICAL DATA, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(2) The loss from discontinued operations includes a disposal loss of \$7.0 million related to the reduction of the carrying value of CDSS to fair value.

	Q	First uarter 2006	Q	econd uarter 2006	arter Quarter			Fourth Quarter 2006(4)		
Total revenues	\$	4,821	\$	5,608	\$	12,200	\$	15,134		
Gross profit		1,743		2,023		5,298		2,894		
Operating income (loss)		326		552		(42,432)		(7,332)		
Income (loss) from continuing										
operations		188		306		(42,870)		(8,002)		
Income (loss) from discontinued										
operations		220		71		152		(946)		
Net income (loss)		408		377		(42,718)		(8,948)		
Net income (loss) per share:										
Basic	\$	0.09	\$	0.09	\$	(6.25)	\$	(1.10)		
Diluted	\$	0.09	\$	0.08	\$	(6.25)	\$	(1.10)		

- (3) For the three months ended December 31, 2005, includes \$40,100 of purchased research and development costs related to the acquisition of Genaissance on October 6, 2005 and Icoria on December 20, 2005.
- (4) For the three months ended March 31, 2006, includes \$400 adjustment to the value of the purchased research and development costs related to the acquisition of Genaissance on October 6, 2005.

F-39

#### **EXHIBIT INDEX**

# Exhibit Number Description

- 2.1 Amended and Restated Agreement and Plan of Merger, dated as of April 29, 2003, among Clinical Data, Landmark and Spectran. Filed as Exhibit 2.1 to the Company s Current Report on Form 8-K, as filed with the Commission on May 12, 2003, and incorporated herein by reference.
- 2.2 Agreement and Plan of Merger, dated as of April 29, 2003, among CDSS, GPSI and Clinical Data. Filed as Exhibit 2.2 to the Company s Current Report on Form 8-K, as filed with the Commission on May 12, 2003, and incorporated herein by reference.
- 2.3 Asset Purchase Agreement, dated as of December 9, 2002, among Elan Pharmaceuticals, Inc., Elan, CDSS and Clinical Data. Filed as Exhibit 2.1 to the Company s Current Report on Form 8-K, as filed with the Commission on December 9, 2002, and incorporated herein by reference.
- 2.4 Amendment No. 1 to Original Asset Purchase Agreement, dated as of February 10, 2003, among Elan Pharmaceuticals, Inc., Elan, CDSS and Clinical Data. Filed as Exhibit 2.4 to the Company s Current Report on Form 8-K, as filed with the Commission on May 12, 2003, and incorporated herein by reference.
- 2.5 Amendment No. 2 to Original Asset Purchase Agreement, dated as of March 18, 2003, among Elan Pharmaceuticals, Inc., Elan, CDSS and Clinical Data. Filed as Exhibit 2.5 to the Company s Current Report on Form 8-K, as filed with the Commission on May 12, 2003, and incorporated herein by reference.
- 2.6 Amendment No. 3 to Original Asset Purchase Agreement, dated as of March 31, 2003, among Elan Pharmaceuticals, Inc., Elan, CDSS and Clinical Data. Filed as Exhibit 2.6 to the Company s Current Report on Form 8-K, as filed with the Commission on May 12, 2003, and incorporated herein by reference.
- 2.7 Amendment No. 4 to Original Asset Purchase Agreement, dated as of April 29, 2003, among Elan Pharmaceuticals, Inc., Elan, CDSS and Clinical Data. Filed as Exhibit 2.7 to the Company s Current Report on Form 8-K, as filed with the Commission on May 12, 2003, and incorporated herein by reference.
- 2.8 Agreement and Plan of Merger, dated as of June 20, 2005, among Clinical Data, Safari Acquisition Corporation and Genaissance Pharmaceuticals, Inc. Filed as Exhibit 2.1 to the Company s Current Report on Form 8-K, as filed with the Commission on June 28, 2005, and incorporated herein by reference.
- 2.9 First Amendment to Agreement and Plan of Merger, dated as of July 28, 2005, among Clinical Data, Safari Acquisition Corporation and Genaissance Pharmaceuticals, Inc. Filed as Exhibit 2.1 to the Company s Current Report on Form 8-K, as filed with the Commission on August 2, 2005, and incorporated herein by reference.
- 2.10 Agreement and Plan of Merger, dated as of September 19, 2005, among Clinical Data, Inc., Irides Acquisition Corporation and Icoria, Inc. Filed as Exhibit 2.1 to the Company s Current Report on Form 8-K, as filed with the Commission on September 22, 2005, and incorporated herein by reference.
- 3.1 Certificate of Incorporation. Filed as Exhibit 3.1 to the Company s Registration Statement on Form S-1 (File No. 2-82494), as filed with the Commission on March 17, 1983, and incorporated herein by reference.
- 3.2 Certificate of Amendment of Certificate of Incorporation filed with the Secretary of State of the State of Delaware on October 1, 2003. Filed as Exhibit 3.1 to the Company s Quarterly Report on Form 10-Q, as filed with the Commission on February 17, 2004, and incorporated herein by reference.
- 3.3 Certificate of Elimination of the Series A Nonvoting Convertible Preferred Stock filed with the Secretary of State of the State of Delaware on July 7, 2005. Filed as Exhibit 3.1 to the Company s Current Report on

- Form 8-K, as filed with the Commission on July 11, 2005, and incorporated herein by reference.
- 3.4 Certificate of Designation of the Series A Preferred Stock filed with the Secretary of State of the State of Delaware on October 4, 2005. Filed as Exhibit 3.2 to the Company s Current Report on Form 8-K, filed with the Commission on October 11, 2005, and incorporated herein by reference.

Exhibit Number	Description
3.5	Certificate of Amendment of Certificate of Incorporation filed with the Secretary of State of the State of Delaware on October 6, 2005. Filed as Exhibit 3.1 to the Company s Current Report on Form 8-K, filed with the Commission on October 11, 2005, and incorporated herein by reference.
3.6	Amended and Restated By-laws of the Company, as of June 20, 2005. Filed as Exhibit 3.1 to the Company s Current Report on Form 8-K, filed with the Commission on June 24, 2005, and incorporated herein by reference.
4.1	Specimen Common Stock Certificate. Filed as Exhibit 4.1 to the Company s Registration Statement on Form S-1 (File No. 2-82494), as filed with the Commission on March 17, 1983, and incorporated herein by reference.
4.2	Specimen Series A Preferred Stock Certificate. Filed as Exhibit 4.2 to the Company s Annual Report on Form 10-K, filed with the Commission on June 29, 2006, and incorporated herein by reference.
10.1	1991 Directors Option Plan and Forms of Option Agreement. Filed as Exhibits to the Company s Registration Statement on Form S-8, filed with the Commission on March 5, 1992, and incorporated herein by reference.
10.2	2002 Incentive and Stock Plan. Filed as Exhibit A to the Company s Proxy Statement on Schedule 14A filed with the Commission on July 29, 2002, and incorporated herein by reference.
10.3	Form of Incentive Stock Option Certificate under the 2002 Equity Incentive and Stock Plan for all U.S. employees, including executive officers. Filed as Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2005, and incorporated herein by reference.
10.4	Form of Non-Statutory Stock Option Certificate under the 2002 Incentive and Stock Plan for all U.S. employees, including executive officers. Filed as Exhibit 10.6 to the Company s Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2005, and incorporated herein by reference.
10.5	Amended and Restated 2005 Equity Incentive Plan. Filed as Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2006, and incorporated herein by reference.
10.6	Form of Stock Option Grant Notice and Stock Option Agreement under the Company s 2005 Equity Incentive Plan for all U.S. employees, including executive officers, and directors. Filed as Exhibit 10.6 to the Company s Annual Report on Form 10-K, filed with the Commission on June 29, 2006, and incorporated herein by reference.
10.7*	Employment Agreement of Israel M. Stein dated October 29, 2001. Filed as Exhibit 10.3 to the Company s Quarterly Report on Form 10-QSB, filed with the Commission on February 14, 2002, and incorporated herein by reference.
10.8*	Amendment No. 1 dated December 16, 2004 to Employment Agreement of Israel M. Stein dated October 29, 2001. Filed as Exhibit 10.1 to the Company s Current Report on Form 8-K, filed with the Commission on December 22, 2004, and incorporated herein by reference.
10.9*	Amendment No. 2 dated July 10, 2006 to Employment Agreement of Israel M. Stein dated October 29, 2001. Filed as Exhibit 99.1 to the Company s Current Report on Form 8-K, filed with the Commission on July 14, 2006, and incorporated herein by reference.
10.10*	Amendment No. 3 dated August 31, 2006 to Employment Agreement of Israel M. Stein dated October 29, 2001. Filed as Exhibit 99.1 to the Company s Current Report on Form 8-K, filed with the Commission on September 7, 2006, and incorporated herein by reference.
10.11*	Executive Employment Agreement of Andrew J. Fromkin effective as of May 12, 2006. Filed as Exhibit 99.2 to the Company s Current Report on Form 8-K/A, filed with the Commission on November 13, 2006, and incorporated herein by reference.

- 10.12\* Executive Employment Agreement of Caesar J. Belbel effective as of May 12, 2006. Filed as Exhibit 99.3 to the Company s Current Report on Form 8-K/A, filed with the Commission on November 13, 2006, and incorporated herein by reference.
- 10.13\* Employment Offer Letter between the Company and C. Evan Ballantyne dated August 7, 2006. Filed as Exhibit 10.2 to the Company s Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2006, and incorporated herein by reference.

Exhibit Number	Description
10.14*	Form of Amended and Restated Indemnification Agreement between the Company and Israel M. Stein, M.D. and Arthur Malman, respectively. Filed as Exhibit 99.1 to the Company s Current Report on Form 8-K, filed with the Commission on July 11, 2005, and incorporated herein by reference.
10.15*	Form of Indemnification Agreement between the Company and certain executive officers and directors of the Company. Filed as Exhibit 99.2 to the Company s Current Report on Form 8-K, filed with the Commission on July 11, 2005, and incorporated herein by reference.
10.16	Loan and Security Agreement, dated March 31, 2003, among LaSalle, as lender, and CDSS, BioClinical Concepts, Inc. and GSPI Acquisition, Inc. as Borrowers. Filed as Exhibit 10.1 to the Company s Current Report on Form 8-K, filed with the Commission on May 12, 2003, and incorporated herein by reference.
10.17	\$10,000,000 Demand Revolving Note, dated March 31, 2003, issued by CDSS in favor of LaSalle. Filed as Exhibit 10.3 to the Company s Current Report on Form 8-K, filed with the Commission on May 12, 2003, and incorporated herein by reference.
10.18	Amendment No. 3 to Loan and Security Agreement, dated November 12, 2003, among LaSalle, CDSS, BioClinical Concepts, Inc. and GSPI Acquisition, Inc. Filed as Exhibit 10.5 to the Company s Quarterly Report on Form 10-QSB, filed with the Commission on November 14, 2003, and incorporated herein by reference.
10.19	Amendment No. 5 to Loan and Security Agreement, dated October 25, 2004, among LaSalle, as lender, and Clinical Data Sales & Service, Inc., as borrower. Filed as Exhibit 10.2 to the Company s Quarterly Report on Form 10-QSB, filed with the Commission on February 11, 2005, and incorporated herein by reference.
10.20	Amendment No. 6 to Loan and Security Agreement, dated January 28, 2005, among LaSalle, as lender, and Clinical Data Sales & Service, Inc., as borrower. Filed as Exhibit 10.10 to the Company s Annual Report on Form 10-KSB, filed with the Commission on June 27, 2005, and incorporated herein by reference.
10.21	Amendment No. 7 to Loan and Security Agreement, dated as of December 2, 2005, between Clinical Data Sales & Service, Inc. and La Salle Business Credit, LLC. Filed as Exhibit 10.11 to the Company s Quarterly Report on Form 10-Q, filed with the Commission on February 14, 2006, and incorporated herein by reference.
10.22	Investor Rights Agreement, dated as of June 20, 2005, between the Company and RAM Trading, Ltd. Filed as Exhibit 99.1 to the Company s Current Report on Form 8-K, filed with the Commission on June 24, 2005, and incorporated herein by reference.
10.238	Form of Securities Purchase Agreement among the Company and the Investors listed therein, dated as of November 17, 2005. Filed as Exhibit 99.1 to the Company s Current Report on Form 8-K, filed with the Commission on November 21, 2005, and incorporated herein by reference.
10.24	Form of Common Stock Purchase Warrant issued in connection with the Securities Purchase Agreement, dated as of November 17, 2005. Filed as Exhibit 99.2 to the Company s Current Report on Form 8-K, filed with the Commission on November 21, 2005, and incorporated herein by reference.
10.25	Form of Registration Rights Agreement among the Company and the Investors listed therein, dated as of November 17, 2005. Filed as Exhibit 99.3 to the Company s Current Report on Form 8-K, filed with the Commission on November 21, 2005, and incorporated herein by reference.
10.26	Omnibus Amendment dated August 31, 2006, by and among the Company, Icoria, Inc. and Laurus Master Fund, Ltd. Filed as Exhibit 99.2 to the Company s Current Report on Form 8-K, filed with the Commission on September 7, 2006, and incorporated herein by reference.
10.27	

Securities Purchase Agreement, by and between Icoria, Inc. and Laurus Master Fund, Ltd., dated as of October 19, 2004. Filed as Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q, filed with the Commission on February 14, 2006, and incorporated herein by reference.

Amended and Restated Securities Purchase Agreement dated August 31, 2006 to Securities Purchase Agreement, by and between Icoria, Inc. and Laurus Master Fund, Ltd., dated as of October 19, 2004. Filed as Exhibit 99.3 to the Company s Current Report on Form 8-K, filed with the Commission on September 7, 2006, and incorporated herein by reference.

Exhibit Number	Description
10.29	Master Security Agreement, by and between Icoria, Inc. and Laurus Master Fund, Ltd., dated as of October 19, 2004. Filed as Exhibit 10.6 to the Company s Quarterly Report on Form 10-Q, filed with the Commission on February 14, 2006, and incorporated herein by reference.
10.30	Amended and Restated Master Security Agreement dated August 31, 2006 to Master Security Agreement, by and between Icoria, Inc. and Laurus Master Fund, Ltd., dated as of October 19, 2004. Filed as Exhibit 99.5 to the Company s Current Report on Form 8-K, filed with the Commission on September 7, 2006, and incorporated herein by reference.
10.31	Registration Rights Agreement, by and between Icoria, Inc. and Laurus Master Fund, Ltd., dated as of October 19, 2004. Filed as Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on February 14, 2006, and incorporated herein by reference.
10.32	Registration Rights Agreement, by and between the Company and Laurus Master Fund, Ltd., dated as of August 31, 2006. Filed as Exhibit 99.7 to the Company s Current Report on Form 8-K, filed with the Commission on September 7, 2006, and incorporated herein by reference.
10.33	Form of Two Year Common Stock Purchase Warrant, dated as of August 31, 2006. Filed as Exhibit 99.8 to the Company s Current Report on Form 8-K, filed with the Commission on September 7, 2006, and incorporated herein by reference.
10.34	Form of Transferor Endorsement dated August 31, 2006. Filed as Exhibit 99.9 to the Company s Current Report on Form 8-K, filed with the Commission on September 7, 2006, and incorporated herein by reference.
10.35	Amended and Restated Secured Convertible Term Note dated August 31, 2006 to Secured Convertible Term Note, by and between Icoria, Inc. and Laurus Master Fund, Ltd., dated as of October 19, 2004. Filed as Exhibit 99.4 to the Company s Current Report on Form 8-K, filed with the Commission on September 7, 2006, and incorporated herein by reference.
10.36	Guaranty dated August 31, 2006. Filed as Exhibit 99.6 to the Company s Current Report on Form 8-K, filed with the Commission on September 7, 2006, and incorporated herein by reference.
10.37	Form of Securities Purchase Agreement among the Company and the Investors, dated as of June 13, 2006. Filed as Exhibit 99.1 to the Company s Current Report on Form 8-K, filed with the Commission on June 15, 2006, and incorporated herein by reference.
10.38	Form of Common Stock Purchase Warrant issued in connection with the Securities Purchase Agreement, dated as of June 13, 2006. Filed as Exhibit 99.2 to the Company s Current Report on Form 8-K, filed with the Commission on June 15, 2006, and incorporated herein by reference.
10.39	Form of Registration Rights Agreement among the Company and the Investors, dated as of June 13, 2006. Filed as Exhibit 99.3 to the Company s Current Report on Form 8-K, filed with the Commission on June 15, 2006, and incorporated herein by reference.
10.40	License, Development and Cooperation Agreement by and between Merck KGaA and Genaissance Pharmaceuticals, Inc., dated September 22, 2004. Filed as Exhibit 99.1 to Genaissance s Current Report on Form 8-K/A, filed with the Commission on October 13, 2004, and incorporated herein by reference.
10.41*	Letter Agreement between the Company s subsidiary, Genaissance Pharmaceuticals, Inc., and Kevin Rakin, a director of the Company. Filed as Exhibit 10.31 to the Company s Annual Report on Form 10-K, filed with the Commission on June 29, 2006, and incorporated herein by reference.
10.42	Selective Share Buy-Back Agreement among Vital Diagnostics Pty. Ltd., Clinical Data, B.V., and Clinical Data, Inc. (with respect to Sections 4.4, 6 and 7 only) dated November 13, 2006. Filed as Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2006, and incorporated herein by reference.
14.1	,,

Code of Business Conduct and Ethics. Filed as Exhibit 14.1 to the Company s Annual Report on Form 10-K, filed with the Commission on June 29, 2006, and incorporated herein by reference.

- 21.1 Subsidiaries of the Company. Filed herewith.
- 23.1 Consent of Deloitte & Touche LLP, an independent registered public accounting firm. Filed herewith.
- Certification of Chief Executive Officer Pursuant to §240.13a-14 or §240.15d-14 of the Securities Exchange Act of 1934, as amended. Filed herewith.

### **Table of Contents**

Exhibit Number	Description
31.2	Certification of Chief Financial Officer Pursuant to §240.13a-14 or §240.15d-14 of the Securities Exchange Act of 1934, as amended. Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350. Filed herewith.

<sup>\*</sup> Indicates a contract with management.

Confidential treatment requested as to certain portions, which portions have been filed separately with the Commission.