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, 2009

OR

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

For the transition period from to

Commission File 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, Newton, Massachusetts	**02458**
(Address of Principal Executive Offices)	*(Zip Code)*

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 ☐ NO ☑

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 ☐ NO ☑

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit ad post such files). YES ☐ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 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. ☑

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

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

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

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, 2008) was approximately $158,620,000.

The number of shares outstanding of the registrant's common stock as of June 12, 2009 was 23,702,364.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement for the 2009 Annual Meeting of Shareholders to be held on or about September 17, 2009, are incorporated by reference in Part III hereof.

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FOR THE FISCAL YEAR ENDED MARCH 31, 2009

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 — are 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 Annual Report on 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 United States Securities and Exchange Commission (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 Annual Report on Form 10-K.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, known as the Exchange Act, and in accordance with such laws, we file annual, quarterly and other reports, proxy statements and other information with the SEC. You may read and copy any document we file at the public reference facilities of the SEC at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. Our SEC filings are also available to the public at the SEC's web site at http://www.sec.gov and at our website at http://www.clda.com.

PART I

ITEM 1. *BUSINESS*

General

Clinical Data, Inc. is a Delaware corporation headquartered in Newton, Massachusetts. Our main operating business is PGxHealth.

We are a biotechnology company with a primary focus on the development of therapeutics. Our late-stage compounds include: (i) vilazodone — a potential first-in-class drug candidate for the treatment of depression, which recently completed its second Phase III trial successfully; and (ii) apadenoson which is trademarked under the name Stedivaze — a potential best-in-category vasodilator for use in myocardial perfusion imaging, which is entering its Phase III clinical trial program.

Vilazodone

Vilazodone, a novel dual-acting serotonergic antidepressant, is a potent and selective serotonin reuptake inhibitor, or SSRI, a first line therapy for major depressive disorder, and partial agonist of the 5-hydroxytryptamine 1a, or 5-HT_{1A}, receptor, a first-line therapy for anxiety disorders. Vilazodone has greater *in vitro* potency and selectivity for serotonin reuptake than compounds such as fluoxetine. *In vitro* binding studies also indicate that vilazodone has a greater potency for the 5-HT_{1A} receptor than specific 5-HT_{1A} ligands such as buspirone. There is evidence that a partial 5-HT_{1A} agonist taken in combination with an SSRI for the treatment for major depressive disorder, may reverse the adverse sexual side effects induced by the SSRI [*Journal of Clinical Psychopharmacology 19(3): 268-71, 1999*]. Thus, we expect vilazodone not to induce the adverse sexual side effects associated with SSRIs in the market today.

Our second Phase III vilazodone clinical trial has been completed. In the study, vilazodone achieved statistically significant results on the primary endpoint and secondary efficacy endpoints related to major depressive disorder. Top-line study results suggest that vilazodone was generally well-tolerated and the efficacy and safety data were consistent with the findings from the previous Phase III trial. In addition, study findings corroborate that there was no impairment of sexual function as measured by a validated scale. This is an important finding since many antidepressants have been associated with causing or exacerbating sexual dysfunction. A statistically significant improvement in the symptoms of anxiety associated with major depressive disorder was also observed. Separately, the Phase III study also sought to replicate a proprietary biomarker associated with response to vilazodone from the first Phase III trial. Although this preselected biomarker did not replicate, analyses remain ongoing.

Based on the results of these and additional activities, including the manufacture of registration batches of the active pharmaceutical ingredient and the commercial product, we intend to file a New Drug Application, or NDA, for vilazodone with the United States Food and Drug Administration, or FDA, by the end of calendar year 2009.

The U.S. market size for antidepressants in 2008, as defined by IMS Health's National Prescription Audit, or NPA, indicated more than 208 million prescriptions were written. This represents a growth rate of slightly more than 2% over 2007 prescriptions. SSRIs and selective norepinephrine reuptake inhibitors, or SSNIs, lead the category of products prescribed for depression and, according to NPA the U.S. market for antidepressants was roughly $11.6 billion in 2008 while the worldwide market was approximately $20.0 billion.

Stedivaze

Stedivaze is a selective adenosine receptor 2A, or A_{2A}, agonist in development as a vasodilator used for myocardial perfusion imaging. We plan to launch our Phase III clinical development program for Stedivaze in the next several months. Phase II data showed potential best-in-category attributes with an improved adverse event profile over the current standard of care and favorable pharmacokinetic and target binding affinity profiles. We conducted an End of Phase II meeting with the FDA in January 2009. Based on this meeting, we believe that we have reached agreement with the FDA on the overall design elements for our Phase III trial program. Our Phase III trial protocol has been submitted to the FDA and we are awaiting comment. Stedivaze could be marketed by us

directly to providers or partnered as a complementary and valuable compound to the pipelines of other well-established biotechnology and specialty healthcare companies.

Over 7.6 million myocardial perfusion imaging tests were performed in the United States in 2008 to determine the extent and location of cardiac ischemia, the effectiveness of percutaneous coronary intervention or coronary artery bypass grafting surgeries, or prognosis after myocardial infarction [AMR Monthly Monitor]. Approximately 3.5 million of these patients required the use of a pharmacological agent to generate maximum coronary blood flow in lieu of exercise [AMR Monthly Monitor] with an average branded price per procedure of $242.82 [Source: AMR Monthly SNM: Advanced Molecular Imaging and Therapy, September 15, 2008]. Based on these figures, we believe the value of the U.S. market for vasodilators used in myocardial perfusion imaging could be $800 million annually. As new compounds with better pharmacodynamic and pharmacokinetic profiles expand the use of stress imaging studies, we believe the market will continue to grow substantially and that Stedivaze has the potential to be the best-in-category agent.

Other Therapeutic Compounds

We also have a pipeline of pre-clinical drug development programs with an emphasis in adenosine receptor pharmacology and in oncology. As an underlying core competency, we employ biomarker strategies and other technologies to develop these therapeutic candidates with the potential for advantages in the identification of lead compounds, pre-clinical and clinical development programs, and eventually in the marketplace, thereby offering tangible benefits for patients, healthcare professionals and payers. Our pre-clinical pipeline includes: A_{2A} agonists targeted for inflammatory conditions, pain, oncology and other indications, an A_{2B} antagonist program for diabetes and asthma, and a lead compound that targets the beta-catenin pathway, important in colorectal cancer and other carcinomas.

We are further leveraging our biomarker discovery expertise and intellectual property to develop and commercialize genetic tests to detect or confirm serious diseases and to predict drug safety, tolerability and efficacy. We have built a substantial infrastructure including a sales and marketing team, payor expertise, and a Clinical Laboratory Improvement Acts of 1988, known as CLIA, certified laboratory to support our marketed products including the *FAMILION* family of genetic tests for inherited cardiac disorders.

Company History

We were formed in 1972 and, through a series of acquisitions and dispositions over the past several years, have emerged as a biotechnology company with a primary focus on therapeutics.

On October 6, 2005, we acquired Genaissance Pharmaceuticals, Inc., or Genaissance (including its in-licensed drug compound, vilazodone), 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. Since the acquisition of Genaissance, vilazodone has advanced through two positive Phase III clinical trials and we intend to file an NDA with the FDA by the end of calendar 2009. We have expanded our genetic test offerings, which are branded as the *FAMILION* family of tests, with the intention of marketing these tests to allow healthcare providers to better assist in the diagnosis of complex cardiac diseases and guide the use of specific therapies in individuals.

Through this acquisition, we also gained the expertise to in-license and further develop additional targeted therapeutics and biomarkers to build a pipeline of therapeutics and genetic tests. In December 2006, we changed the name of Genaissance to Cogenics Inc., or Cogenics.

In November 2006, we formed PGxHealth LLC, or PGxHealth, to centralize the development and commercialization of our late-stage compound, vilazodone, and of our proprietary biomarker development as the basis for the commercial sales of our genetic tests under the *FAMILION* family of tests. Our tests are developed to assist providers and payers in diagnosing complex cardiac diseases and determining the most appropriate therapeutic for a particular patient, in turn reducing healthcare costs and improving clinical outcomes.

On August 23, 2007, we acquired Epidauros Biotechnologie A.G., or Epidauros. Included in this acquisition was an intellectual property portfolio that includes biomarkers in genes relating to prominent drug transporters,

such as MDR1, MRP1 and OCT1, and important cytochrome P450 drug metabolizing genes including CYP2B6 and CYP2D6. These genes and specific markers of these genes play an important role in determining drug response in individuals for drugs in a wide variety of therapeutic classes. These biomarkers contribute to our position with respect to advancing our test development and potentially supporting development and advancement of our therapeutics. Following this acquisition, we subsumed this intellectual property portfolio into our PGxHealth business.

On August 4, 2008, we acquired the assets of Adenosine Therapeutics, LLC, or Adenosine Therapeutics, a developer of drug products based on its extensive portfolio of composition of matter and method of use patents relating to selective adenosine receptor modulators, including Stedivaze. This acquisition significantly broadened our pipeline of potential therapeutic products and adds what we believe to be, a very promising, late-stage drug compound, Stedivaze, which is an A_{2A} agonist positioned to be a possible best-in-category vasodilator used for myocardial prefusion imaging. Thus, intellectual property, infrastructure, personnel and other assets from Genaissance, therapeutic pipeline from Adenosine Therapeutics and Avalon Pharmaceuticals, Inc., or Avalon (all discussed below) form the basis for our current business plan.

On October 27, 2008, we entered into a definitive merger agreement to acquire Avalon, a Delaware corporation, headquartered in Germantown, Maryland. Avalon is a biopharmaceutical company focused on the discovery, development and commercialization of cancer therapeutics. This acquisition broadens our therapeutic pipeline and was completed on May 28, 2009.

We have monetized our non-core assets, characterized as those businesses that are not related to our primary business of developing and commercializing targeted therapeutics, as well as the proprietary genetic biomarkers that support our genetic and pharmacogenetic tests. As part of our decision to focus our efforts solely on the development and commercialization of targeted therapeutics and predictive tests, we sold Vital Diagnostics, Pty. Ltd. in November 2006, Clinical Data Sales and Service, Inc., in June 2007, Vital Scientific B.V. in October 2007, Electa Lab s.r.l., in November 2007, and the Cogenics division comprised of Cogenics, Epidauros and Cogenics Genome Express S.A. in April 2009.

With the sale of our Cogenics segment completed and the acquisition of the assets of Adenosine Therapeutics and Avalon, we have transformed ourselves into a biotechnology company focused on the development and commercialization of late-stage compounds that are first-in-class, best-in-category drug candidates, or both.

For a description of our revenue, loss from operations, and total assets, please see the Consolidated Financial Statements contained in Item 15.

OUR INDUSTRIES

Therapeutic Development

Drug development occurs in stages, typically grouped into pre-clinical and clinical, with the latter conducted in three not necessarily discrete phases. Typically, chemical libraries are screened to identify lead compounds that have been determined to bind to specific targets, interrupt certain therapies, or for other reasons are believed to be rational candidates for progression into animal testing. In order to advance a drug candidate into human clinical trials, the compound must be subjected to testing *in vitro* and *in vivo* to determine its pharmacodynamic, or PD, pharmacokinetic, or PK, and toxicology profiles. This leads to the filing of an Investigational New Drug application, or IND, with the FDA or a similar application with other national or regional regulatory agencies. Once the compound is approved for dosing in humans, the next steps are the clinical phases to establish the pharmacology, safety and efficacy of the compound for the intended indication. Finally, the company files an NDA with the FDA for marketing approval. If approved, the drug can then be marketed although additional studies and/or surveillance may be required. Overall, the process of moving a compound from identification through approval can take more than 10 years. The odds of failure are high, with only 1 of every 5,000 to 10,000 compounds gaining marketing approval.

While chemical libraries can be subjected to high-throughput screening to identify compounds for development, the implementation of certain tools early in the pre-clinical development stages can confer significant advantages in lead compound identification, improving the odds of success. One way is to develop a compound library targeted against known and validated targets, such as the adenosine receptors. Such a targeted library can

then be exploited to take advantage of the unique molecular entities to develop drugs that can be precisely targeted, and formulated with PK and PD properties specific to the intended indication. Another method is to identify a pathway known to be operative in a therapeutic target and to employ pharmacogenomic techniques to determine which molecules in the library interrupt or target that pathway.

Targeted Therapeutics

The healthcare industry continues its struggle to manage costs, as evidenced by the projected growth of United States health expenditures to $4.4 trillion in 2018, with prescription drug spending growth expected to be 4.0% in 2009 [National Healthcare Expenditure Data project 2008]. While the use of therapeutics continues to grow, treatment continues, for the most part, to be delivered through a trial-and-error approach and drugs are generally developed to treat broad populations without regard for the difference in response by certain individuals to specific therapeutic regimes. In fact, the cost of prescribing potentially harmful medications in hospitals has been estimated by the Institute of Medicine to be at least $3.5 billion a year, including 400,000 preventable drug-related injuries occur each year in hospitals, 800,000 in long-term care settings, and at least 500,000 in outpatient Medicare recipients [*Institute of Medicine of the National Academies, 2006*].

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 or more or less likely to experience certain side effects, subsequent development efforts could be more effectively targeted. Typically referred to as enrichment techniques, these tools have been increasingly 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 and other biomarkers may be applied to identify specific patient subpopulations that are more or less likely to respond to a drug. This could result in faster and less expensive clinical trials, reduce the risk of a total study failure, and accelerate the timeline to approval. In addition, the commercialized product would be positioned to be differentiated from other agents within its class or therapeutic area, possibly by superior efficacy in the subpopulation 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.

Barriers specific to the development and commercialization of therapeutics and of targeted therapeutics include:

- the ability to identify and develop through toxicology, PK and PD pre-clinical studies to first-in-human trials;
- the ability to integrate our technologies into the overall development program;
- the ability to establish efficacy and safety in a clinical development program;
- the ability to gain marketing approval from the FDA and other regulatory agencies;
- the ability to identify early in the drug development process biomarkers that will enable the clinical development program with the potential for clinical utility;
- the complexity of the disease or syndrome being addressed;
- the complexity of the determinants of drug response which may include host genetic, tumor genetics, environment, culture, age, and other interactions;
- reimbursement policies;
- the ability of patents to protect both the drug and the diagnostic; and
- the ability of the drug to compete in the marketplace against current and future products.

Genetic Biomarker Test Development and Commercialization

In 2007, the global molecular diagnostic market was valued at over $2.6 billion; the United States generated approximately 50% of this revenue. The fast-growing molecular diagnostic market is forecasted to continue double-digit growth with a compound annual growth rate of 14.0% through 2013. In 2007, the total molecular diagnostic market comprised about 7% of the total in-vitro diagnostics, or IVD, market, by 2013, however, the molecular diagnostic segment is expected to comprise over 10% of the global IVD market, underlining this segment's fast-growing nature (all figures taken from DataMonitor, reference code DMHC 2430, November 2008). A similar growth rate is expected in the European markets. The majority of available assays are in oncology, genetic diseases, metabolism, and infectious diseases and many of these assays are performed as laboratory-developed tests. There are more than 900 labs worldwide performing laboratory-developed assays. Approximately 90% of these labs are located in North America, Western Europe and Japan [*SG Cowen — 2001*]. A significant contributor to this growth is projected to be in pharmacogenetic tests in which genomic variation is measured to assess a patient's probability of response, be it positive or negative, to a given treatment intervention. Historically, some genetic biomarkers have been identified but fail to validate in subsequent analyses. The ability to identify, validate and demonstrate clinical utility of these and other biomarkers is a key ability and asset of ours. We have both the content and laboratory operations necessary to develop genetic and pharmacogenetic tests which may then be commercialized to diagnose a complex disease, or as a pharmacogenetic test of response either in direct association with the drug product as a companion diagnostic, or independently of the drug as a pharmacogenetic test.

Many health plans and employers are beginning to view genetic and biomarker testing as an important next step in managing healthcare costs. Despite this, there is an ongoing requirement to develop the data that support these tests and an educational process for providers, patients, and payers required for the adoption of these tests into clinical practice and payment plans. We are working directly with thought leaders, leading academic institutions, physicians, hospitals, payers, professional associations, healthcare coalitions, information technology companies and other healthcare constituents to set the stage for market introduction and adoption of these tests. In September of 2007, we launched our first field sales force to educate providers on the value of our *FAMILION* family of tests with the goal of driving adoption and acceptance of our genetic tests.

Certain barriers exist to the development and penetration of genetic biomarker testing. They include:

- the ability to patent protect genetic biomarkers and its clinical utility;
- operating within an antiquated reimbursement system that does not reflect either the investment to develop or the clinical or economic value of the test;
- demonstrating data to support test adoption and reimbursement;
- educating providers on the value of incorporating genetic testing into their practice;
- the potential for unduly burdensome regulation of these tests;
- establishing validated genetic tests with adequate predictive characteristics;
- the complexity of the genetic underpinnings of disease, and the related complexity of identifying and validating genetic biomarkers;
- other parties who have opposing interests in the commercialization of these tests as they threaten their business models or markets; and
- ethical, legal, regulatory, and social considerations.

Competitors to our genetic testing business include companies fitting a variety of models and who may be business partners with us. While our model is cutting-edge, our genetic testing business competes directly or indirectly with: (i) molecular testing kit companies such as Siemens, Abbott, Third Wave Technologies (now owned by Hologic Inc.), DxS and Roche Diagnostics; (ii) other genetic or pharmacogenetic testing laboratories such as Myriad Genetics, GeneDx (now owned by Bio-Reference Laboratories), Genomic Health and Monogram Biosciences; (iii) full service and reference laboratories such as LabCorp, Quest Diagnostics and Bio-Reference Laboratories; (iv) university/hospital laboratories such as Harvard Partners, the University of Chicago, University

of Utah, ARUP Laboratories and Mayo Medical Laboratories; and (v) genetic marker and biomarker discovery and diagnostic companies such as Celera Diagnostics and Perlegen Sciences. Genomic technology platform providers, such as Illumina, Affymetrix and Luminex, have or seek to establish CLIA testing laboratories. In addition, consortia and academic genomic centers such as National Jewish Hospital and the Duke Genomic Center are increasingly participating in genetic biomarker discovery and validations studies. These groups will also contribute to outcomes studies and analyses.

OUR COMPANY

Our Strategy

We are a biotechnology company focused on the development of first-in-class and/or best-in-category therapeutics. In support of our strategy, we are: (i) advancing the development of vilazodone through the NDA process and ultimately FDA approval (ii) continuing to advance Stedivaze into and through Phase III clinical programs; (iii) advancing our pre-clinical pipeline of therapeutics and potentially of related biomarkers into the clinic or to other stages that are consistent with the program objectives; (iv) developing, acquiring and/or in-licensing and advancing therapeutics; (v) leveraging our know-how and expertise in drug and genetic biomarker development; and (vi) working with providers, payers and others to accelerate uptake and adoption of genetic tests in clinical care with the goal of improving cost and clinical outcomes.

Our Pharmaceutical Pipeline

Vilazodone

About Depression

The National Institute of Mental Health, or NIMH, estimates that major depressive disorder affects approximately 18.1 million adults and that the medical and social costs of depression in the United States in the year 2000 was $83 billion, including both $26 billion in costs of treatment and $57 billion in losses such as absenteeism, reduced productivity at work, and the value of lifetime earnings lost due to suicide-related deaths. Despite advances in the understanding of pharmacotherapy and the ongoing development of new agents, approximately two-thirds of patients do not achieve remission with first-line depression therapies [*Rush, et al. Am J Psychiatry. November 2006 ;163(11):1905-17*]. In current treatment paradigms, if the patient does not respond or responds sub-optimally to antidepressant therapy, they may be switched to another agent within the same class agent with a different mechanism of action or have a second agent added. One commonly selected strategy, often referred to as augmentation, is to add a 5-HT_{1A} agonist. In addition, 40% of patients with major depressive disorder suffer with additional comorbid mental disorders like anxiety, panic disorders and social anxiety disorder.

IMS Health's NPA, indicated more than 208 million prescriptions were written for antidepressants in the twelve months ending April 2009. This represents a 2% growth over the prior twelve months. SSRI's lead the category of products prescribed for depression. Top prescribed SSRIs include: sertraline, escitalopram, fluoxetine, and citalopram. According to IMS Health's National Sales Perspective, the antidepressant market in the U.S. was roughly $12 billion in 2008. While the prescription market has continued to grow, generic entrants for some of the leading products has reduced the total dollar value of the market.

Depression is a highly prevalent disease with significant morbidity and mortality. Today, the physician is faced with choosing among many first-line treatment options, most commonly prescribing one of the many available SSRIs or increasingly, SNRIs, drugs with a dual mechanism of action. In current treatment paradigms, if the patient does not respond or responds sub-optimally to antidepressant therapy, they may be switched to an agent with a different mechanism of action or have a second agent added. One commonly selected strategy, often referred to as augmentation, is to add a 5-HT_{1A} agonist.

Market Opportunity and Competition

Today, no single drug holds more than a 25% market share and, if approved by the FDA, vilazodone's potential competitors include: Pfizer's Zoloft (sertraline); Wyeth's Effexor IR and XR (venlafaxine); Forest's Lexapro (escitalopram); Eli Lilly's Cymbalta (duloxetine); AstraZeneca's Seroquel (quetiapine); and GlaxoSmithKline's

Paxil (paroxetine). We believe vilazodone will differentiate itself from these potential competitors through its novel first-in-class dual mechanism of action, a combination SSRI and a 5-HT_{1A} partial agonist in a single molecule and a favorable side effect profile which is punctuated by a lack of sexual dysfunction common to many antidepressants on the market today. Further, we believe that providers will recognize the unique aspects for their patients associated with combining both a well known and effective antidepressant and anti-anxiety in a single molecule. These positive differentiators will assist vilazodone in competing within the multi-billion dollar depression market.

About Vilazodone

We are proceeding with the development of vilazodone for the treatment of depression, with a worldwide exclusive license from Merck-Serono, or Merck, obtained in 2004. Vilazodone, a novel dual-acting serotonergic antidepressant, is a potent SSRI and a partial agonist of the 5-HT_{1A} receptor. Vilazodone has greater *in vitro* potency and selectivity for serotonin reuptake than compounds such as fluoxetine. *In vitro* binding studies also indicate that vilazodone has a greater potency for the 5-HT_{1A} receptor than specific 5-HT_{1A} ligands such as buspirone [*Journal of Medicinal Chemistry 47: 4684-4692, 2004*]. There is evidence that a partial 5-HT_{1A} agonist taken in combination with an SSRI for the treatment for major depressive disorder, may reverse the adverse sexual side effects induced by the SSRI. Thus vilazodone is the first compound to combine first-line SSRI therapy for major depressive disorder with 5-HT_{1A} partial agonist, an accepted adjunctive treatment for major depressive disorder, and a first-line therapy for anxiety disorders.

In February 2006, we initiated a Phase III study of vilazodone for the treatment of major depressive disorder with enrollment of 410 subjects completed in March 2007. This trial met its primary endpoint of mean change from baseline in the Montgomery-Asberg Depression Rating Scale, or MADRS, for vilazodone-treated patients compared to placebo-treated patients, with a p-value of 0.001. Secondary endpoints such as the Hamilton Depression Rating Scale and the Clinical Global Improvement and Clinical Global Severity Scales were also statistically significant. In addition, statistically significant improvement was observed as early as one week of treatment. The most common adverse events in vilazodone-treated patients were nausea, diarrhea, somnolence, headache and dizziness. In this study, there was no impairment of sexual function by vilazodone as measured by change in the Arizona Sexual Experience Scale. This study included pharmacogenetic analyses for biomarkers of response to vilazodone with the intention of developing a companion genetic test for vilazodone response. Results from the first Phase III study of vilazodone were published in March 2009 in the *Journal of Clinical Psychiatry* [Rickels K, et al. J Clin Psych 2009 Mar 70(3):326-33].

As a result of the completion of this first Phase III study and under the terms of our agreement with Merck, we issued 135,000 shares of Clinical Data Common Stock as a milestone payment to Merck in December 2007. All of the shares issued to Merck are unregistered but carry certain demand and incidental registration rights, as provided under the agreement.

In March 2008, we initiated our second Phase III study which was completed in March 2009. This study was a randomized, double-blind, placebo-controlled trial of 481 patients with major depressive disorder conducted at 12 sites in the United States. The study achieved its primary endpoint of demonstrating a reduction in the symptoms of depression, as measured by a statistical separation from placebo in the MADRS with a p-value of 0.007 after up to 8 weeks of treatment. Vilazodone also met a key secondary endpoint as demonstrated by a statistically significant reduction in depression symptoms, compared to placebo, as measured by mean change from baseline on the Hamilton Depression Rating Scale (HAMD17, p=0.021). These two rating scales are the most common psychometric measures of response to antidepressants used in clinical trials. There was also a statistically significant improvement in symptoms of anxiety associated with depression, as measured by the Hamilton Anxiety Rating Scale (HAMA, p=0.038). The effects of vilazodone on sexual function were comparable to placebo, as measured by a validated sexual function scale, the Changes in Sexual Function Questionnaire. In addition, vilazodone was generally well tolerated. The discontinuation rate due to adverse events for patients on vilazodone was 4.3% vs. 1.7% for those treated with placebo. In this study, the most common adverse events associated with vilazodone included diarrhea (31% vilazodone vs. 11% placebo), nausea (26% vs. 6%), and headache (13% vs. 10%). In the vilazodone treated group, one patient out of 240 patients discontinued the trial due to diarrhea and three patients due to nausea. Separately, the Phase III study also sought to replicate a proprietary biomarker associated with response to vilazodone from the first

Phase III trial. Although this preselected biomarker did not replicate, analyses remain ongoing. We have filed patents on the identified genes.

A long-term safety study of vilazodone was launched in December 2007 and we achieved the goal of having more than 300 patients complete six months of treatment and more than 100 patients complete one year of treatment with vilazodone as recommended by FDA guidelines.

Based on the results of these and additional activities, including the manufacture of registration batches of the active pharmaceutical ingredient and the commercial product, we intend to file an NDA for vilazodone with the FDA, as early as the end of calendar year 2009.

Stedivaze

Overview

Stedivaze is a highly selective A_{2A} agonist in development as a vasodilator used for myocardial perfusion imaging. We plan to launch our Phase III clinical development program for Stedivaze during the next several months. Phase II data showed potential best-in-category attributes with an improved adverse event profile over the current standard of care and favorable pharmacokinetic and target binding affinity profiles. We conducted an End of Phase II meeting with the FDA in January 2009. Based on this meeting, we believe that we have reached agreement with the FDA on the overall design elements for our first Phase III trial. Stedivaze could be marketed by us directly to providers or partnered as a complementary and valuable to the pipelines of other well-established biotechnology and specialty healthcare companies.

About Myocardial Perfusion Imaging

Diagnosing Coronary Artery Disease, or CAD, can be a challenging aspect of patient care for cardiologists and other practitioners. People who experience symptoms of CAD, including chest pain, shortness of breath, and irregular heartbeat, or who have an abnormal ECG, may undergo myocardial perfusion imaging, often referred to as the exercise treadmill or stress test. In this test, images of the heart are captured at rest and during peak exercise when the coronary arteries are maximally dilated, by a method called SPECT imaging. These images are used to detect the presence of ischemia (reduced supply of blood and therefore oxygen to specific regions of the heart) that most often reflects the presence of CAD. In some cases, the ability of patients to undergo a standard myocardial perfusion imaging test may be limited because of long-term physical inactivity and/or concomitant illnesses such as arthritis, peripheral vascular disease or heart failure. For these patients, a pharmacologic stress agent, such as adenosine or dipryidamole can be administered to dilate the coronary vasculature in the absence of exercise. Stedivaze is a next-generation pharmacologic stress agent, offering the potential for advantages due to its dosing, selectivity and side effect profile.

Market Opportunity and Competition

Over 7.6 million myocardial perfusion imaging tests were performed in the United States in 2008 to determine the extent and location of cardiac ischemia, the effectiveness of percutaneous coronary intervention or coronary artery bypass grafting surgeries, or prognosis after myocardial infarction [AMR Monthly Monitor]. Approximately 3.6 million of these patients required the use of a pharmacological agent to generate maximum coronary blood flow in lieu of exercise [AMR Monthly Monitor]. For the past twelve years the myocardial perfusion imaging market has grown at a compound annual growth rate of almost 12% per year [AMR Monthly Monitor]. The current leading blood vessel dilator for myocardial perfusion imaging studies is adenosine, which had annual sales of over $349.0 million in 2007 [Broadpoint Capital, Inc., CVTX, April 11, 2008]. CV Therapeutics, Inc., or CVT, has developed Lexiscan, which has been approved by the FDA. Labeling for Lexiscan shows that it is administered as a single-bolus intravenous, or IV, injection but that it has a comparatively un-differentiated incidence of adverse effects when compared to adenosine. Although the coronary vasodilation evoked by these agents results from activation of the adenosine A_{2A} receptor, their activity on the other 3 adenosine receptor subtypes (A_1, A_{2B}, A_3) produce unwanted side effects. The current U.S. market opportunity value of $800 million has been limited somewhat by the adverse event profile of these compounds; we believe the market opportunity is substantially greater for a compound that fully meets the clinical need [Broadpoint Capital, Inc., April 11, 2008. Morgan Stanley,

January 27, 2009]. As validation for the potential of this class, Astellas reported U.S. sales in the second half of 2008 of $71.1 million for Lexiscan, which was launched in June 2007 [BioCentury Today on CVT/Gilead Deal, March 24, 2009] and is forecasted to achieve worldwide sales of $410.8 million by 2012 [Morgan Stanley, January 27, 2009].

Patients undergoing myocardial perfusion imaging using adenosine usually experience undesirable side effects including chest pain, difficulty breathing, or headaches, and sometimes serious side effects such as severe slowing or stopping of the electrical rhythm of the heart. These side effects arise, for the most part, from the actions of adenosine on the A_1 receptor subtype. Additionally, because activation of the adenosine A_{2B} receptor has been shown to play a role in mast cell degranulation, both adenosine and dipyridamole are contraindicated for patients with respiratory illnesses such as asthma or chronic obstructive pulmonary disease, or COPD. Thus, agents that are more highly selective for the A_{2A} receptor can be expected to have a distinct advantage in safety and tolerability profiles. Other modalities for myocardial perfusion imaging other than single-photon emission computed tomography, or SPECT, imaging have also been developed in recent years. These modalities include PET imaging, MRI, and contrast echocardiography. All of these myocardial perfusion imaging modalities require vasodilation and we therefore believe that these emerging myocardial perfusion imaging modalities represent additional opportunities for market expansion after initial approval of Stedivaze for SPECT myocardial perfusion imaging.

About Stedivaze

Apadenoson is a highly selective and high affinity agonist of the adenosine A_{2A} receptor that is in Phase III clinical development for use as a coronary vasodilator for use in myocardial perfusion imaging. Apadenoson is superior in its selectivity for the adenosine A_{2A} receptor as compared to adenosine and other adenosine A_{2A} receptor agonists currently on the market. Our Phase II data show that Stedivaze has demonstrated coronary vasodilatory activity comparable to that produced by adenosine. The superior selectivity of apadenoson for the adenosine A_{2A} receptor translates into a marked reduction in side effects caused by the non-selective stimulation of other adenosine receptor subtypes. Apadenoson also has the appropriate half-life to be administered as a single-bolus IV injection. This potentially allows for easier and faster administration resulting in potential cost advantages to practitioners. The product can be manufactured cost effectively and has already been scaled up to large commercial scale quantities.

Pre-clinical Programs

ATL844

ATL844 is targeted as an oral therapeutic for the treatment of asthma and/or diabetes. The asthma market was $15 billion in 2006 and is expected to reach $17 billion per year by 2010 [*Malthon, Daniel (18 June 2007). Asthma & COPD — Clearing the air* ING Analyst Report]. The diabetes drug market is currently $25 billion per year with a recent and projected annual growth rate of approximately 10% [*World Diabetes Market Analysis, 2009-2023, ReportLinker.com*]. ATL884 works through antagonism of the adenosine A_{2B} receptor sub-type. The compound has shown significant responses in animal models of both asthma and diabetes. We are proceeding with a toxicology and chemistry program, and with success, we will proceed to an IND filing. ATL844 is the subject of an option agreement to an exclusive license with Novartis.

ATL1222

ATL1222 is a highly selective agonist of the adenosine A_{2A} receptor subtype that is in development for the treatment of acute inflammatory conditions. The compound has shown significant responses in animal models of a number of inflammatory mediated diseases, and has demonstrated a lack of toxicity in both rodent and primate toxicology models at doses expected to be therapeutically relevant. ATL1222 is currently in later stage toxicology development, and with success, we will proceed to an IND filing.

ATL313

ATL313 is a selective agonist of the adenosine A_{2A} receptor subtype that is targeted as a treatment for ophthalmic disease. The compound has shown significant effect in both small and large animal models of disease.

ATL313 is the subject of a confidential collaboration with a pharmaceutical partner, who has an option to the ophthalmic program. This compound may be well positioned to be used in other major indications and some work is being conducted currently to identify and advance these opportunities.

AVN316

In June 2008, Avalon announced that it had identified a compound for clinical development, named AVN316. This compound has good pharmacological properties and potently inhibits the beta-catenin pathway in a variety of model systems.

Cancer researchers have known that proteins within the beta-catenin pathway play key roles in the initiation and progression of many types of cancer, most notably colon cancer. It has been estimated that the beta-catenin pathway is abnormally activated in more than 85% of colon tumors. Colon cancer is the fourth most common type of cancer, causing approximately 105,000 new cancer cases and over 56,000 deaths each year in the United States. Despite intense interest and significant research effort by the pharmaceutical industry, little success has been had identifying and developing drugs that specifically affect the beta-catenin pathway. Avalon developed a gene expression signature that tracks decreased beta-catenin pathway activity, and used it to identify structurally different compounds from Avalon's chemical library.

Strategic Acquisitions

We continually evaluate opportunities that may provide us with, among other things, therapeutic assets, promising biomarkers preferably with intellectual property protections, new technologies and key personnel or capabilities that could augment these efforts. From time to time, we may pursue acquisitions which we believe will meet these or other pre-clinical and clinical program goals.

Our Genetic Tests

Developing and Commercializing Genetic Tests

We currently provide the *FAMILION* family of genetic tests for inherited cardiac syndromes. The *FAMILION* family of tests identifies mutations in genes associated with inherited cardiac syndromes including cardiac channelopathies such as Long-QT Syndrome, or LQTS, Brugada Syndrome, or BrS, and Catecholaminergic Polymorphic Ventricular Tachycardia, or CPVT, and in genes associated with cardiomyopathies including Hypertrophic Cardiomyopathy, or HCM, and Arrhythymogenic Right Ventricular Cardiomyopathy, or ARVC. Although we continue to focus the majority of our resources on the development of our therapeutics, we continue to apply our efforts and expertise to the development of new genetic tests by leveraging our intellectual property and focusing on related disease and therapeutic areas which include, but are not limited to oncology, inflammatory diseases, cardiovascular, and the central nervous system.

Currently, we are continuing to develop and commercialize genetic and related biomarker tests that will assist providers and payers in determining the most appropriate therapeutic intervention for a particular patient. These tests are developed based on our know-how and expertise, in partnership with thought leaders and leading healthcare institutions, and intellectual property that we have developed on our own, licensed from others, or acquired from other parties. Examples of tests that have been commercialized from intellectual property include the *FAMILION* family of tests. Our tests are available to patients by physician's prescription to providers located primarily in the United States and Canada and may be performed in our CLIA-certified laboratories or partnered with other test providers.

Sales and Marketing

In September 2007, we launched a provider focused sales and marketing effort by establishing a sales force to promote our tests, particularly our *FAMILION* family of tests for inherited cardiac syndromes. This sales team calls on pediatric and adult electrophysiologists and cardiologists. Based on the positive results of this effort, the size of the sales force was increased in fiscal 2009. We have also added resources to focus on both the provider and payer markets specifically in managed care contracting, customer service, reimbursement, and billing.

The FAMILION Family of Tests

According to the Centers for Disease Control and Prevention, or CDC, each year 400,000 Americans die suddenly and unexpectedly due to cardiac arrhythmias with about 4,000 of these deaths occurring in people under the age of 35 [*Sudden Arrhythmia Death Syndromes Foundation (SADS) citing CDC 2002*]. Some of these deaths, especially those of young seemingly healthy people, are due to cardiac channelopathies, such as LQTS, BrS, and CPVT and to cardiomyopathies, such as HCM and ARVC.

By reducing uncertainty by finding the specific, underlying genetic causes of these inherited cardiac diseases, genetic testing provides the following clinical benefits:

- aids in the diagnosis of disease;
- aids in comprehensive risk assessment;
- guides lifestyle modifications;
- provides information needed to develop a comprehensive treatment plan, which may include the placement of an internal cardioverter defibrillator;
- determines if family members are at risk, including those who are currently asymptomatic; and
- provides important information for genetic counseling.

The *FAMILION* family of tests continues to reach a broadening market of physicians and patients in the United States and Europe. Of note, the size of the available market is considerably larger than the prevalence of LQTS, since the differential diagnosis includes common symptoms of other diseases and syndromes, and because family members, no all of whom have LQTS, will also undergo testing. Originally, the test detected mutations in five ion channel genes associated with LQTS and BrS. In October 2007, at the request of our *FAMILION* customers, a test for CPVT was added to our testing menu, now marketed as the *FAMILION* family of tests for inherited cardiac syndromes. These three conditions predispose affected individuals to abnormal heart rhythms, known as arrhythmia, which can cause symptoms ranging from syncope to sudden cardiac arrest if left undiagnosed and untreated. Treatment options include life-style modification, the prescription or avoidance of specific classes of drugs, and the insertion of an implantable cardioverter/defibrillator. Until May of 2008, our primary commercial interest was in diagnostic cardiac channelopathies. The launch of tests for HCM followed by ARVC in November 2008 heralded our arrival into the cardiomyopathy testing space as well.

LQTS is a genetic disorder that is three times more common than childhood leukemia [*SADS Foundation*]. Greater awareness of and improved testing for LQTS is illuminating the disease's true prevalence, as it is now estimated that 1 in 3,000 people in the United States has LQTS whereas previous estimates were much lower [*Priori SG, et al., Circulation 1999;99:529-33*]. While BrS and CPVT are less common, they are rapidly gaining recognition as causes of significant morbidity and mortality.

LQTS is characterized by syncope, seizures, and sudden cardiac death, with variable observation of QT-interval prolongation on an electrocardiogram, or ECG. The clinical presentation of LQTS and the subtype as indicated by the results of genetic testing are associated with both the probability and lethality of cardiac events. Diagnosis of all mutation carriers in an LQTS family is important, since carriers may be asymptomatic and electrocardiograms, or ECGs), are often non-diagnostic [*Priori SG, et al., Circulation 1999; 99:529-33*]. Thus, family members of an index case, as determined by pedigree analysis, should undergo Family Specific Testing via the *FAMILION* family of tests to determine their carrier status. BrS onsets primarily during adulthood and, if untreated, the mean age of death is approximately 40 years of age.

CPVT is considered to be highly lethal with the overall mortality of untreated disease estimated to be 30-50% [*Mohamed U, et al. J Cardiovasc Electrophysiol. 2007; 18(7):791-7*]. Genetic testing is important to determine or confirm this diagnosis; it is estimated as many as 30% of CPVT patients have been misdiagnosed as LQTS with a normal QTc interval [*Priori SG, et al., Circulation, 2002;106:69-74*].

In May 2008, we began offering a genetic test for HCM. HCM is an autosomal dominant disease that affects 1 in 500 people [*Keren A, et al., Nature.2008; 5(3):158-68*]. As the most prevalent cardiomyopathy, it is the major

cause of sudden death in people under 30 years of age. Making an HCM diagnosis can be difficult since many conditions mimic the left ventricular hypertrophy, known as LVH, most commonly associated with HCM. Genetic testing for patients suspected of having HCM is important for making an accurate diagnosis, appropriate clinical management, genetic counseling and family testing. Genetic testing is also the most reliable means of identifying pre-symptomatic family members that may be unknowingly at risk. [*Prasad et al., Heart. 1999; 82:8-15*]. There are several issues that can make accurately diagnosing HCM a significant challenge, including conditions or anatomical variants that mimic the disease.

Because HCM is associated with a broad spectrum of symptom severity that can vary from day to day, getting an accurate and conclusive history can be a challenge. Even within the same family, the symptoms experienced and their severity may vary [*Keren, et al, Nature 2008; 5(3); 158-68*]. In addition, since some carriers of an HCM gene mutation may present with little or no LVH accompanied by only discrete ECG abnormalities, both echocardiogram and ECG have limitations. Relying on echocardiogram to diagnose children and adolescents may be misleading since the LVH associated with HCM may not become apparent until later in life [*Prasad, et al., Heart 1999; 82:8-15*].

In November 2008, we began offering a genetic test for ARVC. ARVC is an inherited, progressive cardiomyopathy characterized by loss of heart muscle cells, replacement of the myocardium with fatty and fibrous tissue, electrical instability, ventricular arrhythmias and sudden cardiac death. Prevalence estimates for ARVC range from 1 in 5,000 to 1 in 1,250 [*Muthappan P, Calkins H. Prog Cardiovasc Dis. 2008;51:31-43; Peters S. Int J Cardiol. 2006;113:4-11*]

Diagnosing ARVC can be quite difficult since there is no single clinical criterion for establishing the diagnosis. Diagnostic criteria designed by the Task Force of the Working Group of Myocardial and Pericardial Disease of the European Society of Cardiology and the Scientific Council of Cardiomyopathies lack sensitivity for detecting early-stage and familial ARVC [*McKenna WJ et al. Br Heart J. 1994;71(3):215-218].* ARVC is also associated with a highly variable clinical course and a broad spectrum of symptoms and ECG abnormalities [*Sen-Chowdry S, et al. J Am Coll Cardiol. 2007;50:1813-1821*].

In March of 2009 the Heart Failure Society of America issued Practice Guidelines on Genetic Evaluation of Cardiomyopathy in the Journal of Cardiac Failure [*Volume 15, Issue 2, Pages 83-97*]. The guidelines indicated substantial progress has been made recently in understanding the genetic basis of cardiomyopathy. The guidelines also stated that genetic testing should be considered for the one most clearly affected person in a family and that the primary value, and the primary reason to seek genetic testing for the genetic cardiomyopathies, is to more accurately predict the risk of a family member developing cardiomyopathy who at the present has little or no clinical evidence of cardiovascular disease.

A joint guideline issued by the American College of Cardiology, the American Heart Association, and the European Society of Cardiology, titled *ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death*, emphasizes the importance of the medical profession in critically evaluating the use of diagnostic procedures and therapies. Rigorous and expert analysis of the available data documenting absolute and relative benefits and risks of those procedures and therapies can produce helpful guidelines that improve the effectiveness of care, optimize patient outcomes, and favorably affect the overall cost of care by focusing resources on the most effective strategies. Based on these rigorous criteria, the guidelines, as published in *Circulation [2006;114;1088-1132]*, recommend genetic testing for LQTS, CPVT, and BrS for the management of patients with ventricular arrhythmias and prevention of sudden cardiac death.

To support our efforts to educate physicians, patient and payers, we work with key patient advocacy and other professional groups that offer patient support, such as the Sudden Arrhythmia Death Syndromes, or SADS, Foundation, the National Society of Clinical Geneticists, the Hypertrophic Cardiomyopathy Association, or HCMA, and the Hannah Wernke Memorial Foundation. SADS is a leader in education, research and advocacy for families and individuals at risk for cardiac arrhythmias that can cause sudden death in young people. We have supported the SADS Foundation since 2005 and they are now assisting in the referral of patients to research facilities throughout the country whose *FAMILION* test result is non-diagnostic. HCMA provides information, support and advocacy to patients, their families and medical providers suffering from hypertrophic cardiomyopathy. We are in our second year working with HCMA and support its key outreach initiative, the HCMA annual meeting. In its 12th year, the meeting brings together over 200 HCM patients and their families and provides an opportunity for those patients to interact with leading HCM

expert physicians. Additionally we have made charitable contributions of donated tests that the Association can use at its discretion. The Hannah Wernke Memorial Foundation seeks to build awareness of heart arrhythmia disorders such as CPVT. In 2008, we partnered with the Hannah Wernke Memorial Foundation to develop a program administered by the Foundation to reduce out-of-pocket costs associated with CPVT testing for patients with a suspected diagnosis of CPVT who either do not have insurance coverage, have been denied coverage by their insurance provider or have partial coverage from their insurance provider. These cooperative efforts will add to the understanding of the causes of these inherited cardiac syndromes.

Challenges in Reimbursement

Some of the greatest challenges associated with genetic testing are the complicated pricing and reimbursement structures of the major payers and the out-dated Clinical Laboratory Fee Schedule codes often used by private and public payers. Neither of these systems reflects the complexity or the value of the development and delivery of genetic and pharmacogenetic tests. Current practice is to "stack" applicable Current Procedural Terminology codes in an attempt to reflect the actual laboratory procedures. New and unfamiliar tests, especially when accompanied by code stacking, may trigger review by the payer and denials of payment which must then be appealed on a case-by-case basis. When compounded by the number of payers in the United States healthcare system, attaining reasonable, value-based reimbursement for our tests remains a challenge.

Coverage of new diagnostic tests is further hindered by the fact that most insurers do not have a process for evaluating new tests. Major payers such as Blue Cross and Blue Shield, or BCBS, have instituted or subscribe to technical review boards to evaluate new technologies and diagnostics. While positive reviews of new tests and technologies are valuable, they are rare and often viewed as a recommendation only and do not necessarily constitute immediate approval of a technology by members of that particular system. In February 2008, our *FAMILION* test for LQTS met the BCBS Association Technology Evaluation Center's criteria for establishing the diagnosis of LQTS in certain individuals.

We have also made significant progress in our efforts to contract with private and government health insurers for test coverage and reimbursement. Our work with private insurers resulted in the *FAMILION* LQTS, BrS, and *FAMILION* Family tests receiving S-codes effective October 2008 followed by the *FAMILION* HCM and *FAMILION* HCM Family tests receiving S-codes effective April 2009. We expect that S-codes should speed the adoption of these tests by private insurers. In October 2008, we became an in-network provider with Aetna for healthcare coverage of our *FAMILION* LQTS and Family tests. We are utilizing our national contract with the BCBS Association signed in December 2008 to work with individual BCBS companies to provide their customers with access to our *FAMILION* Family of Tests. In addition, we are an approved Medicare provider for our genetic testing services, and a Medicaid provider in 39 states and the District of Columbia. These providers and other private payers with positive coverage policies offer access to genetic testing for nearly 200 million patients. The positive changes to the reimbursement landscape for our genetic tests demonstrate our commitment to working with private and government payers to improve patient access to these vital tests.

OTHER BUSINESS MATTERS

Government Regulation

Regulation by governmental entities in the United States and other countries is and will continue to be a significant factor in the development, manufacture and marketing of our products. Various federal and state regulations govern or influence the manufacture, 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 us varies depending on the nature of the product or service.

The Protected Health Information, or PHI, and the information systems that manage that information in association with our commercial testing business are managed according to the applicable requirements of the Health Information Privacy and Portability Act.

The Centers for Medicare & Medicaid Services regulates all non-research laboratory testing performed on humans in the United States under 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 CLIA. So-called "laboratory-developed tests," such as our *FAMILION* tests, are currently regulated under CLIA. Whether or not the FDA has the legal authority to regulate these laboratory developed tests is contested by many.

The FDA has issued various draft and final guidance documents relating to pharmacogenomic topics including: pharmacogenomic data submissions, biomarker qualification, tests for inheritable markers, drug-diagnostic co-development, and the regulation of *In Vitro* Multivariate Index Assays. In 2008, the FDA released Pharmacogenomics Definitions and Sample Coding while a second guidance entitled Pharmacogenomic Data Submissions — Companion Guidance remains in draft form. These guidance documents may or may not relate to our products or the potential products in our development pipeline. At this time, although FDA claims authority to regulate our genetic and pharmacogenetic tests, our diagnostic products have not been subject to FDA approval for marketing. It is unknown whether or not such a requirement may be imposed at some time in the future.

When developing genetic and pharmacogenetic tests, we use DNA isolated from clinical samples, usually blood samples. We may receive these samples directly from a partner, in which case samples have been collected according to a protocol including, an informed consent, and an institutional review board, or IRB, approval designed and executed by the partner. In some cases, a contract research organization, or CRO, with which we have a contract collects these blood samples with accompanying personal and medical information about each individual. We will prepare, or, subject to our approval, our CRO may prepare the sample collection protocol and an informed consent and may identify the clinical sites which collect the samples. The individual clinical sites recruit the patients for each clinical study and per the study protocol, explain and obtain an IRB-approved written informed consent from each patient that includes the patient's authorization to use the DNA sample and associated data for developing commercial products. Any contracts with the CRO or individual clinical sites require an independent IRB to approve the study protocol and the informed consent. We may also contract directly with clinical sites to collect the samples plus personal and medical information. By whatever means we receive the samples, we have in place procedures to maintain the confidentiality of any of the individuals from whom we receive clinical information and samples. We believe that these procedures comply with all applicable federal, state and institutional regulations.

Our compounds, vilazodone and Stedivaze, as well as our earlier stage products, will require approval by the FDA in the United States and by other regulatory agencies in other countries in order to be marketed. Gaining marketing approval typically requires pre-clinical studies and clinical trials and often post-marketing surveillance of each compound, in addition to manufacture of the active pharmaceutical ingredient and the drug product(s). 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 developed by us or our customers, impose costly processes and procedures on our assay development or validation activities, diminish competitive advantages and reduce 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 development of vilazodone and Stedivaze, as well as our earlier stage products, are subject to applicable GLP and current Good Manufacturing Practice, or cGMP, as outlined by the FDA and other regulatory agencies and provided to the industry in guidance and other regulatory documents. We believe we are in compliance with applicable regulations and employ consultants as needed to advise us throughout the development program. We conduct audits of laboratory and manufacturing sites and monitor and audit clinical investigators to assure their compliance.

Patents and Proprietary Technology

We rely on patents, trade secrets, non-disclosure/confidentiality agreements to develop and maintain our competitive position. All employees are required to execute agreements providing that all inventions conceived by them while employed by us are our exclusive property.

As of March 31, 2009, we have a patent estate consisting of twelve issued United States patents; forty-eight issued foreign patents, forty-one pending United States patent applications, two United States provisional patent applications, ninety-six pending foreign patent applications, and six international patent applications under the Patent Cooperation Treaty. These patents are directed generally to (i) biomarkers useful for predicting clinically

relevant endpoints (e.g., efficacy of vilazodone), and (ii) adenosine receptor A_{2A} and A_{2B} agonists and antagonists and their use as therapeutics and diagnostics (e.g., Stedivaze).

In addition to the patents that we own, we have exclusively in-licensed rights under a variety of issued patents and pending patent applications as follows:

- Ten issued United States patents, two pending United States patent applications, two-hundred eight-three issued foreign patents, and ninety-eight pending foreign patent applications owned by Merck relating to vilazodone, methods for manufacturing vilazodone, and methods of using vilazodone to treat depression and other anxiety disorders;
- Four issued United States patents, one pending United States patent application, two pending United States provisional patent applications, sixty-eight issued foreign patents, and fifteen pending foreign patent applications owned by the University of Virginia Patent Foundation relating to Stedivaze compositions and methods of using Stedivaze for myocardial perfusion imaging and other imaging modalities;
- One issued United States patent owned by the University of Massachusetts relating to a use for Stedivaze;
- One issued United States patent co-owned by the University of Virginia Patent Foundation and Penn State Research Foundation relating to methods for improving insulin sensitivity or stimulating glucose uptake;
- One pending United States patent application, and four pending foreign patent applications owned by the National Institutes of Health relating to methods for treating cancer;
- Ten issued United States patents, twelve pending United States patent applications, one pending United States provisional patent application, seven issued foreign patents, seventeen pending foreign patent applications, and one pending international patent application under the Patent Cooperation Treaty owned by the University of Virginia Patent Foundation relating to our substantial adenosine-related product pipeline;
- One co-owned pending international patent application under the Patent Cooperation Treaty relating to an ophthalmic indication;
- Five issued United States patents, three issued foreign patents, and seven pending foreign patent applications owned by the University of Utah relating to the diagnosis of inherited LQTS;
- Five issued United States patents, six issued foreign patents, and three pending foreign patent applications owned by Genzyme Corporation relating to the diagnosis of inherited LQTS;
- One pending United States patent application, two pending foreign patent applications, and one pending international patent application under the Patent Cooperation Treaty relating to the diagnosis of inherited ARVC;
- Three pending United States patent applications, three issued foreign patents, and five pending foreign patent applications owned by CHU Tours relating to the use of the FCGR3A V158F variant to predict certain phenotypes, including rituximab efficacy;
- One issued United States patent controlled by Innate Pharma relating to genotyping the FCGR3A V158F variant;
- One pending United States patent application owned by the University of Alabama-Birmingham relating to the use of certain FCGR2B variants to predict certain phenotypes;
- One issued United States patent owned by St. Jude Children's Research Hospital (exclusively sublicensed to Prometheus Laboratories Inc. and Specialty Laboratories, Inc.) relating to genetic markers predictive of thiopurine toxicity;
- One issued United States patent owned by Yale University (exclusively sublicensed to Siemens Medical Solutions Diagnostics) relating to the coupled amplification and sequencing of DNA; and
- One issued United States patent owned by Vanderbilt University relating to a genetic marker predictive of drug-induced cardiac arrhythmia.

Our proprietary technology includes rights to or ownership of certain cell lines, purification technology, molecular models and purification technology that gives us a competitive advantage in the development of new pharmaceutical agents.

Backlog

Backlog is not meaningful to our business.

Employees

We had 161 full-time and 15 part-time employees as of March 31, 2009, all of whom are employed in the United States and Canada.

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

No customer comprises 10% or more of our consolidated revenues.

Discontinued Operations

As part of our decision to focus on the development and commercialization of targeted therapeutics and predictive tests from our growing portfolio of proprietary genetic biomarkers, we sold Vital Diagnostics in November 2006, CDSS in June 2007, Vital Scientific in October 2007, Electa Lab in November 2007, and our Cogenics segment in April 2009. Accordingly, we classified these businesses as discontinued operations and their results of operations, financial position and cash flows are separately reported for all periods presented.

Investor Information

Financial and other information about us is available on our website (http://www.clda.com). We make available on our website, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities and Exchange Act of 1934 as soon as reasonable practicable after we file such material electronically or otherwise furnish it to the SEC.

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

Without additional capital raising opportunities, or a significant change in our operating and development plan, we will not have sufficient cash resources available to fund our current level of activities beyond December 2009, including our New Drug Application submission for vilazodone and Phase III clinical trial programs for Stedivaze.

At March 31, 2009, we had cash, cash equivalents and marketable securities totaling $56.4 million. This amount does not include approximately $13.1 million in proceeds from the sale of our Cogenics segment in April 2009. Our projected uses of cash include cash to fund operations, including continued research and product development, sales and marketing, capital expenditures and existing debt service costs. We have undertaken several steps to improve liquidity and reduce our projected uses of cash, including the divestiture of non-core assets. We believe that our cash and cash availability will be sufficient to fund our operations at least through December 2009. This is based on a steady state view of our financials and does not assume any cash inflows from partnerships,

disposition of non-core assets or other dilutive and non-dilutive financings. We will need additional funds to continue operations and the development of vilazodone and Stedivaze and other products, as well as the operations of Avalon, including demonstrating the advantages and reliability of Avalon's proprietary drug discovery and development technology, AvalonRx, beyond December 2009. Management is always evaluating additional sources of financing and would consider any of the following options:

- partnering opportunities with pharmaceutical or biotechnology companies for development and marketing of our late-stage or pre-clinical compounds;
- sale of non-core assets; and/or
- sale of equity or debt securities.

As evidenced by the September 26, 2008 and the February 25, 2009 private placements, we have been successful in raising capital in the past. We believe that, if required, those same and other investors would consider providing capital in the future. However, the sale of equity or debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or terms acceptable to us, if at all.

If we are unable to obtain financing or partnering opportunities, we may be required to implement cost reduction strategies. The most significant portion of the research and development expenses as well as some portion of sales and marketing expenses are discretionary and in anticipation of development and commercial launch of vilazodone. These cost reduction strategies could reduce the scope of and delay the timing of the planned vilazodone NDA filing which could harm our financial condition and operating results. We are also in the process of prioritizing the various development projects that we acquired through the Adenosine and Avalon acquisitions. Similar to the vilazodone and Stedivaze development, these projects are discretionary. However, the postponement or cancellation of any of these development efforts could have a material impact on our financial condition and operating results.

Given our current product development efforts which have resulted in 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, 2009, we had an accumulated deficit of approximately $251.0 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 vilazodone and Stedivaze.

To become profitable, we, either alone or with collaborators, must successfully develop, manufacture and market our current and future product candidates, including vilazodone and Stedivaze, 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 to become or sustain profitability.

If regulatory authorities fail to timely approve vilazodone for marketing, our results of operations will suffer.

In order to market our lead therapeutic candidate, vilazodone (as well as any other of our therapeutic products that successfully complete clinical trials), in the U.S. and abroad, we will need to obtain the approval of the FDA via an NDA filing expected later in calendar 2009; as well as the approval of European and other regulatory authorities in various countries.

Regulatory authorities denying or delaying these approvals would adversely impact our business and therefore our results of operations. A regulatory authority may deny or delay an approval because it was not satisfied with the structure or conduct of clinical trials or due to its assessment of the data we supply. A regulatory authority, for instance, may not believe that we have adequately established a product's risk-benefit profile or adequately addressed negative safety signals. Clinical data are subject to varied interpretations, and regulatory authorities may disagree with our assessments of our data. In any such case, a regulatory authority could insist that we provide

additional data, which could substantially delay or even prevent commercialization efforts, particularly if we are required to conduct additional pre-approval clinical studies.

Personalized medicine and pharmacogenomics is an emerging field, and therefore regulatory approval of our drug candidates that are paired with a companion diagnostic and diagnostic tests may take longer and be less predictable than approval for untargeted medicines.

Personalized medicine is an emerging field and represents a new approach in healthcare, one which ultimately may not prove successful. Certain components of our business strategy involve seeking marketing approval for our current and potential new drug candidates with the use of a diagnostic test to pre-screen subsets of patient populations most likely to achieve therapeutic benefit and/or minimal side effects. This approach to drug development may not be scientifically feasible 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 independent test, and it remains to be seen how the FDA will develop and implement standards for evaluation of integrated drug/diagnostic 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 marketing approval. Any biomarker association that we identify may not be viewed by the FDA as valid or the FDA may impose unreasonable burdens in establishing efficacy, safety, utility and validity. 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 requirements and 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, where required, 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 and that the magnitude of the effect of these genes is clinically and commercially useful. 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, most are diagnostic products. If our assumption about the role of genes in the disease process is wrong, our development 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 potentially develop compounds and/or tests to target populations in which variation in these genes affects outcomes. Although we have identified genes and polymorphisms that we believe are likely to be associated with certain phenotypes, we may not be correct and may not be successful in identifying any other similar genes or in developing drugs or tests based on these discoveries. 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;
- establish that they are clinically valid and useful;
- 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
- 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* family of tests including LQTS, BrS, CPVT, HCM and AVRC and are currently developing additional DNA-based diagnostic tests or expanding the indications of current tests. Our ability to derive revenues from these tests will depend on, among other things, continued certification of our reference laboratory under CLIA by the State of Connecticut and other states, our continued compliance with applicable regulatory requirements and acceptance of the test by physicians. In addition, we may not be able to secure 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 tests and drugs, we will not achieve sufficient product revenues and our business will suffer.

Even if the FDA approves our drug candidates, physicians and patients may not accept and use them. Acceptance and use of these products may depend on a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drugs;
- published studies demonstrating the cost-effectiveness of our drugs relative to competing products;
- accuracy and reliability of our laboratory testing;
- 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 our drug candidates to find market acceptance would harm our business and could require us to seek additional financing.

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

Our ability to successfully sell our drugs and biomarker tests in the United States and other countries depends on the availability of adequate reimbursement from third-party payers such as private insurance plans, managed care organizations and Medicare and Medicaid. Much of our revenues for such products will be dependent on customers who rely on third party reimbursement. Third-party healthcare payers 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 payers 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 payers 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 payers 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 materially 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 recently have entered into new business areas and may not have the expertise, experience and resources to pursue all of our businesses at once.

Individually, each of the PGxHealth, Adenosine Therapeutics and Avalon organizations has had experience in their respective areas of expertise, but we have only limited experience in pursuing 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, since 2005 we have acquired seven companies, including Genaissance, which provided us with our lead drug candidate, vilazodone, and many of the assets at PGxHealth. 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 and therefore be required to pay a premium for their acquisition.

Due to our recent acquisitions and dispositions, it may be more difficult to obtain additional financing at favorable terms, if at all.

Due to our recent acquisitions and dispositions and because we have not operated as a fully integrated enterprise for several full fiscal years, and 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 acquisition may dissuade new investors. We will need to raise additional capital to fund our current level of activities beyond December 2009. If we are unable to secure adequate financing, we will not be able to pursue our product development and commercialization strategies as currently planned.

Because a significant portion of our total assets are represented by goodwill that is 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.

Approximately 28.5% of our total assets at March 31, 2009 are goodwill and other intangibles, of which approximately $29.5 million is goodwill. In accordance with Statement of Financial Accounting Standards (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. There was no impairment charge during fiscal 2009. 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.

We may be unable to successfully complete the integration of the businesses of Adenosine Therapeutics and Avalon.

We may not achieve successful integration of the Adenosine Therapeutics and Avalon businesses in a timely manner, or at all, and we may not realize the benefits and synergies of the acquisitions to the extent, or in the timeframe, anticipated. During fiscal year 2009, we acquired Adenosine Therapeutics and entered into a merger agreement with Avalon Pharmaceuticals which was completed on May 28, 2009. We believe these acquisitions will result in benefits arising out of the combination of the companies. The successful integration of the three companies will require, among other things, integration of the Adenosine Therapeutics' and Avalon's businesses into ours. 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 dispersed across our operations in Massachusetts, Connecticut, Maryland, and Virginia, which increases the difficulty of integrating these 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;
- eliminating corporate overhead and consolidating administrative functions;
- 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.

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 we acquire 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 R. Reed, M.D., our Chief Medical Officer. The loss of the service of any of these persons or other senior managers and key scientific and other personnel could seriously harm our business operations, product development and commercialization efforts.

In order to conduct clinical trials and to market our drugs, we will have to develop methods 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 will then need to implement the necessary technology in order to produce the drugs to exacting standards set by us and regulatory bodies. This is an uncertain and time consuming process; 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.

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. 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. While we have signed contracts with suppliers for the production of vilazodone material and tablets for our clinical trials and have contracted for sufficient materials to complete these trials, we rely on these contract manufacturers to fulfill this need. Failure of those contract manufacturers would seriously harm our ability to complete our clinical trial program for vilazodone and to have suitable product to commercialize.

The manufacture of our products for clinical trials and commercial purposes is subject to cGMP regulations promulgated by the FDA. 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, 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.

New drug and genetic and pharmacogenetic test 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 tests.

Before we can develop diagnostic tests and commercialize any new products, we need to accomplish some or all of the following:

- collect and analyze DNA samples;
- conduct association studies to discover and replicate relationships between genetic variations in the DNA samples and phenotype of interest;
- 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, where necessary, marketing approvals from the FDA and other regulatory agencies; and
- find collaborative partners with manufacturing and commercial capabilities for our current and future drug candidates and related diagnostics.

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 validity and utility of our products.

Success in early clinical trials is not replicated often in later studies; 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, 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.

The covenants in the convertible notes restrict our financial and operational flexibility.

We are subject to certain covenants under the convertible notes we issued in 2009 that restrict our financial and operational flexibility. For example, we are restricted from incurring additional indebtedness, redeeming or declaring or paying any cash dividend or cash distribution on our common stock, or issuing or selling any rights, warrants or options to subscribe for or purchase our common stock or securities convertible into or exercisable for our common stock at a price which is less than the then market price of the common stock, other than in connection with an underwritten public offering. As a result of these covenants, our ability to finance our operations through the incurrence of additional debt or the issuance of shares of our common stock is limited.

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 that have been issued to us or our subsidiaries or that 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 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:

- pending patent applications may not result in issued patents;
- the claims of any issued patents may not provide meaningful protection;
- the claims of any issued patents may be invalidated or held unenforceable under current law or upon changes in patent law:
- 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 we have developed or may develop technology upon which our technology platform depends. If patent offices issue patents on these patent applications and we wish to use those 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 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 its 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 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.

Patents on our testing products may not prevent our competitors from designing around and developing similar tests that may compete successfully with our products. Such third party tests 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.

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 NDA 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.

Patents pending may not issue.

A number of our products are covered by patent applications that have not yet had their claims approved. Though we only submit patent applications that we believe have a reasonable probability of issuing, there is significant risk the patent applications may not be granted, or, if they are granted, may be granted with claims significantly less desirable than for which were originally applied.

We may be unable to achieve milestones contained in our licensing agreements and have our license revoked by our licensors.

Obtaining the milestones set forth in some of our licensing agreements requires performance on the part of us and may also depend on the successful work of suppliers, contractors, and sub-licensees. We cannot assure that there will be scientific, operational, or other success that will enable us to achieve the milestones to which we have agreed. Nor can we guarantee that we will be able to successfully renegotiate milestones with our licensors in the event that we desire or need to do so. In such instances, revocation of its license to the intellectual property upon which our business is built is a possibility and would significantly decrease our opportunities for success. Alternatively, licensees may impose additional goals or requirements on us in order to agree to extend the time of performance of our existing goals. Any termination of license agreements could significantly decrease our opportunities for success.

Risk Factors Relating to Regulatory Matters

Pre-clinical and clinical trials are time consuming, expensive, and uncertain processes.

Before the FDA approves a drug candidate for marketing, it is tested for safety and efficacy in pre-clinical testing and human clinical trials. The pre-clinical phase involves the discovery, characterization, product formulation and animal testing necessary to prepare an IND for submission to the FDA. The IND must be accepted by the FDA before the drug can be tested in humans in the United States. The clinical phase of development follows a successful IND submission and involves the activities necessary to demonstrate the safety, tolerability, efficacy, dose and dose schedule of the product candidate in humans, as well as the ability to produce the substance in accordance with cGMP requirements. Pre-clinical testing and clinical development are long, expensive and uncertain processes. During the process, we expect to incur significant expenses to conduct trials and follow required regulatory processes.

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, our current clinical trials for vilazodone or Stedivaze 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 or technologies; and
- competing clinical trials and new drugs approved for the conditions or indications 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.

Additionally, we cannot be certain that the necessary types of patients can be enrolled in the required time frame, if ever. The clinical program for Stedivaze, for instance, may require the enrollment of patients with severe

cardiac disease and these patients may be difficult or impossible to enroll. It may also be necessary to utilize other drug products in our clinical trials. We cannot be certain that supplies of other agents will be available for our trials.

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.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory agencies or by us if it is believed that the patients participating in trials are being exposed to unacceptable health risks or if deficiencies are found 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.

Although we recently announced positive results of a second Phase III study initiated in March 2008, manufacture of clinical trial supplies and commercial supplies are also in progress, as well as completion of the non-clinical and other clinical requirements necessary for an NDA filing, which is anticipated before the end of calendar 2009. The efforts related to the development of vilazodone or any other product candidates may be delayed for any of the reasons described above, and may take longer than anticipated to initiate and/or to complete.

Even if our drug candidates obtain regulatory approval, we will be subject to on-going government regulation.

Even if our drug candidates obtain regulatory approval, our products will be subject to continuing regulation by the FDA, including record keeping requirements, submitting periodic reports to the FDA, reporting of any adverse experiences with the product, and complying with drug sampling and distribution requirements. In addition, updated safety and efficacy information must be maintained and provided to the FDA. We or our collaborative partners, if any, must comply with requirements concerning advertising and promotional labeling, including the prohibition against promoting and non-FDA approved or "off-label" indications or products. Failure to comply with these requirements could result in significant enforcement action by the FDA, including warning letters, orders to pull the promotional materials, and substantial fines.

Quality control and manufacturing procedures must continue to conform to cGMP after approval. Drug and biologics manufacturers and their subcontractors are required to register their facilities and products manufactured annually with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMP regulations. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance. Further FDA inspections may identify compliance issues at our contract manufacturers that may disrupt production or distribution or require substantial resources to correct.

After FDA approval of a product, the discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer, or holder of an approved marketing application. These include withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay or prevent further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, the FDA may require post-market testing and surveillance to monitor the product's safety or efficacy, including additional clinical studies, known as Phase IV trials, to evaluate long-term effects.

Compliance with post-marketing regulations may be time-consuming and costly and could delay or prevent us from generating revenue from the commercialization of our drug candidates.

We have only limited experience in regulatory affairs which may affect our ability or the time we require to obtain necessary regulatory approvals.

We have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals. This lack of experience may impede our ability to obtain timely regulatory approvals, if we receive such approval at all. We will not be able to commercialize any of our drug candidates, until we obtain either FDA approval in the United States or approval by comparable authorities in other countries.

Third parties engaged to produce our drug candidates for clinical use may fail to comply with regulatory requirements, which could harm our clinical trials.

We intend to rely on third parties to produce drug candidates for clinical use. All facilities and manufacturing processes used by third parties to produce our drug products for clinical use in the United States must conform with cGMPs. These facilities and practices are subject to periodic regulatory inspections to ensure compliance with cGMP requirements. Their failure to comply with applicable regulations could extend, delay, or cause the termination of clinical trials conducted for our drug candidates.

Our operations involve hazardous materials and medical waste and are subject to environmental, health and safety controls and regulations Any claim relating to our improper handling, storage or disposal of biological and hazardous materials could be time-consuming and costly, and may exceed our resources.

We are subject to environmental, health and safety laws and regulation, including those governing the use of biological and hazardous materials as well as medical waste. The cost of compliance with environmental, health and safety regulations is substantial.

Our business activities involve the controlled use of hazardous materials, and we cannot eliminate the risk of accidental contamination or injury from these materials. While we believe that we are currently in compliance with all material rules and regulations governing the use of hazardous materials and, to date, we have not had any adverse experiences, in the event of accident or environmental discharge. We may be held liable for any resulting damages, which may exceed our financial resources and may materially harm our business, financial condition and results of operations.

Our business involves animal testing and changes in laws, regulations or accepted clinical procedures or social pressures could restrict our use of animals in testing and adversely affect our research and development efforts.

Many of the research and development we sponsor involve the use of laboratory animals. Changes in laws, regulations or accepted clinical procedures may adversely affect these research and development efforts. Social pressures that would restrict the use of animals in testing or actions against us or our partners by groups or individuals opposed to testing using animals could also adversely affect these research and development efforts.

In addition, pre-clinical animal studies conducted by us or third parties on our behalf may be subject to the United States Department of Agriculture regulations for certain animal species. Failure to comply with applicable regulations could extend or delay clinical trials conducted for our drug candidates.

Risk Factors Relating to Our Industry

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 pharmaceutical 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 may 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. 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 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 and globally 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:

- diagnostic and pharmaceutical companies;
- companies developing drug discovery technologies;
- 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.

Risk Factors Relating to Our 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 in one or more transactions, 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 September 2008, June 2006 and November 2005 private placements, as well as any shares issuable upon the conversion of the $50.0 million convertible notes sold in February 2009, as well as the shares issuable upon exercise of the warrants issued to the investors in those transactions, have been registered, or in the case of the February 2009 private placement, will be registered, under the Securities Act of 1933, known as the 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.

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 46.3% of our outstanding common stock as of 12, 2009, and are thus 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 technology companies in particular, experience volatility which has often been unrelated to the operating performance of any particular company or companies. Our common stock is thinly 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, contracts or acquisitions;
- variations in results of operations;
- changes in earnings estimates 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.

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 1.5 million 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 us 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, 2009, we leased or subleased a total of approximately 43,300 square feet of office and laboratory space. The leased and subleased properties are described below:

Location	Approximate Square Footage	Use	Expiration Date
One Gateway Center, Suite 702 Newton, Massachusetts	6,700	Corporate office	8/31/2011
5 Science Park New Haven, Connecticut	29,300	Office and laboratory	1/11/2010
310 4th Street, NE Charlottesville, Virginia	2,600	Office	5/31/2009
1630-1670 Discovery Drive Charlottesville, Virginia	3,700	Laboratory	10/31/2010
94B Industrial Road Troy, Virginia	1,000	Laboratory	5/31/2010

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, 2009 there were no asserted claims against us which, in the opinion of management, if adversely decided, would have a material adverse effect on our consolidated financial statements.

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 2009 and 2008 as reported by the NASDAQ.

	Sales Prices	
	High	Low
Fiscal Year Ended March 31, 2009		
First Quarter	$19.68	$14.25
Second Quarter	$19.59	$12.74
Third Quarter	$16.46	$ 7.15
Fourth Quarter	$11.93	$ 6.38
Fiscal Year Ended March 31, 2008(1)		
First Quarter	$16.19	$13.00
Second Quarter	$26.99	$13.25
Third Quarter	$28.90	$19.83
Fourth Quarter	$23.26	$15.34

(1) The prices for the quarters ended before October 1, 2007 have been adjusted to reflect the 3-for-2 stock split effected on that date.

Holders of Common Stock

As of June 12, 2009, there were approximately 440 holders of record of our common stock.

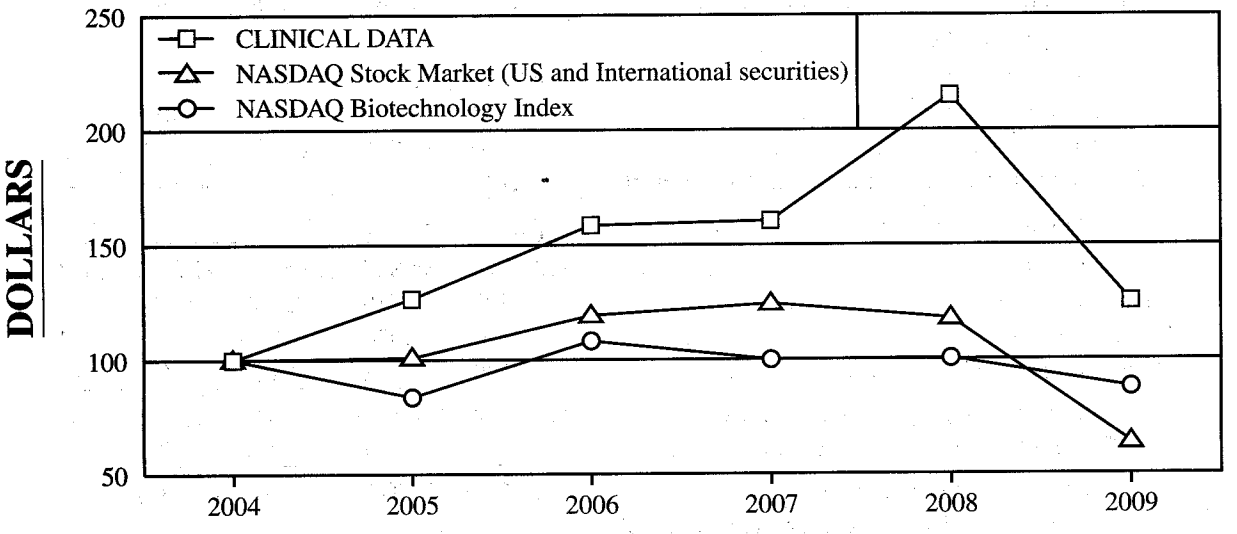
Dividends

We have not declared any cash dividends during either of the past two fiscal years. 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.

Price Performance

The following performance graph compares the performance of our cumulative stockholder return with that of one broad market index, the NASDAQ U.S. and Foreign Index, and a published industry or line of business index, the NASDAQ Biotech Index.

Comparison of 5 Year Cumulative Total Return
Assumes Initial Investment of $100



Company/NASDAQ Stock Market/Nasdaq Biotechnology Index	3/31/2004	3/31/2005	3/31/2006	3/31/2007	3/31/2008	3/31/2009
CLINICAL DATA	100.00	126.48	158.50	160.34	214.94	125.14
NASDAQ Stock Market (US and International securities)	100.00	100.91	119.18	124.21	117.74	63.68
NASDAQ Biotechnology Index	100.00	83.61	108.11	99.85	100.36	87.75

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 Affecting the Comparability of the Selected Consolidated Financial Data

As described above in Item 1, we acquired the following three (3) businesses:

Acquiree	Date of Acquisition
Genaissance Pharmaceuticals, Inc.	October 6, 2005
Epidauros Biotechnologie A.G.	August 23, 2007
Adenosine Therapeutics	August 4, 2008

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. These transactions are described in further detail in Note 4 to consolidated financial statements.

Further, we have discontinued certain operations that are now classified as discontinued operations. These transactions are described in further detail in Note 3 to consolidated financial statements.

	Years Ended March 31,				
	2009	2008	2007	2006	2005
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data					
Revenues	$ 10,442	$ 5,107	$ 3,828	$ 1,660	$ —
Cost of revenues	6,489	2,627	2,240	3,045	—
Gross profit	3,953	2,480	1,588	(1,385)	—
OPERATING EXPENSES:					
Research and development	44,134	16,889	9,265	2,797	—
Sales and marketing	7,764	3,612	1,210	408	—
General and administrative	19,730	16,806	14,959	6,919	863
Purchased in-process research and development	55,100	—	—	36,300	—
Total operating expenses	126,728	37,307	25,434	46,424	863
Operating loss	(122,775)	(34,827)	(23,846)	(47,809)	(863)
Interest expense	(1,802)	(76)	(220)	(228)	(31)
Interest income	716	2,020	323	61	2
Other income (expense), net	179	305	210	(59)	10
Loss from continuing operations before taxes	(123,682)	(32,578)	(23,533)	(48,035)	(882)
Benefit from (provision for) income taxes	—	230	(233)	(102)	—
Loss from continuing operations	(123,682)	(32,348)	(23,766)	(48,137)	(882)
Income (loss) from discontinued operations, net of taxes	(8,756)	(2,982)	(13,756)	(2,744)	4,277
Net (loss) income	(132,438)	(35,330)	(37,522)	(50,881)	3,395
Preferred stock dividend	—	—	(104)	(97)	—
Net (loss) income applicable to common stockholders	$(132,438)	$(35,330)	$(37,626)	$(50,978)	$3,395
Loss (income) per basic and diluted share:					
Continuing operations	$ (5.63)	$ (1.69)	$ (1.68)	$ (5.39)	$ (0.13)
Discontinued operations	(0.40)	(0.16)	(0.97)	(0.30)	0.65
Net (loss) income	$ (6.03)	$ (1.85)	$ (2.65)	$ (5.69)	$ 0.52
Cash dividends paid per common share	$ —	$ —	$ —	$ 0.04	$ 0.07
Weighted average shares:					
Basic and diluted	21,962	19,081	14,186	8,953	6,584

	As of March 31,				
	2009	2008	2007	2006	2005
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 56,355	$ 67,480	$14,071	$ 7,225	$ 4,171
Total assets	120,917	129,448	87,490	109,789	41,130
Long-term obligations	63,123	5,122	3,236	7,345	—
Stockholders' equity	29,412	106,075	50,720	59,789	23,809

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 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 United States 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

We are a biotechnology company with a primary focus on the development of therapeutics. Our late-stage compounds include: (i) vilazodone — a potential first-in-class drug candidate for the treatment of depression, which recently completed its second Phase III trial successfully; and (ii) apadenoson, which is trademarked under the name Stedivaze, — a potential best-in-category vasodilator for use in myocardial perfusion imaging, which is entering its Phase III clinical trial program.

Our sources of liquidity as of March 31, 2009 include our cash, cash equivalents and marketable securities balance of approximately $56.4 million. This amount does not include approximately $13.1 million in proceeds from the sale of our Cogenics segment in April 2009. Our projected uses of cash include cash used to fund operations, capital expenditures, existing debt service costs and continued research and product development.

We believe that our cash and cash availability will be sufficient to fund our operations at least through December 2009. We will need additional funds to continue development of vilazodone and Stedivaze beyond December 2009. The sale of any equity or debt securities may result in additional dilution to our stockholders, and 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 financing, we may be required to reduce the scope and timing of the planned clinical and pre-clinical programs, which could harm our financial condition and operating results.

Therapeutics:

Vilazodone

Vilazodone, a novel dual-acting serotonergic antidepressant, is a potent and selective serotonin reuptake inhibitor, or SSRI, a first line therapy for major depressive disorder, and a partial agonist of the 5-hydroxytryptamine 1a, or 5-HT_{1A}, receptor, a first-line therapy for anxiety disorders. Vilazodone has greater *in vitro* potency and selectivity for serotonin reuptake than compounds such as fluoxetine. *In vitro* binding studies also indicate that vilazodone has a greater potency for the 5-HT_{1A} receptor than specific 5-HT_{1A} ligands such as buspirone [*Journal of Medicinal Chemistry 47: 4684-4692, 2004*]. There is evidence that a partial 5-HT_{1A} agonist, taken in combination with an SSRI for the treatment for major depressive disorder, may reverse the adverse sexual side effects induced by the SSRI [*Journal of Clinical Psychopharmacology 19(3): 268-71, 1999*]. Thus, we expect vilazodone not to induce adverse sexual side effects associated with SSRIs in the market today.

Our second Phase III vilazodone clinical trial has been completed. In the study, vilazodone achieved statistically significant results on the primary endpoint and secondary efficacy endpoints related to major depressive disorder. Top-line study results suggest that vilazodone was generally well-tolerated and the efficacy and safety data were consistent with the findings from the previous Phase III trial. In addition, study findings corroborate that there was no impairment of sexual function as measured by a validated scale. This is an important finding since many antidepressants have been associated with causing or exacerbating sexual dysfunction. A statistically significant improvement in the symptoms of anxiety associated with major depressive disorder was also observed. Separately, the Phase III study also sought to replicate a proprietary biomarker associated with response to vilazodone from the first Phase III trial. Although this preselected biomarker did not replicate, analyses remain ongoing.

Based on the results of these and additional activities, including the manufacture of registration batches of the active pharmaceutical ingredient and the commercial product, we intend to file an NDA for vilazodone with the FDA by the end of calendar year 2009.

Stedivaze

Stedivaze is a selective adenosine receptor 2A, or A_{2A}, agonist in development as a vasodilator used for myocardial perfusion imaging. We plan to launch our Phase III clinical development program for Stedivaze in the next several months. Phase II data showed potential best-in-category attributes with an improved adverse event profile over the current standard of care and favorable pharmacokinetic and target binding affinity profiles. We conducted an End of Phase II meeting with the FDA in January 2009. Based on this meeting, we believe that we have reached agreement with the FDA on the overall design elements for our Phase III trial program. Our Phase III trial protocol has been submitted to the FDA and we are awaiting comment. Stedivaze could be marketed by us directly to providers or partnered as a complementary and valuable to the pipelines of other well-established biotechnology and specialty healthcare companies.

If we are successful in Phase III clinical development, there is no assurance that we will be successful marketing Stedivaze. We believe that Stedivaze has the potential to be well differentiated and become the best-in-category. In addition, while some new modalities offer growth potential to work adjunctively with Stedivaze, other diagnostic imaging techniques may be developed in the coming years that will limit the market for myocardial perfusion imaging.

Other Therapeutic Products

We are developing ATL844 as an oral therapeutic for the treatment of asthma and/or diabetes, both of which are multi-billion dollar growing markets. Working through antagonism of the adenosine A_{2B} receptor sub-type, the compound has shown significant responses in animal models of both asthma and diabetes. We are proceeding with a toxicology and chemistry program, and with success, we will proceed to an investigation new drug, or IND, filing. ATL844 is the subject of an option agreement to an exclusive license purchased by Novartis.

ATL1222 is a highly selective agonist of the adenosine A_{2A} receptor subtype that is in development for the treatment of acute inflammatory conditions. The compound has shown significant responses in animal models of a number of inflammatory mediated diseases, and has demonstrated a lack of toxicity in both rodent and primate toxicology models at doses expected to be therapeutically relevant. ATL1222 is currently in later stage toxicology development, and with success, we will proceed to an IND filing.

ATL313 is a selective agonist of the adenosine A_{2A} receptor subtype that is targeted as a treatment for ophthalmic disease. The compound has shown significant effect in both small and large animal models of disease. ATL313 is the subject of a confidential collaboration with a larger pharmaceutical partner, who has an option to the ophthalmic program. This compound may be well positioned to be used in other major indications and some work is being conducted currently to identify and advance these opportunities.

In June 2008, Avalon announced that it had identified a compound for clinical development, named AVN316. This compound has good pharmacological properties and potently inhibits the beta-catenin pathway in a variety of model systems. Avalon is currently conducting lead optimization efforts around AVN316 and has synthesized compounds in this family that kill human cancer cells *in vitro*, cause a cell cycle arrest that is characteristic of inhibition of the beta-catenin pathway, and cause a dose dependent decrease in beta-catenin protein levels. Studies with these compounds in animal models have shown good pharmacological properties, bioavailability, modulation of pharmacodynamic markers, and growth inhibition in tumor xenograft studies. To date, Avalon is not aware of any specific inhibitors of the beta-catenin pathway that are on the market or in clinical development.

Genetic Tests

We are pursuing additional tests for complex and difficult to diagnose diseases and syndromes that will complement our *FAMILION* family of tests. These activities are required to reduce the cost of delivery and to increase laboratory capacity relating to delivery of our tests, enhance scalability of lab operations as demand grows for our tests, drive adoption of existing tests, commercialize new tests and enhance reimbursement for the tests, among other key metrics.

We have also made significant progress in our efforts to contract with private and government health insurers for test coverage and reimbursement. Our work with private insurers resulted in the *FAMILION* LQTS, BrS, and *FAMILION* Family tests receiving S-codes effective October 2008 followed by the *FAMILION* HCM and *FAMILION* Family tests receiving S-codes effective April 2009. We expect that S-codes should speed the adoption of these tests by private insurers. In October 2008, we became an in-network provider with Aetna for healthcare coverage of our *FAMILION* LQTS and Family tests. We are utilizing our national contract with the BCBS Association signed in December 2008 to work with individual BCBS companies to provide their customers with access to our *FAMILION* Family of Tests. In addition, we are an approved Medicare provider for our genetic testing services, and a Medicaid provider in 39 states and the District of Columbia. These providers and other private payers with positive coverage policies offer access to genetic testing for nearly 200 million patients. The positive changes to the reimbursement landscape for our genetic tests demonstrate our commitment to working with private and government payers to improve patient access to these vital tests.

Financial Operations Overview

Revenue. The majority of our revenue is from services related to genetic tests. We maintain relationships with certain healthcare providers as well as healthcare insurance companies; revenue from these arrangements is recognized net of contractual allowances.

Cost of Revenue. Cost of revenue consists primarily of salaries and related expenses for personnel, including stock-based compensation expense, laboratory expenses, depreciation, and facility costs.

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

Research and Development Expense. Research and development expense consists primarily of fees paid to professional service providers in conjunction with independent monitoring of 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, salaries and related expenses for personnel, including stock-based compensation expense, costs of materials, depreciation, rent, utilities and other facilities costs. In addition, research and development expenses include the cost to in-license technologies to support current development efforts. We expense research and development costs as incurred.

General and Administrative Expense. General and administrative expense consists primarily of salaries and other related costs for personnel, including stock-based compensation expense, 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 of Adenosine Therapeutics and Avalon that had not yet reached technological feasibility, defined as being equivalent to FDA approval, and had no alternative use at their date of its acquisition. Such costs were expensed in accordance with 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, cash equivalents and marketable securities. Other income (expense), net consists primarily of foreign currency gains (losses).

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 United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue, allowances for doubtful accounts, 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 majority of our current revenue is from services related to genetic tests. We maintain relationships with certain healthcare providers as well as healthcare insurance companies; revenue from these arrangements is recognized net of contractual allowances. Revenue is also derived from fees for licenses of intellectual property.

Allowance for Doubtful Accounts and Contractual Allowances — Allowances for doubtful accounts are maintained for estimated losses resulting from the inability of our customers to make required payments. These estimated allowances of $1.3 million, $500,000 and $346,000 at March 31, 2009, 2008 and 2007, respectively, are periodically reviewed, analyzing the customers' payment history and information known to us regarding customers' credit worthiness as well as the contract terms and history of collections with third-party payors. The increase in 2009 reflects the increase in revenue. If the financial condition of our customers were to deteriorate additional allowances may be required. Actual losses incurred and contractual write-offs have not been significantly different than management's estimates in recent history.

Valuation of Intangibles and Goodwill — As discussed in Note 4 to the consolidated financial statements, we completed one business combination during fiscal 2006, one in fiscal 2008 and one in fiscal 2009. 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 $6.5 million and goodwill totaling $29.5 million. 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%.

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, 2008, the most recent evaluation date, there was no impairment of goodwill. Following the disposal of our Cogenics segment, we operate as a single operating segment and expect to have a single reporting unit. Our fair value will be measured using our market capitalization; however, given our significant accumulated deficit, our carrying value is significantly lower than our market capitalization as of March 31, 2009.

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.

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 for 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.

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, 2009, we had federal tax net operating loss carryforwards, after limitation for changes in ownership of acquired entities, of $206.7 million, which expire starting in 2011, federal tax credit carryforwards of $2.7 million and net deferred tax assets of $115.5 million. We have recorded a valuation allowance of $115.5 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.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued Statement No. 157, *Fair Value Measurements,* or SFAS 157. SFAS 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice resulting from the application of this Statement relate to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. SFAS 157 was effective for us beginning on April 1, 2008 and did not have a significant impact on our financial statements. In February 2008, the FASB deferred the implementation of SFAS 157 for certain non-financial assets and liabilities; that portion of SFAS 157 will become effective for us beginning on April 1, 2009. We are evaluating the impact of SFAS No. 157, if any, related to certain non-financial assets and liabilities on our consolidated financial statements.

In July 2007, the Emerging Issues Task Force, or EITF, issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities,* or EITF 07-3. EITF 07-3 clarifies the accounting for nonrefundable advance payments for goods or services that will be used or rendered for research and development activities. EITF 07-3 states that such payments should be capitalized and recognized as an expense as the goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or the services rendered, the capitalized advance payment should be charged to expense. EITF 07-3 was effective for us on April 1, 2008 and did not have a significant impact on our financial statements as we typically don't have any advance payments for research and development activities.

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements,* or EITF 07-1. EITF 07-1 requires participants in a collaborative arrangement to report costs incurred and revenue generated from transactions with third parties in the income statement. EITF 07-1 is effective for us beginning on April 1, 2009. We are currently evaluating the effect of EITF 07-1 on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations,* or SFAS 141R. SFAS 141R retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in the Statement. That replaces SFAS 141's cost-allocation process, which required the cost of an acquisition to be allocated to the individual assets acquired and liabilities assumed based on their estimated fair values. The Statement retains the guidance in SFAS 141 for identifying and recognizing intangible assets separately from goodwill. SFAS 141R requires the acquiring entity to recognize in process research and development at fair value at the date of acquisition and subsequently account for it as an indefinite-lived intangible asset until completion or abandonment of the associated research and development efforts. SFAS 141R will now require acquisition costs to be expensed as incurred, restructuring costs associated with a business combination must generally be expensed prior to the acquisition date and changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date generally will affect income tax expense. SFAS 141R applies prospectively to our business combinations for which the acquisition date is on or after April 1, 2009. See Note 3 — Business Combinations for further discussion related to the impact of adopting SFAS 141R.

In June 2008, the FASB ratified EITF 07-5, *Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity's Own Stock* (EITF 07-5). EITF 07-5 provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. EITF 07-5 also clarifies the impact of exercise prices that are denominated in a foreign currency and valuation consideration of market-based employee stock options. EITF 07-5 is effective for the Company beginning April 1, 2009. We are currently evaluating the effect of EITF 07-5 on our consolidated financial statements.

In April 2009, the FASB issued three FASB Staff Positions, or FSPs, related to fair value measurement and disclosure. FSP FAS 157-4, *Determining Fair Value when the Volume and Level of Activity for the Asset or Liability have Significantly Decreased and Identifying Transactions that are not Orderly,* provides additional guidance on the factors that should be considered in estimating fair value when there has been a significant decrease in market

activity for an asset or liability. The FASB also issued FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-than-Temporary Impairments*, amending the accounting guidance for other-than-temporary impairments of debt securities and the disclosure requirements of equity securities and debt securities. The FASB also issued FSP FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. FSP 107-2 and APB 28-1 require the disclosure of fair value for assets and liabilities within the scope of SFAS 107, *Disclosures about Fair Value of Financial Instruments*, for interim periods. These pronouncements are not expected to have a material impact on our financial position or results of operations but will require additional disclosures once adopted. We will adopt these FSPs during the quarter ended June 30, 2009.

Results of Operations

Fiscal Year Ended March 31, 2009 Compared to Fiscal Year Ended March 31, 2008

Revenue. Revenue increased $5.3 million, or 104%, from $5.1 million in fiscal 2008 to $10.4 million in fiscal 2009. This increase was solely driven by the increase in sales of our genetic tests of $5.3 million, or 116%, from the same period a year ago. The introduction of our new commercial sales and marketing team in September 2007 and increased coverage from third-party payors, such as Medicare, Medicaid and Aetna, has had a significant impact on revenue. As of March 31, 2009, we are an approved Medicare provider for our genetic testing services, and a Medicaid provider in 39 states and the District of Columbia, up from just seven states in January 2008. In an effort to continue the acceleration of revenue growth, we continued to expand and invest in the development of our sales force and have expanded our service offerings by adding two new genetic tests in fiscal 2009: Hypertrophic Cardiomyopathy, or HCM, was launched in May 2008 and Arrhythmogenic Right Ventricular Cardiomyopathy, or ARVC, was launched in November 2008. We expect to continue to expand our sales force, third-party payor base and our product offerings in fiscal 2010.

Gross Profit. Gross profit margins decreased from 49% in fiscal 2008 to 38% in fiscal 2009. Gross margins for fiscal 2009 were 38% compared with 49% for fiscal 2008. However, in fiscal 2009, our gross margins increased from 28% in the first fiscal quarter to 49% in the fourth fiscal quarter. The decline from fiscal 2008 to 2009 was primarily due to the exclusion of shared infrastructure costs which were born by the Cogenics segment in early fiscal 2008, and planned investment in our infrastructure, equipment and a new laboratory information system, which were designed to increase productivity and lab efficiencies. Gross margins are expected to improve as infrastructure improvements drive efficiencies. Our cost structure, which includes personnel, equipment and facilities, is largely fixed in nature, thus, as revenue increases our gross margin should increase.

Research and Development Expense. Research and development expenses increased $27.2 million to $44.1 million for fiscal 2009, or 161%, from $16.9 million for the year ended March 31, 2008. The increase is primarily related to the recently completed vilazodone safety and Phase III confirmatory trials, which began in December 2007 and March 2008, respectively, and to a lesser extent, costs incurred with advancing the Adenosine Therapeutics pipeline since the acquisition date for its clinical and pre-clinical programs. We expect our ongoing research and development costs to continue to increase as we prepare for the NDA filing for vilazodone and begin our Stedivaze Phase III clinical trials and In addition, stock-based compensation expense charged to research and development expense increased $775,000 for the year ended March 31, 2009 to $1.3 million from $523,000 for the same period in fiscal 2008.

Sales and Marketing Expense. Sales and marketing expenses increased $4.2 million to $7.8 million for fiscal 2009, or 115%, from $3.6 million for the year ended March 31, 2008. The increase was principally due to a full year of expense relating to our sales force and marketing team. In fiscal 2008 and 2009, we implemented plans to aggressively expand our sales force. Although we expect to continue to expand our sales force, increasing expense in this area should take place at a lower rate as we build upon an already established organization. Stock-based compensation expense charged to sales and marketing increased $507,000 for the year ended March 31, 2009 to $1.1 million from $564,000 for the same period in fiscal 2008.

General and Administrative Expense. General and administrative expenses increased $2.9 million to $19.7 million for fiscal 2009, or 17%, from $16.8 million for the year ended March 31, 2008. The increase was, in part, the result of an increase in stock-based compensation charged to general and administrative expense of $1.0 million for the year ended March 31, 2009 to $5.5 million from $4.5 million for the same period in fiscal 2008.

Purchased In-Process Research and Development Expense. Purchased in-process research and development expense of $55.1 million for the year ended March 31, 2009 includes $3.0 million related to the May 2009 acquisition of Avalon and $52.1 million related to the acquisition of Adenosine Therapeutics. Because the nature and economics of the term loan were to fund the losses of Avalon, we have recognized in our financial statements a portion of the losses incurred by Avalon during the period from October 27, 2008 to March 31, 2009 as purchased in-process research and development expense. The amount recognized was determined based upon a ratable allocation of the net loss of Avalon during the period from October 27, 2008 to March 31, 2009 and the consideration of the proceeds of the term loan relative to the total cash available to Avalon prior to receipt of the proceeds of the term loan. The $52.1 million related to the acquisition of Adenosine Therapeutics represents the fair value of the in-process research and development projects at Adenosine Therapeutics at the date of its acquisition, in particular Stedivaze. Stedivaze was valued based on discounted future cash flows. We prepared revenue and expense projections as well as technology assumptions through 2025 for Stedivaze. The revenue for Stedivaze was 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 expected remaining costs to complete Stedivaze. We discounted the projected cash flows using a risk adjusted discount rate and considered the probability of success, where appropriate. The rate utilized to discount the net cash flows to their present values was the internal rate of return, or IRR, based on the purchase price paid. Management believed that the IRR reflected the difficulties and uncertainties in completing the project and thereby achieving technological feasibility, the stage of completion of the 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 considerations, the IRR of 24% was deemed an appropriate discount for valuing the IPRD. Since the cost relates to a project that had not yet reached technological feasibility, defined as being equivalent to FDA approval, and which had no alternative use at the date of acquisition, the costs were expensed during fiscal 2009. There were no such costs in fiscal 2008.

Interest and Other Income (Expense), Net. Interest expense increased $1.7 million from $76,000 in fiscal 2008 to $1.8 million in fiscal 2009. This increase was primarily due to the interest on the notes issued in connection with the Adenosine Therapeutics acquisition and to a lesser extent the interest on the convertible notes issued in February 2009. Interest income decreased $1.3 million from $2.0 million in fiscal 2008 to $716,000 in fiscal 2009. We expect interest income to continue to decline as our invested cash, cash equivalents and marketable securities balances decrease. Other income, net decreased $126,000 to $179,000 in fiscal 2009 from $305,000 in fiscal 2008.

Fiscal Year Ended March 31, 2008 Compared to Fiscal Year Ended March 31, 2007

Revenue. Revenue increased $1.3 million, or 33%, to $5.1 million in fiscal 2008 from $3.8 million in fiscal 2007. This increase was primarily driven by the increase in sales of our genetic tests of $1.3 million, or 41%, from the same period a year ago. The introduction of our new commercial sales and marketing team in September 2007 had a notable impact on revenue for the last half of fiscal 2008.

Gross Profit. Gross profit margins increased from 41% in fiscal 2007 to 49% in fiscal 2008. The increase was largely due to the increase in revenue. Our cost structure, which includes personnel, equipment and facilities, is largely fixed in nature, thus, as revenue increases our gross margin should increase due to leveraging of an economy of scale.

Research and Development Expense. Research and development expenses increased $7.6 million to $16.9 million in fiscal 2008, or 82%, from $9.3 million in fiscal 2007. The increase is primarily related to a $3.6 million equity payment made to Merck associated with the successful completion of the first vilazodone Phase III clinical trials as well as the initiation of the vilazodone Phase III confirmatory and safety trials. During fiscal 2007, we recorded a $1.6 million equity milestone charge for manufacturing rights acquired from Merck.

Sales and Marketing Expense. Sales and marketing expenses increased $2.4 million to $3.6 million in fiscal 2008, or 199%, from $1.2 million in fiscal 2007. The increase was due primarily to the development of a new sales and marketing function within PGxHealth, including the hiring of a new sales force and senior level sales and marketing management. In addition, stock-based compensation expense charged to sales and marketing expense was $564,000 in fiscal 2008 compared to $0 in fiscal 2007.

General and Administrative Expense. General and administrative expenses increased $1.8 million to $16.8 million in fiscal 2008, or 12%, from $15.0 million in fiscal 2007. The increase was primarily the result of the increase in stock-based compensation expense charged to general and administrative expense of $1.9 million in fiscal 2008 to $4.5 million from $2.6 million in fiscal 2007.

Interest and Other Income (Expense), Net. Interest expense decreased $144,000 from $220,000 in fiscal 2007 to $76,000 in fiscal 2008. Interest income increased $1.7 million from $323,000 in fiscal 2007 to $2.0 million in fiscal 2008. As a result of the financing transaction completed in July 2007 for net proceeds of $71.4 million, we invested our cash not required to fund current operations in interest bearing assets. Other income, net increased $95,000 to $305,000 in fiscal 2008 from $210,000 in fiscal 2007.

Liquidity and Capital Resources

We had cash, cash equivalents and marketable securities of approximately $56.4 million at March 31, 2009. Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table:

	Year End March 31,		
	2009	2008	2007
		(In thousands)	
Cash (used in) provided by:			
Operating activities	$(60,250)	$(24,532)	$(12,874)
Investing activities	(7,074)	(5,190)	753
Financing activities	69,885	69,984	18,447
Effect of exchange rate	(2,136)	422	520
Increase in cash and cash equivalents	$ 425	$ 40,684	$ 6,846

Significant sources and uses of cash flows during the fiscal year ended March 31, 2009 were as follows:

- In February 2009, we completed a $50.0 million convertible debt financing.
- In October 2008 concurrent with the Avalon merger agreement, we entered into the following transactions with Avalon:
  - Purchased 3.4 million shares of Avalon's common stock for $237,000;
  - Entered into a royalty free, fully-paid, worldwide, perpetual, irrevocable, sub-licensable, exclusive license agreement to use the AvalonRx platform for a one-time access fee of $1.0 million; and
  - Funded a $4.0 million term loan payable May 31, 2009, as amended.
- In September 2008, we sold approximately 1.5 million shares of our common stock for net proceeds of $25.0 million.
- In August 2008, we acquired Adenosine Therapeutic for approximately $10.7 million in cash, net of $301,000 purchase price adjustment.

Our total debt obligations were $74.3 million at March 31, 2009.

The following table summarizes our contractual obligations at March 31, 2009, excluding the Cogenics segment, and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Fiscal 2010	Fiscal 2011 through Fiscal 2012	Fiscal 2013 through Fiscal 2014	After Fiscal 2014
			(In thousands)		
Contractual Obligations(1):					
Short and long-term debt(2)	$116,517	$12,602	$22,669	$16,666	$64,580
Capital lease obligations(2)	1,048	804	229	15	—
Operating lease obligations	1,264	998	266	—	—
Total contractual cash obligations . .	$118,829	$14,404	$23,164	$16,681	$64,580

(1) Excludes the obligations of our Cogenics segment, which was sold on April 14, 2009

(2) Includes interest expense

Currently, we do not enter into financial instruments for trading or speculative purposes.

During fiscal 2009, we made capital expenditures of approximately $1.7 million primarily to introduce new products, improve production processing of existing and planned product offerings and to upgrade our laboratory information systems.

Our sources of liquidity as of March 31, 2009 include our cash, cash equivalents and marketable securities balance of approximately $56.4 million. This amount does not include approximately $13.1 million from the sale of our Cogenics segment, which closed on April 14, 2009. Our projected uses of cash include cash used to fund operations, capital expenditures, existing debt service costs and continued research and product development.

We believe that our cash and cash availability will be sufficient to fund our operations at least through December 2009. We will need additional funds to continue development of vilazodone and Stedivaze beyond December 2009. The sale of any equity or debt securities may result in additional dilution to our stockholders, and 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 financing, we may be required to reduce the scope and timing of the planned clinical and pre-clinical programs, which could harm our financial condition and operating results.

Off-Balance Sheet Arrangements

We do not have any special purpose entities or other off-balance sheet arrangements.

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

We are exposed to market risks, which include changes in interest rates, changes in credit worthiness and liquidity of our marketable securities.

Interest Rate Risk

We use a combination of fixed rate term loans and fixed rate leases to partially finance our activities. Our long-term debt and capital leases are all at fixed rates over their lives and carry no interest rate risk.

Auction Rate Preferred Securities

At March 31, 2009, we held auction rate preferred securities, or ARPS, with a par value of $1.2 million, which approximates fair value. The investments at March 31, 2009 consisted of preferred stock issued by closed end mutual funds; none of the auction rate securities in our portfolio are mortgage-backed. The most recent auctions for the ARPS in our investment portfolio failed. Our goal is to liquidate these securities as soon as possible; however, as

a result of the failed auctions we continue to hold these securities and the issuers continue to pay interest at the maximum contractual rate. Based on current market conditions, it is likely that auctions related to these securities will be unsuccessful in the near term. Unsuccessful auctions will result in our holding these securities beyond their next scheduled auction reset dates, thus limiting the short-term liquidity of these investments. While these failures in the auction process have affected our ability to access these funds in the near term, we do not believe that the underlying securities or collateral have been adversely impacted. We believe that the higher reset rates on failed auctions provide sufficient incentive for the security issuers to address this lack of liquidity. If the credit rating of the security issuers deteriorates or the liquidity issues persist, we may be required to adjust the carrying value of these investments through an impairment charge. Based on our ability to access our cash, our expected operating cash flows, and our available credit lines, we do not anticipate the current lack of liquidity in these investments to have a material impact on our financial condition or results of operation.

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*

(a) Evaluation of Disclosure Controls and Procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as of the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of March 31, 2009. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of March 31, 2009 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

(b) Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our company's internal control over financial reporting is a process designed under the supervision of our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of our management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on the financial statements.

There are inherent limitations in the effectiveness of any internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal controls can provide only reasonable assurances with respect to financial statement preparation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our company's internal control over financial reporting as of March 31, 2009. In making this assessment, management used the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on management's assessment and those criteria, management determined that we maintained effective internal control over financial reporting as of March 31, 2009.

Deloitte & Touche LLP, our independent registered public accounting firm, has issued their report on the effectiveness of our internal control over financial reporting, which appears below.

Changes in Internal Controls

There have been no changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities and Exchange Act) during the quarter ended March 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the internal control over financial reporting of Clinical Data, Inc. and subsidiaries (the Company) as of March 31, 2009, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management's Annual Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on that risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2009, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended March 31, 2009, of the Company and our report dated June 12, 2009, which report expressed an unqualified opinion on those financial statements and included an explanatory paragraph concerning doubt about the Company's ability to continue as a going concern.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
June 12, 2009

ITEM 9B. *OTHER INFORMATION*

None.

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

The information required in this item will be contained in our definitive Proxy Statement to be filed with the Securities and Exchange Commission (SEC) in connection with our 2009 Annual Meeting of Stockholders (the Proxy Statement) under the headings "Election of Directors'," "Board of Directors and Committees of the Board" and "Executive Officers and Corporate Governance" and is incorporated herein by reference.

ITEM 11. *EXECUTIVE COMPENSATION*

The information required in this item is incorporated by reference to the Proxy Statement under the heading "Executive Compensation."

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

The information required in this item is incorporated by reference to the Proxy Statement under the heading "Security Ownership of Management" and "Security Ownership of Certain Beneficial Holders."

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

The information required in this item is incorporated by reference to the Proxy Statement under the heading "Certain Transactions and Business Relationships."

ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*

The information in required in this item is incorporated by reference to the Proxy Statement under the heading "Principal Accountant Fees and Services."

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*

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this Annual Report on Form 10-K.

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 15, 2009.

CLINICAL DATA, INC.

/s/ Andrew J. Fromkin

Andrew J. Fromkin
President and Chief Executive Officer
(Principal Executive Officer)

Dated: June 15, 2009

/s/ C. Evan Ballantyne

C. Evan Ballantyne
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Dated: June 15, 2009

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 15, 2009

/s/ Andrew J. Fromkin

Andrew J. Fromkin
President and Chief Executive Officer, Director

Dated: June 15, 2009

/s/ Larry D. Horner

Larry D. Horner
Director

Dated: June 15, 2009

/s/ Arthur B. Malman

Arthur B. Malman
Director

Dated: June 15, 2009

/s/ Burton E. Sobel

Burton E. Sobel
Director

Dated: June 15, 2009

/s/ Richard J. Wallace

Richard J. Wallace
Director

Dated: June 15, 2009

CLINICAL DATA, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders 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, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended March 31, 2009. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements for the year ended March 31, 2009 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, recurring losses and cash used in operations and the expectation that the Company will continue to incur operating losses in the future raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of March 31, 2009, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated June 12, 2009 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
June 12, 2009

CLINICAL DATA, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	March 31, 2009	March 31, 2008
	(In thousands, except share and per share amounts)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 55,180	$ 54,755
Marketable securities, at fair value	1,175	—
Accounts receivable, net	2,471	1,243
Prepaid expenses and other current assets	1,240	678
Assets of discontinued operations	18,541	6,903
Total current assets	78,607	63,579
Marketable securities, at fair value	—	12,725
Property, plant and equipment, net	2,942	1,978
Goodwill	29,496	29,496
Intangible assets, net	4,747	5,353
Other assets, net	4,405	257
Assets of discontinued operations	—	16,060
TOTAL ASSETS	$ 120,197	$ 129,448
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Current portion of long-term debt	$ 6,337	$ 816
Current portion of capital leases	730	138
Accounts payable	5,562	3,354
Accrued expenses	6,131	4,421
Liabilities of discontinued operations	8,902	9,522
Total current liabilities	27,662	18,251
Long-Term Liabilities:		
Long-term debt, net of current portion	46,832	1,740
Capital lease obligations, net of current portion	226	445
Other long-term liabilities	26	26
Contingent acquisition costs (Note 3)	16,039	—
Liabilities of discontinued operations	—	2,911
Total long-term liabilities	63,123	5,122
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Preferred Stock, $.01 par value, 1,500,000 shares authorized; none issued and outstanding respectively	—	—
Common stock, $.01 par value, 60,000,000 shares authorized; 22,742,000 and 21,151,000 shares issued at March 31, 2009 and 2008, respectively; 22,742,000 and 21,136,000 shares outstanding at March 31, 2009 and 2008, respectively	227	212
Additional paid-in capital	276,788	221,059
Accumulated deficit	(251,204)	(118,766)
Treasury stock, -0- and 15,000 shares held in treasury at March 31, 2009 and 2008, respectively	—	(47)
Accumulated other comprehensive income	3,601	3,617
Total stockholders' equity	29,412	106,075
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 120,197	$ 129,448

See notes to consolidated financial statements.

CLINICAL DATA, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended March 31,		
	2009	2008	2007
	(In thousands, except share and per share amounts)		
Revenues	$ 10,442	$ 5,107	$ 3,828
Cost of revenues	6,489	2,627	2,240
Gross profit	3,953	2,480	1,588
OPERATING EXPENSES:			
Research and development	44,134	16,889	9,265
Sales and marketing	7,764	3,612	1,210
General and administrative	19,730	16,806	14,959
Purchased in-process research and development	55,100	—	—
Total operating expenses	126,728	37,307	25,434
Operating loss	(122,775)	(34,827)	(23,846)
Interest expense	(1,802)	(76)	(220)
Interest income	716	2,020	323
Other income, net	179	305	210
Loss from continuing operations before taxes	(123,682)	(32,578)	(23,533)
Benefit from (provision for) income taxes	—	230	(233)
Loss from continuing operations	(123,682)	(32,348)	(23,766)
Loss from discontinued operations, net of taxes	(8,756)	(2,982)	(13,756)
Net loss	(132,438)	(35,330)	(37,522)
Preferred stock dividend	—	—	(104)
Net loss applicable to common stockholders	$(132,438)	$(35,330)	$(37,626)
Loss per basic and diluted share:			
Continuing operations	$ (5.63)	$ (1.69)	$ (1.68)
Discontinued operations	(0.40)	(0.16)	(0.97)
Net loss	$ (6.03)	$ (1.85)	$ (2.65)
Weighted average shares:			
Basic and diluted	21,962	19,081	14,186

See notes to consolidated financial statements.

CLINICAL DATA, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED MARCH 31, 2009, 2008 AND 2007

	Preferred Stock Shares	Preferred Stock Par Value	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Deferred Compensation	Accumulated Other Comprehensive Income	Total	Comprehensive Loss
			(In thousands)								
BALANCE at April 1, 2006	234	$ 2	12,780	$128	$105,102	$ (45,810)	$ (47)	$(318)	$ 732	$ 59,789	
Conversion of Series A preferred stock into common stock	(50)	—	75	1	(1)	—	—	—	—	—	
Adoption of FAS 123R	—	—	—	—	(318)	—	—	318	—	—	
Exercise of stock options	—	—	153	1	574	—	—	—	—	575	
Private placement of equity, net of transaction costs of $63	—	—	1,560	16	16,840	—	—	—	—	16,856	
Exercise of stock warrants	—	—	286	3	3,702	—	—	—	—	3,705	
Dividends accrued on preferred stock	—	—	—	—	—	(104)	—	—	—	(104)	
Common stock issued for Merck license	—	—	154	1	1,622	—	—	—	—	1,623	
Purchase of treasury stock	—	—	—	—	—	—	(234)	—	—	(234)	
Retirement of treasury stock	—	—	(24)	—	(234)	—	234	—	—	—	
Issuance of warrants	—	—	—	—	120	—	—	—	—	120	
Equity issued in connection with acquisitions	—	—	23	—	347	—	—	—	—	347	
Stock-based compensation	—	—	26	—	4,631	—	—	—	—	4,631	
Translation adjustment	—	—	—	—	—	—	—	—	934	934	$ 934
Net loss	—	—	—	—	—	(37,522)	—	—	—	(37,522)	(37,522)
Total comprehensive loss											$ (36,588)
BALANCE at March 31, 2007	184	2	15,033	150	132,385	(83,436)	(47)	—	1,666	50,720	
Conversion of Series A preferred stock into common stock	(184)	(2)	276	3	(1)	—	—	—	—	—	
Exercise of stock options	—	—	199	2	1,751	—	—	—	—	1,753	
Exercise of stock warrants	—	—	162	2	2,561	—	—	—	—	2,563	
Issuance of common stock, net of transaction costs of $4.5 million	—	—	5,175	52	71,312	—	—	—	—	71,364	
Common stock issued for Merck license	—	—	135	1	3,618	—	—	—	—	3,619	
Conversion of convertible debt	—	—	140	2	2,335	—	—	—	—	2,337	
Stock-based compensation	—	—	31	—	6,985	—	—	—	—	6,985	
Other	—	—	—	—	113	—	—	—	—	113	
Translation adjustment	—	—	—	—	—	—	—	—	2,451	2,451	$ 2,451
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	(500)	(500)	(500)
Net loss	—	—	—	—	—	(35,330)	—	—	—	(35,330)	(35,330)
Total comprehensive loss											$ (33,379)
BALANCE at March 31, 2008	—	—	21,151	212	221,059	(118,766)	(47)	—	3,617	106,075	
Exercise of stock options	—	—	38	—	209	—	—	—	—	209	
Exercise of stock warrants	—	—	17	—	—	—	—	—	—	—	
Issuance of common stock and warrants, net of transaction costs of $36	—	—	1,515	15	24,949	—	—	—	—	24,964	
Warrants issued in connection with the convertible notes	—	—	—	—	10,767	—	—	—	—	10,767	
Beneficial conversion feature of the convertible notes	—	—	—	—	10,428	—	—	—	—	10,428	
Retirement of treasury stock	—	—	(15)	—	(47)	—	47	—	—	—	
Stock-based compensation	—	—	36	—	9,423	—	—	—	—	9,423	
Translation adjustment	—	—	—	—	—	—	—	—	(1,838)	(1,838)	$ (1,838)
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	1,822	1,822	1,822
Net loss	—	—	—	—	—	(132,438)	—	—	—	(132,438)	(132,438)
Total comprehensive loss											$(132,454)
BALANCE at March 31, 2009	—	$—	22,742	$227	$276,788	$(251,204)	$ —	$ —	$ 3,601	$ 29,412	

See notes to consolidated financial statements.

CLINICAL DATA, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended March 31,		
	2009	2008	2007
		(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(132,438)	$(35,330)	$(37,522)
Less loss from discontinued operations	8,756	2,982	13,756
Loss from continuing operations	(123,682)	(32,348)	(23,766)
Adjustments to reconcile loss from continuing operations to net cash used in operating activities:			
Depreciation and amortization	1,670	673	539
Purchased in-process research and development	55,100	—	—
Stock-based compensation including Merck license	8,130	9,523	4,702
Accretion of discount on convertible note	106	—	—
Loss on sales of equipment	51	10	—
Changes in current assets and liabilities, net of acquired assets and liabilities:			
Accounts receivable	(1,228)	(323)	(176)
Prepaid expenses and other current assets	(553)	(319)	157
Other assets	155	(229)	41
Accounts payable and accrued expenses	3,664	4,522	(446)
Other liabilities	(2)	—	—
Cash used in continuing operations	(56,589)	(18,491)	(18,949)
Cash (used in) provided by discontinued operations	(3,661)	(6,041)	6,075
Net cash used in operating activities	(60,250)	(24,532)	(12,874)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of equipment	(1,241)	(511)	(241)
Proceeds from sales of equipment	—	84	—
Purchases of marketable securities	—	(15,275)	—
Proceeds from sale of marketable securities	12,050	2,050	—
Cash used in business combinations, net of cash acquired	(16,850)	(11,997)	(222)
Cash used in investing activities — continuing operations	(6,041)	(25,649)	(463)
Cash (used in) provided by investing activities — discontinued operations	(1,033)	20,459	1,216
Net cash (used in) provided by investing activities	(7,074)	(5,190)	753

(continued)

See notes to consolidated financial statements.

CLINICAL DATA, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended March 31,		
	2009	2008	2007
		(In thousands)	
CASH FLOWS FROM FINANCING ACTIVITIES:			
Borrowings under other debt arrangements	50,000	—	18
Payment on debt and capital leases	(3,703)	(413)	(589)
Proceeds from the sale of common stock and warrants, net of transaction costs	24,964	71,364	20,561
Purchase of treasury shares	—	—	(234)
Exercise of stock options and warrants	209	4,316	575
Cash provided by financing activities — continuing operations	71,470	75,267	20,331
Cash (used in) provided by financing activities — discontinued operations	(1,585)	(5,283)	(1,884)
Net cash provided by financing activities	69,885	69,984	18,447
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(2,136)	422	520
NET INCREASE IN CASH AND CASH EQUIVALENTS	425	40,684	6,846
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	54,755	14,071	7,225
CASH AND CASH EQUIVALENTS, END OF PERIOD	$55,180	$54,755	$14,071
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Interest	$ 930	$ 76	$ 220
Income taxes	$ —	$ —	$ —
Non-cash investing and financing transactions:			
Equipment acquired through capital leases	$ 307	$ 567	$ 279
Accrued acquisition costs	$ 207	$ —	$ —
Debt issued in business acquisitions	$25,200	$ —	$ —
Equity issued to acquired technology rights	$ —	$ 3,619	$ 1,623
Issuance of common stock upon note conversion	$ —	$ 2,337	$ —
Warrants issued in connection with amendment of convertible note payable	$ —	$ —	$ 120
Accrued preferred stock dividends	$ —	$ —	$ 146
Equity issued in business acquisitions	$ —	$ —	$ 219

(concluded)

See notes to consolidated financial statements.

(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's main operating business is PGxHealth.

The Company is a biotechnology company with a primary focus on the development of therapeutics. Its late-stage compounds include: (i) vilazodone — a potential first-in-class drug candidate for the treatment of depression; and (ii) apadenoson, which is trademarked under the name Stedivaze — a potential best-in-class vasodilator for use in myocardial perfusion imaging.

As part of its decision to focus on therapeutics and genetic tests, the Company sold Vital Diagnostics Pty. ("Vital Diagnostics") in November 2006, Clinical Data Sales & Service ("CDSS") in June 2007, Vital Scientific BV ("Vital Scientific") in October 2007, Electa Lab s.r.l. ("Electa Lab"), in November 2007, and Cogenics, Inc., Epidauros Biotechnologie AG and Cogenics Genome Express S.A. (collectively "Cogenics") in April 2009. Accordingly, these operating units have been presented in the consolidated financial statements as discontinued operations. These transactions are described in more detail in Note 3 — Discontinued Operations.

Basis of Presentation

On August 4, 2008, the Company acquired the assets of Adenosine Therapeutics, LLC ("Adenosine Therapeutics"), a developer of drug products based on its extensive portfolio of composition of matter and method of use patents relating to selective adenosine receptor modulators (See Note 4 — Business Combinations).

On September 26, 2008, the Company closed a private placement of common stock in which it sold 1.5 million shares of common stock and warrants to purchase an additional 757,000 shares of common stock for net proceeds of $25.0 million, after transaction expenses of $36,000, to certain institutional investors, including the Chairman of the Company's Board of Directors and certain of his affiliates. The unit price was $16.50 per share. The exercise price of the warrants is $16.44. The warrants are exercisable any time after March 26, 2009 through March 26, 2014.

On October 27, 2008, the Company entered into a definitive merger agreement to acquire Avalon Pharmaceuticals, Inc. ("Avalon") for 800,641 shares of Clinical Data's common stock (See Note 4 — Business Combinations). Concurrent with the merger agreement, the Company purchased 19.9% of Avalon's issued and outstanding common stock for $237,000, provided a $3.0 million term loan to Avalon and provided an upfront cash payment of $1.0 million to Avalon in exchange for a royalty-free, exclusive worldwide license to Avalon's proprietary drug and biomarker discovery platform. On March 30, 2009, an additional $1.0 million was loaned to Avalon. On May 8, 2009, Avalon repaid the term loan in full. The merger with Avalon was completed on May 28, 2009.

On February 25, 2009, the Company sold (i) unsecured convertible notes of the Company (the "Notes"), in an aggregate principal amount of $50.0 million, bearing interest at a rate of 9.72% per year and maturing on February 25, 2017, and (ii) warrants (the "Warrants") to purchase an aggregate of 3,055,300 shares of the Company's common stock to certain accredited investors (the "Investors") affiliated with Randal J. Kirk, the Chairman of the Company's Board of Directors. The principal on the Notes convert, at the Investors' discretion, into the Company's common stock at a fixed price of $8.18 per share. Interest on the Notes is payable annually on its anniversary, with the first interest payment due on February 25, 2010. One half of the Warrants has an exercise price of $8.12, and the other half of the Warrants has an exercise price of $9.74. The Warrants are exercisable at any time after August 25, 2009 through August 25, 2014.

On April 14, 2009, the Company sold its Cogenics segment for $13.1 million in cash. An additional $2.5 million of cash is being held in escrow for a period of up to eighteen months.

The accompanying consolidated financial statements of the Company and subsidiaries 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.

At March 31, 2009, the Company had cash, cash equivalents and marketable securities totaling $56.4 million. The Company's projected uses of cash include cash to fund operations, including continued research and product development, sales and marketing, capital expenditures, existing debt service costs. The Company has undertaken several steps to improve liquidity and reduce its projected uses of cash, including the divestiture of non-core assets. The Company believes that its cash and cash availability will be sufficient to fund its operations at least through December 2009. This is based on a management's current operations and planned activities at normal levels and does not assume any cash inflows from partnerships, disposition of additional non-core assets or other dilutive or non-dilutive financings.

The Company will need additional funds to continue operations and the development of vilazodone, Stedivaze and other products, as well as the operations of Avalon, beyond December 2009. Management is always evaluating additional sources of financing and would consider any of the following options:

- partnering opportunities with pharmaceutical or biotechnology companies for the marketing of vilazodone;
- license, sublicense, or other sources of financing relating to the development programs of the recently acquired Adenosine Therapeutics' compounds and/or patents;
- sale of non-core assets; and/or
- sale of equity or debt securities.

As evidenced by the September 2008 and February 2009 private placements, the Company has been successful in raising capital with specific investors in the past. The Company believes that, if required, those same investors would consider providing capital in the future. However, the sale of any equity or debt securities may result in additional dilution to the Company's stockholders, and the Company cannot be certain that additional financing will be available in amounts or on terms acceptable to it, if at all. Additionally, the Company has from time to time strategically monetized non-core assets.

If the Company is unable to obtain financing, or enter into licensing, divestiture, or partnering arrangements on acceptable terms, the Company will be required to implement aggressive cost reduction strategies. The most significant portion of the research and development expenses, as well as some portion of sales and marketing expenses, are discretionary and are in anticipation of development and commercial launch of vilazodone and the development of Stedivaze and other adenosine compounds. These cost reduction strategies could reduce the scope of the activities related to these development and commercialization programs planned clinical and pre-clinical programs, development of other compounds and commercialization and development of other marker and test programs, which could harm the Company's long-term financial condition and operating results. The Company is prioritizing the various development projects that were acquired through the Adenosine Therapeutics and Avalon acquisitions to focus its critical resources on the most valuable assets. Similar to the vilazodone development, these projects are discretionary. However, the postponement or cancellation of any of these development efforts could have a material impact on the future value of these assets for the Company and its shareholders and on the Company's financial condition and operating results.

(2) Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned 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 money market accounts.

Marketable Securities

At March 31, 2009 and 2008, the Company held auction rate preferred securities ("ARPS") with a par value of $1.2 million and $13.2 million, respectively. The Company's investment in ARPS consists of variable-rate preferred shares in several closed-end mutual funds under one management investment company. These securities pay dividends and are tied to short-term interest rates with maturities on the face of the securities in excess of 90 days. The Company's investment in these auction rate securities are accounted for as available-for-sale securities under Statement of Financial Accounting Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities*.

At March 31, 2008, the fair values of these securities were estimated utilizing a discounted cash flow analysis (a level 3 input as defined in SFAS No. 157, *Fair Value Measurements* ("SFAS No. 157")). As a result of this analysis and the lack of evidence as to the near term liquidity of these instruments, these securities were classified as non-current assets and the Company recorded an unrealized loss of $500,000 to accumulated other comprehensive income in the consolidated balance sheet at March 31, 2008.

During the year ended March 31, 2009, ARPS with a par value of $12.0 million have been redeemed at par. As a result of these redemptions by the issuer and expected continued redemptions, the Company believes that the par value of the remaining ARPS approximates the fair value as of March 31, 2009 and has classified these securities as current assets and reversed the aforementioned unrealized loss of $500,000 from accumulated other comprehensive income in the consolidated balance sheet at March 31, 2009.

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:

	2009	2008	2007
	(In thousands)		
Allowance for uncollectible accounts — beginning of year	$ 500	$346	$151
Provisions	1,015	189	272
Less: deductions	(223)	(35)	(77)
Allowance for uncollectible accounts — end of year	$1,292	$500	$346

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 the fixed asset over their estimated useful lives. The estimated useful lives, by asset classification, are as follows:

Asset Classification	Useful Lives
Laboratory equipment	2-7 years
Leasehold improvements	Lesser of useful life or lease term
Computer equipment	3-7 years
Furniture and fixtures	2-7 years

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that 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.

Goodwill and Intangibles

The Company's goodwill is not being amortized and intangibles, which primarily consist of completed technology and customer relationships, are being amortized over their useful lives.

The Company completed its annual impairment test of goodwill, as required by SFAS No. 142, *Goodwill and other Intangible Assets*, as of December 31, 2008 and concluded that there was no impairment of goodwill. In performing the most recent annual goodwill assessment, the Company concluded that the Company was comprised of two reporting units. The Company continues to reevaluate its internal reporting and management structure. Management expects that future impairment tests will be performed based upon the newly formed segment reporting and related identification of reporting units. The 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.

Intangibles are 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.

Revenue Recognition

The majority of the Company's current revenue is from services related to genetic tests. The Company maintains relationships with certain healthcare providers as well as healthcare insurance companies; revenue from these arrangements is recognized net of contractual allowances.

Revenue is also derived from fees for licenses of intellectual property, which is recognized as earned.

Research and Development Costs

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

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.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions and other issues. Prior to April 1, 2007, these reserves were recorded when management determined that it was probable that a loss would be incurred related to these matters and the amount of the loss was reasonably determinable. Effective April 1, 2007, the Company adopted Financial Accounting Standard Board ("FASB") Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ("FIN 48"). As a result, reserves recorded subsequent to adoption are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is "more likely than not" to be realized following resolution of any potential contingencies present related to the tax benefit, assuming that the matter in question will be raised by the tax authorities. The Company's policy is to record penalties with respect to income tax assessments as general and administrative expenses whereas interest associated with such uncertain tax positions is recorded as interest expense.

Comprehensive Loss

Comprehensive loss includes charges and credits to equity that are not the result of transactions with stockholders. Included in other comprehensive loss for the Company are the cumulative translation adjustments related to the net assets of the foreign operations and changes in unrealized gains and losses on marketable securities. These adjustments are accumulated within the consolidated statements of stockholders' equity under the caption accumulated other comprehensive loss.

The components of accumulated other comprehensive income were as follows:

	March 31,	
	2009	2008
	(In thousands)	
Foreign currency translation adjustment	$2,279	$4,117
Unrealized loss on marketable securities	—	(500)
Unrealized gain on investment in Avalon	1,322	—
Total	$3,601	$3,617

Foreign Currency

Assets and liabilities of the Company's foreign subsidiaries denominated in foreign currency are translated to United States dollars at year-end exchange rates and income statement accounts are translated at weighted-average rates in effect. For those subsidiaries whose functional currency is other than the United States dollar, the translation adjustment into United States 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. Foreign exchange gains and (losses) were not material in the periods presented.

Loss per Share

Basic net loss per share is determined by dividing net loss applicable to common stockholders by the weighted average shares of common stock outstanding during the period. Diluted net loss per share is determined by dividing net loss applicable to common stockholders by diluted weighted average shares outstanding. Net loss applicable to common stockholders is determined after consideration of preferred stock dividends, which were not material for any period presented. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as common stock options and warrants calculated using the treasury stock method and convertible preferred stock and convertible notes using the "if-converted" method.

The following dilutive securities were not included in the diluted earnings per share calculations as at March 31, 2009, 2008 and 2007 because the inclusion of these amounts would have been anti-dilutive because the Company has a net loss:

	2009	2008	2007
		(In thousands)	
Common stock options	3,630	2,539	2,010
Common stock warrants	4,567	1,011	1,183
Convertible note payable	6,110	—	134
Restricted common stock	—	—	12
Convertible Series A preferred stock	—	—	276
Total	14,307	3,550	3,615

Equity-Based Compensation

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.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist primarily of cash, cash equivalents, marketable securities and accounts receivable. The Company maintains substantially all of its cash, cash equivalents and marketable securities 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. During fiscal 2009, 2008 and 2007, there were no significant customers.

Fair Value of Financial Instruments

The Company's financial instruments consist of accounts receivable, marketable securities, accounts payable, capital leases and long-term debt. SFAS No. 157 establishes a fair value hierarchy, which classifies fair value measurements based on the inputs used in measuring fair value. These inputs include: Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The carrying amounts of accounts receivable and accounts payable are considered reasonable estimates of their fair value, due to the short maturity of these instruments. Based on the borrowing rates currently available to the Company for capital leases and long-term debt with similar terms and average maturities as the Company's instruments, the fair value of capital leases and long-term debt was not significantly different than the carrying value at March 31, 2009.

The following table presents information about the assets and liabilities measured at fair value on a recurring basis as of March 31, 2009:

Description	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$37,659	$—	$ —	$37,659
Marketable securities — ARPS	—	—	1,175	1,175
Marketable securities — Avalon common stock	1,560	—	—	1,560

Assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) are as follows:

	Auction Rate Securities
	(In thousands)
Balance at March 31, 2008	$ 12,725
ARPS redeemed at par	(12,050)
Reversal of unrealized loss recorded in other comprehensive income	500
Balance at March 31, 2009	$ 1,175

Segment and Geographical Information

SFAS No. 131, *Disclosures About Segments of an Enterprise and Related Information*, requires certain financial and supplementary information to be disclosed for each reportable operating segment of an enterprise, as defined. Prior to the quarter ended March 31, 2009, the Company operated its business as two reporting segments: PGxHealth and Cogenics.

As discussed in Notes 1 and 3, the Company disposed of its Cogenics segment unit on April 14, 2009. This transaction has significantly changed the focus of the Company. During the quarter ended March 31, 2009 and into fiscal 2010, management has modified and expects to continue to modify its management structure and internal reporting to align with the new strategic focus of the Company. For the year ended March 31, 2009, the Company has reported its business as a single reporting segment as there is limited discrete financial information for any of the Company's individual products or service offerings as well as the fact that the Company's chief decision maker, who is the Chief Executive Officer, regularly evaluates the Company on a consolidated basis. As the management structure and internal reporting structure are refined, the Company will re-assess its reporting segments.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS 157, which establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice resulting from the application of this Statement relate to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. SFAS 157 was effective for the Company beginning on April 1, 2008 and did not have a significant impact on the Company's financial statements. In February 2008, the FASB deferred the implementation of SFAS 157 for certain non-financial assets and liabilities; that portion of SFAS 157 will become effective for the Company beginning on April 1, 2009. The Company is evaluating the impact of SFAS No. 157, if any, related to certain non-financial assets and liabilities on the consolidated financial statements.

In July 2007, the Emerging Issues Task Force ("EITF") issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities* ("EITF 07-3"). EITF 07-3 clarifies the accounting for nonrefundable advance payments for goods or services that will be used or rendered for research and development activities. EITF 07-3 states that such payments should be capitalized and recognized as an expense as the goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or the services rendered, the capitalized advance payment should be charged to expense. EITF 07-3 was effective for the Company on April 1, 2008 and did not have a significant impact on the consolidated financial statements as the Company typically does not have any advance payments for research and development activities.

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, ("EITF 07-1"). EITF 07-1 requires participants in a collaborative arrangement to report costs incurred and revenue generated from transactions with third parties in the income statement. EITF 07-1 is effective for the Company

beginning on April 1, 2009. The Company is currently evaluating the effect of EITF 07-1 on the consolidated financial statements.

In December 2007, FASB issued SFAS No. 141 (revised 2007), *Business Combinations* ("SFAS 141R"). SFAS 141R retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS No. 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in the Statement. That replaces SFAS 141's cost-allocation process, which required the cost of an acquisition to be allocated to the individual assets acquired and liabilities assumed based on their estimated fair values. The Statement retains the guidance in SFAS 141 for identifying and recognizing intangible assets separately from goodwill. SFAS 141R requires the acquiring entity to recognize in-process research and development at fair value at the date of acquisition and subsequently account for it as an indefinite-lived intangible asset until completion or abandonment of the associated research and development efforts. SFAS 141R will now require acquisition costs to be expensed as incurred, restructuring costs associated with a business combination must generally be expensed prior to the acquisition date and changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date generally will affect income tax expense. SFAS 141R applies to the Company prospectively to business combinations for which the acquisition date is on or after April 1, 2009.

In June 2008, the FASB ratified EITF 07-5, *Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity's Own Stock* ("EITF 07-5"). EITF 07-5 provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. EITF 07-5 also clarifies the impact of exercise prices that are denominated in a foreign currency and valuation consideration of market-based employee stock options. EITF 07-5 is effective for the Company beginning April 1, 2009. The Company is currently evaluating the effect of EITF 07-5 on the consolidated financial statements.

In April 2009, the FASB issued three FASB Staff Positions, or FSPs, related to fair value measurement and disclosure. FSP FAS 157-4, *Determining Fair Value when the Volume and Level of Activity for the Asset or Liability have Significantly Decreased and Identifying Transactions that are not Orderly*, provides additional guidance on the factors that should be considered in estimating fair value when there has been a significant decrease in market activity for an asset or liability. The FASB also issued FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-than-Temporary Impairments*, amending the accounting guidance for other-than-temporary impairments of debt securities and the disclosure requirements of equity securities and debt securities. The FASB also issued FSP FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. FSP 107-2 and APB 28-1 requires the disclosure of fair value for assets and liabilities within the scope of SFAS 107, *Disclosures about Fair Value of Financial Instruments*, for interim periods. These pronouncements are not expected to have a material impact on the Company's financial position or results of operations but will require additional disclosures once adopted. The Company will adopt these FSPs during the quarter ended June 30, 2009.

(3) Discontinued Operations

During fiscal 2009, 2008 and 2007, the Company determined that the Cogenics segment, Vital Scientific and Electa Lab, and Vital Diagnostics and CDSS, respectively, did not fit with the Company's strategic direction. Management believed that the Company's capital resources and the cash derived from the sale of these businesses could be better allocated to investments and growth opportunities to increase the Company's presence in the therapeutics and genetic testing markets. Accordingly, the Company has classified these businesses as discontinued operations and their results of operations, financial position and cash flows are separately reported for all periods presented.

Vital Diagnostics

On November 13, 2006 the Company sold Vital Diagnostics, a distributor of scientific instrumentation, equipment and reagents in Australia and New Zealand, for net proceeds of $1.0 million. The buyer was funded by Adrian Tennyenhuis, Vital Diagnostic's general manager and holder of a 7.5% minority interest, and New River Management IV, LP ("NRM"), an affiliate of Third Security LLC, which is controlled by Randal J. Kirk, the Chairman of the Company's Board of Directors. The Company recorded a loss on disposal of $178,000 in connection with the sale in the fiscal year ended March 31, 2007.

CDSS

On June 18, 2007, the Company sold CDSS, a distributor of scientific instrumentation, equipment and reagents, and lab management and consulting services, to Vital Diagnostics Holding Corp. ("VDHC"), which is funded and controlled by NRM, for proceeds at closing of $7.0 million. During the year ended March 31, 2007, the Company recorded a loss of $7.0 million to adjust the net assets of CDSS to fair value. Based on the final closing working capital adjustments and the costs of the transaction, an additional loss of $635,000 was recognized in the year ended March 31, 2008.

Vital Scientific

On October 25, 2007, the Company sold Vital Scientific, a manufacturer and distributor of clinical laboratory instrumentation and related assays, to the ELITech Group, an unrelated third-party, for total proceeds of $15.0 million. A gain of $8.6 million was recorded in fiscal 2008.

On April 9, 2008, the ELITech Group paid €200,000 as additional consideration based on the final closing balance sheet resulting in a total gain on the sale of Vital Scientific of $8.9 million. The additional gain of approximately $315,000 was recognized in the first quarter of fiscal 2009.

Electa Lab

On November 14, 2007, the Company sold Electa Lab, a manufacturer and distributor of clinical laboratory instrumentation and related assays, to Vital Diagnostics B.V. ("VDBV"), which is funded and controlled by NRM, for $2.5 million. A loss of $38,000 from the sale was recorded in the year ended March 31, 2008.

Cogenics

In March 2009, the Company entered into a letter of intent to sell its Cogenics segment, which was comprised of Cogenics, Inc., Epidauros Biotechnologie AG, and Cogenics Genome Express S.A., a provider of genomic services. Cogenics was sold on April 14, 2009 for proceeds of $13.1 million and a gain is expected to be recognized in the quarter ending June 30, 2009.

Summarized statement of operations data for Vital Diagnostics, CDSS, Vital Scientific, Electa Lab and the Cogenics segment for the years ended March 31, 2009, 2008 and 2007 is set forth below:

	2009	2008	2007
		(In thousands)	
Revenue	$27,018	$ 50,381	$ 84,665
Loss from Operations Before Disposal:			
Loss before taxes and minority interest	$(8,288)	$ (9,518)	$ (5,436)
Minority interest	—	—	(9)
Loss before taxes	(8,288)	(9,518)	(5,445)
Income taxes	(216)	(1,365)	(1,133)
Loss from discontinued operations, net of taxes	(8,504)	(10,883)	(6,578)
Disposal:			
Loss on disposal, net of taxes	(252)	7,901	(7,178)
Loss from discontinued operations, net of tax	$(8,756)	$ (2,982)	$(13,756)

Summarized balance sheet information for the discontinued operations at March 31, 2009 and 2008 is set forth below:

	March 31,	
	2009	2008
	(In thousands)	
Accounts receivable, net	$ 4,832	$ 5,047
Prepaid expenses and other current assets	1,678	1,856
Property, plant and equipment, net	5,708	7,191
Goodwill	1,416	1,584
Intangible assets, net	4,499	6,764
Other assets	408	521
Assets of discontinued operations	$18,541	$22,963
Current portion of capital leases and long-term debt	$ 1,397	$ 1,609
Accounts payable	1,731	2,779
Other accrued expenses	2,248	2,878
Customer advances	2,192	2,256
Capital leases and long-term debt, net of current portion	1,235	2,829
Other long-term liabilities	99	82
Liabilities of discontinued operations	$ 8,902	$12,433

(4) Business Combinations

Adenosine Therapeutics, LLC

On August 4, 2008, the Company acquired the assets of Adenosine Therapeutics, a developer of drug products, based on its extensive portfolio of composition of matter and method of use patents relating to selective adenosine receptor modulators. The Company paid $11 million in cash and entered into a $22 million five-year promissory note and a separate $3.2 million 32-month promissory note with the members of Adenosine Therapeutics, LLC (the "Sellers"). Contingent consideration of up to $30 million in cash may be paid upon the achievement of certain

regulatory and commercial milestones. Two compounds in the Adenosine Therapeutics pipeline are the subject of licensing option agreements. Novartis holds an option to partner on the development of ATL844, in pre-clinical study for the treatment of diabetes and asthma, and a confidential partner holds an option on another compound in pre-clinical development for an ophthalmic indication.

The acquisition of Adenosine Therapeutics significantly expands the Company's therapeutics offerings by adding a late-stage drug candidate, Stedivaze, for use as a cardiac perfusion agent and other early stage drug candidates in cardiology, diabetes, asthma, inflammatory diseases, and sickle cell anemia. Stedivaze is expected to enter Phase III clinical trials in calendar 2009.

In accordance with SFAS No. 141, *Business Combinations* ("SFAS No. 141"), the purchase price was allocated to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The estimated fair value of the assets acquired and liabilities assumed exceeded the initial payments by $15.7 million. Pursuant to SFAS No. 141, the Company recorded contingent consideration totaling $15.7 million as a liability. When the contingency is resolved and the consideration is issued or becomes issuable, any excess of the cost over the $15.7 million that was initially recognized as a liability shall be recognized as an additional cost of the acquired entity. If the fair value of the consideration issued or issuable is less than $15.7 million, that amount shall be allocated as a pro rata reduction of the amounts assigned to non-current assets acquired in accordance with SFAS No. 141. Any amount that remains after reducing those assets to zero shall be recognized as an extraordinary gain. The allocation of the purchase price remains subject to potential adjustments, including contingent consideration.

The purchase price provided for an adjustment to the cash purchase price and in January 2009 the Sellers refunded $301,000 to the Company. This adjustment was recorded during the quarter ended March 31, 2009 as a reduction to cash consideration with a corresponding increase to contingent acquisition costs, therefore having no effect on the purchase price.

The components of the preliminary purchase price allocation are as follows:

	(In thousands)
Cash	$10,699
Debt	25,200
Contingent acquisition costs	16,039
Transaction costs	400
	$52,338

	(In thousands)
Preliminary Purchase Price Allocation	
Prepaid expenses and other current assests	$ 9
Property and equipment	351
Other assets	23
Purchased in-process research and development costs	52,100
Accrued vacation	(47)
Capital lease obligations	(96)
Deferred rent	(2)
Total purchase price	$52,338

Of the total purchase price, $52.1 million was allocated to purchased in-process research and development ("IPRD") projects and was charged to operations at the date of acquisition. 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 FDA's approval.

The IPRD charge relates to Stedivaze, a selective A_{2A} adenosine receptor agonist in development as a vasodilator used for myocardial perfusion imaging. Phase II data showed potential best-in-category attributes with an adverse event profile showing improvement over the current market leader and a rapid onset and offset of action. Planned Phase III trials are expected to commence during the first half of calendar 2009.

Stedivaze was valued based on discounted future cash flows. The Company prepared revenue and expense projections as well as technology assumptions through 2025 for Stedivaze. The revenue for Stedivaze was 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 expected remaining costs to complete Stedivaze.

The Company discounted the projected cash flows using a risk adjusted discount rate and considered the probability of success, where appropriate. The rate utilized to discount the net cash flows to their present values was the internal rate of return ("IRR") based on the purchase price paid. Management believed that the IRR reflected the difficulties and uncertainties in completing the project and thereby achieving technological feasibility, the stage of completion of the 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 considerations, the IRR of 24% was deemed an appropriate discount for valuing the IPRD.

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 failure of Stedivaze to reach commercial success could have a material impact on the Company's expected results.

The results of operations of Adenosine Therapeutics have been included in the accompanying financial statements since the date of acquisition. Had the acquisition of Adenosine Therapeutics occurred at the beginning of the periods presented, the Company's pro forma results would have been as follows:

	Year Ended March 31,	
	2009	2008
	(In thousands) (Unaudited)	
Revenue	$ 11,411	$ 7,733
Net loss	(134,243)	(92,811)
Basic and diluted net loss per share	$ (6.11)	$ (4.86)

The pro forma net loss indicated above includes a charge of $52.1 million for purchased IPRD cost for all periods presented.

This unaudited pro forma financial information may not be representative or be indicative of what would have occurred had the acquisition been made at the beginning of the periods presented, or results which may occur in the future.

Avalon Pharmaceuticals, Inc.

On October 27, 2008, the Company entered into a definitive merger agreement to acquire Avalon for approximately 800,641 shares of Clinical Data's common stock. Additionally, as part of the merger, Clinical Data will issue contingent value rights to Avalon stockholders, of up to 200,160 additional shares of Clinical Data's common stock, upon the receipt of certain milestone payments that Avalon may receive under its collaboration agreements with Merck & Co., Inc. and Novartis Institute for Biomedical Research, Inc. prior to June 30, 2010. Avalon stockholders were asked to vote on the proposed transaction at a special meeting held on May 28, 2009 and

approved the transaction, which closed that same day. The combined company will have a significantly expanded oncology business with a pipeline of promising oncology biomarkers and compounds, and a biomarker discovery platform to identify additional therapeutic and diagnostic candidates.

In addition to the merger agreement, three additional definitive agreements were entered into by the companies: 1) a private placement; 2) a secured term loan agreement; and 3) an exclusive license to Avalon's drug and biomarker discovery platform.

As of March 31, 2009, the merger had not been consummated and accordingly, the financial position does not include the effects of the purchase accounting nor have the results of operations of Avalon been included for any period presented. The Company will account for this transaction as a purchase business combination in accordance with SFAS 141R in fiscal 2010. In accordance with SFAS 141R, the value of common stock issued in the transaction will be measured as of May 28, 2009. The transaction costs that have been incurred through March 31, 2009 totaling $721,000 that have been capitalized will be recognized upon the adoption of SFAS 141R on April 1, 2009. Transaction costs incurred after March 31, 2009 will be recognized as an expense as incurred. Finally, amounts allocated to in-process research and development will be recognized as an intangible asset and subject to amortization or impairment analysis.

Private Placement

The Company purchased 3.4 million shares of Avalon's common stock, equivalent to 19.9% of Avalon's issued and outstanding shares for a total purchase price of approximately $237,000. In addition, the Company received warrants to purchase up to an additional 1.7 million shares of Avalon's common stock at an exercise price of $0.86 per share. The warrants expired on May 28, 2009 upon the consummation of the merger.

The Avalon shares are accounted for in accordance with SFAS No. 115. As of March 31, 2009, the fair value of the Avalon shares was $0.46 per share, or $1.6 million, resulting in an unrealized gain of $1.3 million which is included in other comprehensive income on the accompanying balance sheet as of March 31, 2009.

The fair value of the Avalon shares, together with costs incurred as of March 31, 2009 of $721,000 associated with the merger, is recorded as prepaid merger consideration at March 31, 2009 and is included in other non-current assets in the accompanying balance sheet.

Term Loan

The Company provided a $3.0 million term loan to Avalon, secured by a first priority lien on all of Avalon's intellectual property. The loan bears interest at 7% and all principal and accrued interest was due the Company in full on March 1, 2009. On January 12, 2009, Avalon and the Company extended the maturity of the note until April 30, 2009. On March 30, 2009, the term loan was amended to provide an additional $1.0 million and to extend the maturity of the note until May 31, 2009. On May 8, 2009, Avalon repaid the term loan in full.

The Company provided the term loan to Avalon primarily to ensure that Avalon had sufficient cash to finance Avalon's development efforts on its therapeutic and diagnostic drug candidates during the period between the announcement of the transaction and the actual completion of the transaction. Because the nature and economics of the term loan were to fund the losses of Avalon, the Company has recognized in the Company's financial statements a portion of the losses incurred by Avalon during the period from October 27, 2008 to March 31, 2009. These losses have been reported within IPRD in the accompanying consolidated statement of operations for the year ended March 31, 2009. The amount recognized of $3.0 million was determined based upon a ratable allocation of the net loss of Avalon during the period from October 27, 2008 to March 31, 2009 and the consideration of the proceeds of the term loan relative to the total cash available to Avalon prior to receipt of the proceeds of the term loan. The classification of these losses as IPRD and development is considered appropriate given that substantially all of the losses incurred by Avalon during this period were comprised of research and development expenses. The difference between the amounts advanced under the term note of $4.0 million and the $3.0 million recognized as purchased in-

process research and development, has been capitalized as of March 31, 2009 and is included in other non-current assets in the accompanying balance sheet.

Exclusive License Agreement

The Company provided a cash payment of $1.0 million to Avalon in exchange for a royalty-free, exclusive worldwide perpetual license to Avalon's proprietary drug and biomarker discovery platform, AvalonRx®.

The amounts advanced under the licensing agreement are recorded as prepaid merger consideration at March 31, 2009 and are included in other non-current assets in the accompanying balance sheet.

(5) Property, Plant and Equipment

Property, plant and equipment consist of the following at March 31:

	2009	2008
	(In thousands)	
Laboratory equipment	$ 1,197	$ 517
Leasehold improvements	1,527	1,416
Computer equipment and software	2,022	938
Furniture and fixtures	187	143
	4,933	3,014
Less: accumulated depreciation and amortization	(1,991)	(1,036)
	$ 2,942	$ 1,978

Laboratory and computer equipment includes capital leases with a principal value of $859,000 and $583,000 at March 31, 2009 and 2008, respectively.

(6) Intangible Assets

The intangible asset balances are as follows at March 31:

	Average Useful Life	2009	2008
		(In thousands)	
Completed technology	8.4 years	$ 5,955	$ 5,955
Customer relationships	5.0 years	400	400
Other	7.0 years	100	100
		6,455	6,455
Less: accumulated amortization		(1,708)	(1,102)
Intangible assets, net		$ 4,747	$ 5,353

During fiscal 2009, 2008 and 2007, amortization of intangible assets totaled $606,000, $446,000 and $446,000, respectively.

Amortization with regard to the intangible assets at March 31, 2009 is expected to total, $887,000 in 2010, $849,000 in 2011, $807,000 in 2012, $711,000 in 2013, $607,000 in 2014 and $886,000 in 2015 and beyond.

(7) Accrued Expenses

Accrued expenses consist of the following at March 31:

	2009	2008
	(In thousands)	
Payroll and payroll-related expenses	$2,020	$2,800
Project expenses	1,147	—
Commissions, royalties and license fees	1,063	745
Other	1,901	876
	$6,131	$4,421

(8) Debt

The Company's long-term debt obligations are as follows at March 31:

	2009	2008
	(In thousands)	
Notes payable, bearing interest at 6.5%, with maturities between February 2009 and May 2011 and secured by certain of PGxHealth's leasehold improvements	$ 2,001	$2,556
Note payable, bearing interest at 11% with monthly principal payments of $100 through April 1, 2011, secured by substantially all of the assets of the Company	2,500	—
Note payable, bearing interest at 6% with quarterly principal payments of $1,000 through July 13, 2013, secured by substantially all of the assets of the Company	19,800	—
Convertible notes payable	50,000	—
	74,301	2,556
Less: current portion	(6,337)	(816)
unamortized discount	(21,132)	—
	$ 46,832	$1,740

Interest on the convertible notes is payable annually at a rate of 9.72% annually, with the first interest payment due on February 25, 2010. The principal on the Notes is prepayable at the option of the Company at no cost or penalty. Further, the holders of the Notes may elect to convert the Notes in part or in whole at any time into the Company's common stock at a fixed price of $8.18 per share. The Notes are unsecured.

The proceeds from the convertible notes totaling $50.0 million were allocated to detachable warrants issued in connection with the convertible notes and a beneficial conversion feature, which resulted in an aggregate debt discount of $21.2 million, which is being amortized over the term of the Notes using the effective interest method. The principal and interest on the convertibles notes, issued in February 2009, are convertible at any time into the Company's common stock at a conversion price of $8.18 per share. The Company recognized and measured the beneficial conversion feature of the convertible notes and associated warrants by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital. The difference between the effective conversion price and the fair value of the securities into which the debt is convertible at the commitment date resulted in a beneficial conversion feature on the convertible notes aggregating to $10.4 million. The beneficial conversion feature was recognized as a discount to the debt, which will be amortized over the term of the note. Amortization of the debt discount totaled $106,000 in fiscal 2009.

In accordance with the term of the convertible notes, the Company is restricted from incurring additional indebtedness, redeeming or declaring or paying any cash dividend or cash distribution on its common stock, or issuing or selling any rights, warrants or options to subscribe for or purchase its common stock or securities convertible into or exercisable for common stock at a price which is less than the then market price of the Company's common stock, other than in connection with an underwritten public offering.

The maturities of the long-term debt as of March 31, 2009 are as follows:

2010	$ 6,337
2011	6,635
2012	4,729
2013	4,400
2014	2,200
After	50,000
Total	$74,301

(9) Commitments and Contingencies

Litigation

The Company is, from time to time, subject to disputes arising in the normal course of business. While ultimate results of any such disputes cannot be predicted with certainty, at March 31, 2009, 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 consolidated financial statements.

Contractual Commitments and Commercial Obligations

The Company leases facilities, vehicles and computer equipment under operating and capital leases. Future minimum lease payments under these leases as of March 31, 2009, excluding the Cogenics segment, are as follows (in thousands):

Year Ending March 31,	Operating Leases	Capital Leases
2010	$ 998	$ 804
2011	244	130
2012	22	99
2013	—	15
2014	—	—
Thereafter	—	—
Total	$1,264	1,048
Less: amount representing interest		(92)
Total principal obligations		956
Less: current portion		(730)
Long-term capital lease		$ 226

Rent expense was $984,000, $356,000 and $160,000 during fiscal 2009, 2008 and 2007, respectively.

During fiscal 2009, 2008 and 2007, the Company financed equipment purchased under capitalized leases with a principal value of $307,000, $567,000 and $279,000, respectively.

Vilazodone Commitments

Under the terms of the Company's license agreement with Merck, if the Company is successful in the continuation of its development of vilazodone, the Company will be obligated to pay Merck certain additional milestone payments, all of which are payable in the Company's common stock. Specifically, a milestone payment of €12.5 million ($16.5 million at March 31, 2009) will be payable to Merck within 30 days of acceptance of an NDA filing in the United States or a Marketing Authorization Application ("MAA") filing in the European Union for the first indication of vilazodone. In addition, separate €9.5 million ($12.5 million at March 31, 2009) payments would each be payable to Merck within 30 days of receipt of approval of the NDA or MAA, and the first sale of vilazodone in the United States or the European Union, and Merck will also be entitled to certain royalty payments if the Company is successful in commercializing vilazodone. The Company may enter into sublicensing transactions with third parties subject to Merck's right of first negotiation with respect to co-development and co-commercialization of vilazodone.

Adenosine Therapeutics Acquisition Commitments

In connection with the acquisition of Adenosine Therapeutics, for a period of ten years following the closing, contingent consideration of up to $30 million (of which $16.0 million is recorded in long-term liabilities as of March 31, 2009) in cash may be paid by the Company to the Sellers upon the achievement of certain regulatory and commercial milestones as follows: (i) $5 million upon the approval by the FDA for sale in the United States of any product covered by any of Adenosine Therapeutics' patents (a "Seller Compound"); (ii) $10 million upon the initial achievement of $100 million in aggregate gross sales of any Seller Compound in any fiscal year; (iii) $15 million upon the initial achievement of $250 million in aggregate gross sales of any Seller Compound; and (iv) one-third of all licensing and/or sublicensing revenue received by the Company with respect to license and/or sublicense of any Seller Compound or any of Adenosine Therapeutics' patents, up to a maximum aggregate of $15 million payable to the Sellers; provided, however, (a) that all amounts up to the first $5 million paid to the Sellers under section (iv) shall offset on a dollar-for-dollar basis the payment required by section (i) above and (b) all amounts paid to the Sellers in excess of $5 million pursuant to section (iv) shall offset on a dollar-for-dollar basis the payment required by section (ii) above. Along with these acquisition costs, the Company has assumed all of Adenosine Therapeutics rights and obligations under licensing agreements with the University of Virginia Patent Foundation, the Public Health Service of the National Institutes of Health, the University of Massachusetts and the Penn State Research Foundation.

(10) Equity

Preferred Stock

In connection with the acquisition of Genaissance Pharmaceuticals, Inc. in October 2005, the Company authorized and issued 484,000 shares of Series A Preferred Stock. The Series A Preferred Stock had a par value of $0.01 per share. The Series A Preferred Stock was senior in right of payment of dividends and on liquidation to the common stock. During the year ended March 31, 2008, all remaining outstanding shares were converted to common stock. On June 10, 2008, the Board of Directors approved the elimination of the designation of the Series A Preferred Stock.

Common Stock

On June 10, 2008, The Board of Directors of the Company approved the restoration of the 15,000 shares of the Company's common stock held as treasury to the status of authorized but unissued shares of common stock.

On September 26, 2008, the Company closed a private placement of common stock in which it sold 1.5 million shares of common stock and warrants to purchase an additional 757,000 shares of common stock for net proceeds of $25.0 million, after transaction costs of $36,000, to certain institutional investors, including the Chairman of the

Company's Board of Directors. The unit price was $16.50 per share. The exercise price of the warrants is $16.44. The warrants are exercisable any time after March 26, 2009 through March 26, 2014.

On February 25, 2009, the Company closed a private placement in which it sold $50 million convertible notes convertible into 6.1 million shares of common stock and warrants to purchase 3.1 million shares of common stock for proceeds of $50.0 million to certain institutional investors, including the Chairman of the Company's Board of Directors. One half of the warrants have an exercise price of $8.12, equaling the closing bid price of the Company's common stock on the NASDAQ Global Market on the Closing Date, and the other half of the warrants have an exercise price of $9.74. The warrants are exercisable any time after August 25, 2009 through August 25, 2014.

As of March 31, 2009, the Company has warrants to purchase 4.6 million shares of the Company's common stock outstanding at an average exercise price of $11.53 per share. The warrants have an average remaining contractual term of 4.71 years.

(11) Income Taxes

The Company adopted FIN 48 effective April 1, 2007. FIN 48 clarifies and sets forth consistent rules for accounting for uncertain income tax positions in accordance with SFAS 109, *Accounting for Income Taxes* ("SFAS 109"). The effect of applying the provisions of this interpretation upon adoption was to reverse a tax contingency recorded in connection with the acquisition of Genaissance totaling $1.6 million against goodwill. There were no unrecognized tax benefits upon adoption and there have been no changes in unrecognized tax benefits since adoption.

The Company files income tax returns in the United States and several foreign countries. The Company remains subject to tax examinations in the following jurisdictions at March 31, 2009:

Jurisdiction	Tax Years
United States	2006-2009
United Kingdom	2006-2009
France	2006-2009
Germany	2004-2009

The components for loss before income taxes were as follows at March 31:

	2009	2008	2007
		(In thousands)	
United States	$(124,410)	$(31,272)	$(24,805)
Foreign	728	(1,306)	1,272
	$(123,682)	$(32,578)	$(23,533)

The provision for (benefit from) income taxes shown in the accompanying consolidated statements of operations consists of the following for fiscal 2009, 2008 and 2007:

	2009	2008	2007
		(In thousands)	
Current:			
Federal	$—	$ (16)	$ —
Foreign	—	(214)	197
Total Current	—	(230)	197
Deferred:			
Federal	—	—	192
Foreign	—	—	—
Change in valuation allowance	—	—	(156)
Total Deferred	—	—	36
	$—	$(230)	$ 233

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 2009, 2008 and 2007:

	2009	2008	2007
		(In thousands)	
Benefits from taxes at statutory rate	$(42,052)	$(11,076)	$(8,001)
Stock-based compensation	2,606	1,072	750
Change in valuation reserves	36,228	9,575	5,685
Other	3,218	199	1,799
	—	(230)	233

The income tax effect of each type of temporary difference comprising the net deferred tax (liability) asset at March 31 is as follows:

	2009	2008
	(In thousands)	
Deferred tax assets:		
Net operating losses	$ 81,695	$ 66,402
Capitalized research costs	6,730	10,480
Purchased intangibles	17,766	—
Capital losses	4,545	1,733
Tax credits	2,752	295
Other reserves and accrued liabilities	2,019	369
Total assets	115,507	79,279
Deferred tax liabilities:		
Purchased intangibles	—	(875)
Total liabilities	—	(875)
Net deferred tax asset	115,507	78,404
Less: valuation allowance	(115,507)	(78,404)
	$ —	$ —

SFAS No. 109 requires the Company to assess whether it is more likely than not that the Company will realize its deferred tax assets. 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 full valuation allowance has been provided for all periods.

The Company has United States federal net operating loss carryforwards, after limitation for a change in ownership, of $206.7 million; these carryforwards will expire from 2011 through 2029. In addition, the Company has available United States federal tax credit carryforwards of $2.7 million. These carryforwards which will expire between 2028 and 2029 may be used to offset future taxable income, if any. The Company has net operating loss carryforwards of $250.7 million for state purposes which expire from 2010 through 2029. Changes in the Company's ownership of, as defined in the United States Internal Revenue Code, as well as changes in ownership of acquired entities, may limit the Company's ability to utilize the tax credits and net operating loss carryforwards.

The Company has foreign net operating loss carryforwards of $1.1 million of which $243,000 are not subject to expiration and $904,000 that expire between 2017 and 2018.

(12) Stock Incentive Plans and Equity Based Compensation

In September 2002, the stockholders approved the establishment of the 2002 Incentive and Stock Option Plan (the "2002 Plan") under which an aggregate of 375,000 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 1.5 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 1.5 million to 3.0 million and (b) increased the maximum number of shares that may be awarded to any participant in any tax year from 225,000 to 750,000 shares. On September 23, 2008, the stockholders approved an amendment to the 2005 Plan to increase the aggregate number of shares issuable from 3.0 million to 4.6 million. All options are granted at not less than the fair market value of the stock on the date of grant. Substantially all awards are expected to rest.

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.

The following table summarizes stock option activity.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
	(In thousands, except for per share amounts)			
Outstanding April 1, 2008	2,539	$14.53		
Granted	1,256	12.93		
Cancelled/Expired	(123)	18.28		
Exercised	(42)	6.71		
Outstanding March 31, 2009	3,630	$13.61	8.1 years	$1,664
Exercisable March 31, 2009	1,625	$13.56	7.0 years	$ 326
Exercisable March 31, 2008	936	$14.19		
Available for future grants March 31, 2009	956			

The intrinsic value of options exercised during fiscal 2009, 2008 and 2007 was $377,000, $2.6 million and $1.2 million, respectively.

During fiscal 2009, 2008 and 2007, the Company granted 38,000, 31,000 and 24,000 shares of restricted common stock, respectively, to certain members of the Board of Directors; one-half vested immediately and the remainder vest one year after grant. The fair value of these shares totaled $587,000 or $16.00 per share in fiscal 2009, $707,000 or $23.03 per share in fiscal 2008, and $239,000 or $9.87 per share in fiscal 2007.

The following table presents the stock-based compensation expense for the period ended March 31:

	2009	2008	2007
		(In thousands)	
Cost of revenues	$ 258	$ 301	$ —
Sales and marketing	1,071	564	—
Research and development	1,298	523	474
General and administrative	5,503	4,515	2,605
Pre-tax stock based compensation expense	$8,130	$5,903	$3,079
Income tax benefits	—	—	—
Stock based compensation expense, net	$8,130	$5,903	$3,079

In addition, the Company expensed $1.3 million, $1.1 million and $1.6 million in net income (loss) from discontinued operations in fiscal 2009, 2008 and 2007, respectively.

As of March 31, 2009, there was $13.0 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements granted under the stock plans. That cost is expected to be recognized over a weighted average remaining period of 1.42 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 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 Bulletins 107 and 110 due to lack of history of employee exercises. The risk-free interest rate is based on zero-coupon United States 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.

For 2009, 2008 and 2007 the Company used the following assumptions to estimate the fair value of share-based payment awards:

	2009	2008	2007
Weighted-average interest rate	1.50 - 3.50%	2.75 - 4.75%	4.00-5.18%
Expected dividend yield	0.00%	0.00%	0.00%
Expected lives	6 years	6 years	5 - 6 years
Expected volatility	65 - 69%	71 - 79%	73 - 82%
Forfeiture rate	5.00%	0.00%	0.00%
Weighted average grant date fair value	$7.96	$12.30	$6.89

(13) Defined Contribution Plans

The Company sponsors defined contribution plans for its employees. Contributions and expenses incurred by the Company amounted to $220,000, $102,000 and $258,000 during fiscal 2009, 2008 and 2007, respectively.

(14) Related Party Transactions

The Company was billed for sales commissions by an affiliate of Mr. Kirk in the amount of $89,000 in fiscal 2007. There were no commissions in fiscal 2008 and 2009.

On June 9, 2006, the Company issued convertible promissory notes to two affiliates of Mr. Kirk. The lenders provided the Company with $2.0 million to fund working capital needs until such time as the Company 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 Company's 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 $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 1.6 million shares of common stock and warrants to purchase an additional 780,000 shares of common stock for net proceeds of $17.0 million, after transaction expenses of $63,000, to certain institutional investors, including certain members of the Board of Directors. The unit price was $10.85, which equaled the closing bid price of the Company's common stock on the NASDAQ on the closing date, plus $0.04 per share. The exercise price of the warrants is $12.97, 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 286,000 shares of common stock at a price of $12.97 for net proceeds to the Company of $3.7 million.

On November 13, 2006 the Company sold Vital Diagnostics for net proceeds of $1.0 million. The buyer was funded by Adrian Tennyenhuis, Vital Diagnostic's general manager and holder of a 7.5% minority interest, and NRM. The Company recorded a loss on disposal of approximately $178,000 in connection with the sale in the fiscal year ended March 31, 2007.

On June 18, 2007, the Company sold CDSS to VDHC for proceeds at closing of $7.0 million. During the year ended March 31, 2007, the Company recorded a loss of $7.0 million to adjust the net assets of CDSS to fair value. Based on the final closing working capital adjustments and the costs of the transaction, an additional loss of $635,000 was recognized in the year ended March 31, 2008.

On July 23, 2007, the Company sold approximately 3.4 million shares of its common stock to an affiliate of Mr. Kirk as part of the public offering.

On November 14, 2007, the Company sold Electa Lab to VDBV for $2.5 million. A loss of $38,000 from the sale was recorded in the year ended March 31, 2008.

On September 26, 2008, the Company sold an aggregate of 1.5 million shares of the Company's common stock and warrants to purchase an additional 757,000 shares of common stock, for an aggregate purchase price of $25.0 million to Mr. Kirk. The unit price was $16.50, which equaled the closing bid price of the common stock on the NASDAQ Global Market on the Closing Date, plus $0.06 per share. The exercise price of the Warrants is $16.44. The Warrants are exercisable at any time after March 26, 2009 through March 26, 2014.

On February 25, 2009 (the "Closing Date"), the Company sold to Investors affiliated with Mr. Kirk (i) Notes in an aggregate principal amount of $50.0 million, bearing interest at a rate of 9.72% per year and maturing on February 25, 2017, and (ii) warrants to purchase an aggregate of 3,055,300 shares of the Company's common stock. The principal on the Notes convert, at the Investors' discretion, into the Company's common stock at a fixed price of $8.18 per share, which equaled the closing bid price of the Company's common stock on the NASDAQ Global Market on the Closing Date plus $0.06 per share. Interest on the Notes is payable on each yearly anniversary of the Closing Date, with the first interest payment due on February 25, 2010. One half of the warrants has an exercise price of $8.12 and the other half of the warrants has an exercise price of $9.74. The warrants are exercisable at any time between August 25, 2009 and August 25, 2014.

(15) Quarterly Summarized Financial Information (Unaudited)

During the fourth quarter of fiscal 2009, the Company entered into an agreement to sell its Cogenics segment. As a result, the following quarterly financial information has been reclassified to reflect the operations of the Cogenics segment as discontinued operations.

	Fiscal year ended March 31, 2009			
	1st Quarter	2nd Quarter(1)	3rd Quarter	4th Quarter
	(In thousands, except per share amounts)			
Net revenue	$ 2,037	$ 2,400	$ 2,781	$ 3,224
Gross profit	564	856	964	1,567
Operating loss	(12,806)	(67,438)	(22,203)	(20,328)
Loss from continuing operations	(12,526)	(67,276)	(22,403)	(21,477)
Income (loss) from discontinued operations	(2,338)	(2,734)	(1,275)	(2,409)
Net loss	(14,864)	(70,010)	(23,678)	(23,886)
Net loss per basic and diluted share:				
Continuing operations	$ (0.59)	$ (3.17)	$ (0.98)	$ (0.94)
Discontinued operations	$ (0.11)	$ (0.13)	$ (0.06)	$ (0.11)

	Fiscal year ended March 31, 2008			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
	(In thousands, except per share amounts)			
Net revenue	$ 950	$ 1,137	$ 1,428	$ 1,592
Gross profit	551	767	356	806
Operating loss	(3,924)	(6,668)	(12,471)	(11,764)
Loss from continuing operations	(3,882)	(5,678)	(11,796)	(10,992)
Income (loss) from discontinued operations	(1,531)	(5,204)	7,447	(3,694)
Net loss	(5,413)	(10,882)	(4,349)	(14,686)
Net loss per basic and diluted share:				
Continuing operations	$ (0.26)	$ (0.30)	$ (0.56)	$ (0.52)
Discontinued operations	$ (0.11)	$ (0.27)	$ 0.36	$ (0.18)

(1) The operating loss for the quarter ended September 30, 2008 includes $52.1 million related to inprocess research and development expense arising from the acquisition of Adenosine Therapeutics.

EXHIBIT INDEX

Exhibit Number	Description
2.1	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.
2.2	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.
2.3	Agreement and Plan of Merger and Reorganization, dated as of October 27, 2008, by and among Clinical Data, Inc., API Acquisition Sub II, LLC and Avalon Pharmaceuticals, Inc. Filed as Exhibit 99.1 to Clinical Data's Current Report on Form 8-K, filed with the Commission on October 31, 2008, and incorporated herein by reference.
2.4	First Amendment to the Agreement and Plan of Merger and Reorganization, dated January 12, 2009, between Clinical Data, Inc., API Acquisition Sub II, LLC and Avalon Pharmaceuticals, Inc. Filed as Exhibit 2.2 to the Company's Registration Statement on Form S-4/A (File No. 333-156011), filed with the Commission on January 13, 2009, and incorporated herein by reference.
2.5	Second Amendment to the Agreement and Plan of Merger and Reorganization, dated March 30, 2009, between Clinical Data, Inc., API Acquisition Sub II, LLC and Avalon Pharmaceuticals, Inc. Filed as Exhibit 10.9 to the Company's Registration Statement on Form S-4/A (File No. 333-156011), filed with the Commission on April 2, 2009, and incorporated herein by reference.
2.6	Stock Purchase Agreement, dated April 1, 2009, among Clinical Data, Inc., Clinical Data B.V., Beckman Coulter, Inc., Beckman Coulter GmbH, and Beckman Coulter Holdings GmbH. Filed as Exhibit 2.1 to the Company's Current Report on Form 8-K/A, filed with the Commission on April 27, 2009, and incorporated herein by reference.
3.1	Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on June 11, 2008. Filed as Exhibit 3.2 to the Company's Annual Report on Form 10-K, filed with the Commission on June 16, 2008, and incorporated herein by reference.
3.2	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 Certificate of Contingent Value Rights to receive common stock. Filed herewith.
10.1	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.
10.2	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.
10.3	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.
10.4	Amended and Restated 2005 Equity Incentive Plan. Filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2007, and incorporated herein by reference.
10.5	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.
10.6*	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.

Exhibit Number	Description
10.7*	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.
10.8*	Executive Employment Agreement of C. Evan Ballantyne effective as of June 16, 2008. Filed as Exhibit 10.8 to the Company's Annual Report on Form 10-K, filed with the Commission on June 16, 2008, and incorporated herein by reference.
10.9*	Form of Amended and Restated Indemnification Agreement between the Company and Arthur Malman. 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.
10.10*	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.
10.11*	Amended and Restated Executive Employment Agreement of Carol R. Reed, M.D. effective as of June 16, 2008. Filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 11, 2008, and incorporated herein by reference.
10.12	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.
10.13	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.
10.14	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.
10.15	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.
10.16	Asset Purchase Agreement, dated August 4, 2008, by and among PGxHealth, LLC and Adenosine Therapeutics, L.L.C. Filed as Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 8, 2008, and incorporated herein by reference.
10.17	Share Purchase Agreement, dated as of August 23, 2007, among Clinical Data, Inc., Clinical Data B.V, and the stockholders of Epidauros Biotechnologie AG. Filed as Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 29, 2007, and incorporated herein by reference.
10.18	Stock Purchase Agreement, dated as of October 25, 2007, among Clinical Data, Inc., Clinical Data B.V, Financiere Elitech S.A.S. and Elitech Holding B.V. Filed as Exhibit 99.2 to the Company's Current Report on Form 8-K, filed with the Commission on October 30, 2007, and incorporated herein by reference.
10.19	Secured Promissory Note (Principal Amount $22,000,000), dated August 4, 2008, among PGxHealth, LLC and Adenosine Therapeutics, LLC. Filed as Exhibit 99.2 to the Company's Current Report on Form 8-K, filed with the Commission on August 8, 2008, and incorporated herein by reference.
10.20	Secured Promissory Note (Principal Amount $3,200,000), dated August 4, 2008, among PGxHealth, LLC and Adenosine Therapeutics, LLC. Filed as Exhibit 99.3 to the Company's Current Report on Form 8-K, filed with the Commission on August 8, 2008, and incorporated herein by reference.
10.21	Security Agreement, dated as of August 4, 2008, among PGxHealth, LLC and Adenosine Therapeutics, LLC. Filed as Exhibit 99.4 to the Company's Current Report on Form 8-K, filed with the Commission on August 8, 2008, and incorporated herein by reference.
10.22	Guaranty, dated as of August 4, 2008, among the Company and Adenosine Therapeutics, LLC. Filed as Exhibit 99.5 to the Company's Current Report on Form 8-K, filed with the Commission on August 8, 2008, and incorporated herein by reference.
10.23	Express CreditLine Revolving Loan Agreement and Amendment to Express CreditLine or Express Credit Loan Agreement, each dated September 17, 2008. Filed as Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the Commission on September 23, 2008, and incorporated herein by reference.

Exhibit Number	Description
10.24	Form of Securities Purchase Agreement, dated September 26, 2008, among Clinical Data, Inc. and Purchasers as listed therein. Filed as Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the Commission on September 30, 2008, and incorporated herein by reference.
10.25	Form of Registration Rights Agreement, dated September 26, 2008, among Clinical Data, Inc. and Purchasers as listed therein. Filed as Exhibit 99.2 to the Company's Current Report on Form 8-K, filed with the Commission on September 30, 2008, and incorporated herein by reference.
10.26	Form of Common Stock Purchase Warrant, dated September 26, 2008. Filed as Exhibit 99.3 to the Company's Current Report on Form 8-K, filed with the Commission on September 30, 2008, and incorporated herein by reference.
10.27	Voting Agreement, dated October 27, 2008 (separate Voting Agreements have been entered into between Clinical Data, Inc. and each of the following Avalon Pharmaceuticals, Inc. stockholders: J. Michael Hamilton, Stephen K. Horrigan, Kenneth C. Carter, David S. Kabakoff, Bradley G. Lorimier, Philip Frost, C. Eric Winzer, Michael R. Kurman, and William H. Washecka). Form filed as Exhibit 99.3 to Clinical Data's Current Report on Form 8-K, filed with the Commission on October 31, 2008, and incorporated herein by reference.
10.28	Securities Purchase Agreement, dated October 27, 2008, between Clinical Data, Inc. and Avalon Pharmaceuticals, Inc. Filed as Exhibit 99.4 to Clinical Data's Current Report on Form 8-K, filed with the Commission on October 31, 2008, and incorporated herein by reference.
10.29	Common Stock Purchase Warrant issued by Avalon Pharmaceuticals, Inc. to Clinical Data, Inc. Filed as Exhibit 99.5 to Clinical Data's Current Report on Form 8-K, filed with the Commission on October 31, 2008, and incorporated herein by reference.
10.30	Contingent Value Rights Agreement, dated May 28, 2009, among Clinical Data, Inc. and America Stock Transfer and Trust Co. Filed as Exhibit 99.2 to Clinical Data's Current Report on Form 8-K, filed with the Commission on June 3, 2009, and incorporated herein by reference.
10.31	Letter Agreement, dated November 17, 2008, between Clinical Data, Inc. and Avalon Pharmaceuticals, Inc. Filed as Exhibit 10.3B to the Company's Registration Statement on Form S-4 (Registration No. 333-156011), filed with the Commission on December 9, 2008, and incorporated herein by reference.
10.32	License Agreement, dated October 27, 2008, between Clinical Data, Inc. and Avalon Pharmaceuticals, Inc. Filed as Exhibit 99.7 to the Company's Current Report on Form 8-K, filed with the Commission on October 31, 2008, and incorporated herein by reference.
10.33	Note Purchase Agreement, dated October 27, 2008, between Clinical Data, Inc. and Avalon Pharmaceuticals, Inc. Filed as Exhibit 99.8 to the Company's Current Report on Form 8-K, filed with the Commission on October 31, 2008, and incorporated herein by reference.
10.34	Term Note, dated October 27, 2008, issued by Avalon Pharmaceuticals, Inc. to Clinical Data, Inc. Filed as Exhibit 99.9 to the Company's Current Report on Form 8-K, filed with the Commission on October 31, 2008, and incorporated herein by reference.
10.35	Amendment No. 1 to Term Note, dated January 12, 2009, issued by Avalon Pharmaceuticals, Inc. to Clinical Data, Inc. Filed as Exhibit 10.7 to Amendment No. 1 to the Company's Registration Statement on Form S-4/A (File No. 333-156011), filed with the Commission on January 13, 2009, and incorporated herein by reference.
10.36	Amendment No. 2 to Term Note, dated March 30, 2009, issued by Avalon Pharmaceuticals, Inc. to Clinical Data, Inc. Filed as Exhibit 10.9 to Amendment No. 2 to the Company's Registration Statement on Form S-4/A (File No. 333-156011), filed with the Commission on April 2, 2009, and incorporated herein by reference.
10.37	Term Note, dated March 30, 2009, issued by Avalon Pharmaceuticals, Inc. to Clinical Data, Inc. Filed as Exhibit 10.10 to the Company's Registration Statement on Form S-4/A (File No. 333-156011), filed with the Commission on April 2, 2009, and incorporated herein by reference.
10.38	Intellectual Property Security Agreement, dated October 27, 2008, between Clinical Data, Inc. and Avalon Pharmaceuticals, Inc. Filed as Exhibit 99.10 to Clinical Data's Current Report on Form 8-K, filed with the Commission on October 31, 2008, and incorporated herein by reference.

Exhibit Number	Description
10.39†	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.
10.40	Form of Securities Purchase Agreement, dated February 25, 2009, among Clinical Data, Inc. and Buyers listed therein. Filed as Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 26, 2009, and incorporated herein by reference.
10.41	Form of Registration Rights Agreement, dated February 25, 2009, among Clinical Data, Inc. and Buyers listed therein. Filed as Exhibit 99.2 to the Company's Current Report on Form 8-K, filed with the Commission on February 26, 2009, and incorporated herein by reference.
10.42	Form of Note, dated February 25, 2009. Filed as Exhibit 99.3 to the Company's Current Report on Form 8-K, filed with the Commission on February 26, 2009, and incorporated herein by reference.
10.43	Form of Common Stock Purchase Warrant (Series A), dated February 25, 2009. Filed as Exhibit 99.4 to the Company's Current Report on Form 8-K, filed with the Commission on February 26, 2009, and incorporated herein by reference.
10.44	Form of Common Stock Purchase Warrant (Series B), dated February 25, 2009. Filed as Exhibit 99.5 to the Company's Current Report on Form 8-K, filed with the Commission on February 26, 2009, and incorporated herein by reference.
10.45	Escrow Agreement, dated April 14, 2009, among Clinical Data, Inc., Beckman Coulter, Inc. and Wells Fargo, N.A. Filed as Exhibit 99.2 to the Company's Current Report on Form 8-K/A, filed with the Commission on April 27, 2009, and incorporated herein by reference.
10.46	Transition Services Agreement, dated April 14, 2009, by and among Clinical Data, Inc., Cogenics, Inc., Epidauros Biotechnologie, Aktiengesellschaft, and Cogenics Genome Express, S.A. Filed as Exhibit 99.3 to the Company's Current Report on Form 8-K/A, filed with the Commission on April 27, 2009, and incorporated herein by reference.
10.47	Patent License Agreement, dated April 14, 2009, by and between PGxHealth, LLC and Beckman Coulter, Inc. Filed as Exhibit 99.4 to the Company's Current Report on Form 8-K/A, filed with the Commission on April 27, 2009, 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.
31.1	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.
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.

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* Indicates a contract with management.

† Confidential treatment requested as to certain portions, which portions have been filed separately with the Commission.