



Clinical Data, Inc. Reports Fourth Quarter and Fiscal Year 2009 Results

Transforms into a Drug Development Company with Late-stage Products Positive Results for Second Phase III Trial of Vilazodone in Treatment of Depression to Support NDA Filing this Year

NEWTON, Mass., Jun 15, 2009 (BUSINESS WIRE) -- Clinical Data, Inc. (NASDAQ: CLDA) today announced financial results for the fourth quarter and fiscal year ended March 31, 2009, reporting strong revenue growth and continued achievement of key business and clinical program objectives for the periods.

"Today Clinical Data is a biotechnology company with a pipeline of late-stage candidates that are first-in-class or potentially best-in-category. This achievement is due to rapid and systematic execution of our strategy to focus operations on growing our asset base, divesting non-core assets and devoting the majority of our resources to the most promising drug candidates," commented Drew Fromkin, Clinical Data's President and Chief Executive Officer.

"Foremost, our internal drug development expertise has successfully driven the vilazodone clinical program through two consecutive, successful Phase III registration trials for depression and we intend to file a new drug application for submission to the FDA by the end of this calendar year. We believe that vilazodone's novel dual-acting serotonergic mechanism of action and its tolerability profile will offer strong differentiation in a largely unsatisfied, multi-billion dollar antidepressant market. Market research indicates that vilazodone will be well-received by doctors and their patients given its differentiation from other antidepressants, including a lack of impairment of sexual function when measured by validated, objective scales. Sexual dysfunction is a common and undesirable side effect associated with many antidepressants. Importantly, to continue the momentum in our clinical development pipeline, we are moving our next promising drug candidate, Stedivaze, a vasodilator used for cardiac stress testing, into a Phase III clinical program."

Fiscal 2009 Highlights

- **Acquired Adenosine Therapeutics, LLC.** Significantly expanded the Company's therapeutics pipeline, adding drug candidates in cardiology, diabetes and inflammatory diseases, including Stedivaze(TM) (apadenoson), which is entering a Phase III clinical program as a potential best-in-category vasodilator used for cardiac stress testing.
- **Completed Financings.** Company secured \$50 million in convertible debt financing in March 2009 to fund a new drug application (NDA) filing for vilazodone and initiation of the Stedivaze Phase III clinical program. In September 2008, Clinical Data completed a private placement of 1,514,922 shares of newly issued common stock for proceeds of \$25 million. Both of these transactions were funded by Randal J. Kirk, Chairman of Clinical Data's Board of Directors, and certain of his affiliates.
- **Launched New Genetic Tests.** PGxHealth division launched two new genetic tests for inherited cardiac syndromes: (i) Hypertrophic Cardiomyopathy (HCM), and (ii) Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC), an often fatal heart condition.
- **Additional Insurance Coverage.** Signed a new in-network contract with Aetna and a contract with the Blue Cross and Blue Shield Association to provide individual Blue Cross and Blue Shield companies with access to the *FAMILION* Long QT Syndrome (LQTS) genetic test for inherited cardiac syndromes. To date, positive coverage policies offer access to *FAMILION* tests for over 200 million patients.
- **Journal Publications.** Complete results from the first Phase III study of vilazodone were published in the *Journal of Clinical Psychiatry*.

Recent Highlights

- **Positive Results from Second Phase III Trial of Vilazodone.** Vilazodone, a novel dual-acting serotonergic antidepressant, is a potent and selective serotonin reuptake inhibitor (SSRI), and a partial agonist of the 5-hydroxytryptamine 1a (5-HT_{1A}) receptor, thereby combining first-line antidepressant therapy with an accepted adjunctive treatment for depression and first-line therapy for anxiety. In June 2009, the Company reported top-line results on its second Phase III trial for vilazodone. This study demonstrated statistically significant results on the primary endpoint and secondary efficacy endpoints related to depression. In addition, vilazodone was generally well tolerated, with safety data consistent with the findings from the previous trial. A statistically significant improvement in the symptoms of anxiety associated with depression was also observed. Effects of vilazodone on sexual function, as measured by a validated, objective scale, were comparable to placebo, which is an important finding as many antidepressants have been

associated with causing or exacerbating sexual dysfunction. An NDA filing with the U.S. Food and Drug Administration (FDA) for vilazodone for the treatment of depression is expected by the end of 2009.

- **Acquisition of Avalon Pharmaceuticals.** Expanded therapeutics pipeline with the closing of the acquisition of Avalon Pharmaceuticals in May 2009, gaining promising oncology biomarkers and compounds.
- **Announced Plan to Launch Enhanced LQTS Test.** PGxHealth division will launch a newly enhanced *FAMILION* LQTS Test, which will double the number of genes analyzed to detect genetic mutations to help guide treatment and prevent possible sudden cardiac death.
- **Divestiture of Genomics Services Business to Beckman Coulter.** To support the Company's focus on drug development, the Cogenics genomic services division was sold to Beckman Coulter.
- **Additional Research Collaborations.** Research collaborations were established with the Dana-Farber Cancer Institute and the University of Pittsburgh to further examine the role of FCGR3A and potentially other variants for predicting response to monoclonal antibody therapies in cancer treatment.

Financial Results: Q4 2009

Fiscal 2009 fourth quarter revenue increased 103% or \$1.6 million to \$3.2 million compared to \$1.6 million in fiscal 2008. This increase was driven primarily by the expansion of the PGxHealth sales and marketing force and increased payor coverage during the last 18 months.

Gross margin in the fourth quarter of fiscal 2009 was 49% compared with 51% in the same period in fiscal 2008. However, in fiscal 2009, gross margins increased from 28% in the first fiscal quarter to 49% in the fourth fiscal quarter. The overall decline from fiscal 2008 to 2009 was primarily due to the planned investments in infrastructure, equipment and a new laboratory information management system (LIMS), which were designed to increase productivity and lab efficiencies as sales of PGxHealth tests grow in future periods. Gross margins are expected to continue to improve as infrastructure investments drive efficiencies.

Research and development expenses increased by \$7.5 million to \$12.8 million in the fourth quarter of fiscal 2009, or 140%, from \$5.3 million for the same period in fiscal 2008. The increase was due primarily to the vilazodone Phase III confirmatory clinical and safety trials, which were initiated in late fiscal 2008 and completed in June 2009.

Sales and marketing expenses increased \$0.6 million, or 40%, from \$1.5 million in the fourth quarter of 2008 to \$2.1 million for the same period in fiscal 2009. The increase related to further development of the PGxHealth sales force, marketing to new territories and managed care contracting efforts.

General and administrative expenses decreased \$0.7 million, or 13%, from \$5.7 million in the fourth quarter of fiscal 2008, to \$5.0 million for the same period in fiscal 2009. The decrease was, in part, due to a Company decision made in light of the current economic environment, to reduce overall executive compensation, including year-end bonuses.

The net loss from continuing operations for the fourth quarter of fiscal 2009 was \$20.3 million, compared to a net loss in the prior year's period of \$11.8 million, an increase of \$8.6 million or 73%. The increase was due primarily to increased research and development expenses and a charge of \$2.0 million for purchased in-process research and development (IPR&D) associated with the recent acquisition of Avalon Pharmaceuticals.

At March 31, 2009, the Company had cash and marketable securities totaling \$56.4 million. This amount does not include \$13.1 million in proceeds received from the sale of the Cogenics division in April 2009, with an additional \$2.5 million held in escrow.

Financial Results: Fiscal Year 2009

Fiscal 2009 revenues increased 104% or \$5.3 million to \$10.4 million, compared to \$5.1 million in fiscal 2008. PGxHealth test revenues for the full fiscal year increased 116%, or \$5.3 million to \$9.9 million, compared to fiscal 2008 revenue of \$4.6 million. This increase was driven primarily by the build-up of the PGxHealth sales and marketing force and the increased payor coverage during the last 18 months.

Gross margins for fiscal 2009 were 38% compared with 49% for fiscal 2008. However, in fiscal 2009, PGxHealth gross margins increased from 28% in the first fiscal quarter to 49% in the fourth fiscal quarter. The overall 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 PGxHealth infrastructure, including equipment and a new LIMS, which were designed to increase productivity and lab efficiencies. Gross margins are expected to continue to improve as infrastructure investments drive efficiencies.

Research and development expenses increased by \$27.2 million to \$44.1 million in fiscal 2009, or 161%, from \$16.9 million in fiscal 2008. The increase was due primarily to the vilazodone Phase III confirmatory clinical and safety trials, which were both

initiated in late fiscal 2008 and completed in June 2009. Ongoing research and development expenses will continue to be significant with the planned NDA filing for vilazodone and the initiation of the Phase III Stedivaze clinical program.

Sales and marketing expenses increased \$4.2 million, or 115%, from \$3.6 million in fiscal 2008 to \$7.8 million in fiscal 2009. The increase related to further development of the PGxHealth sales force, marketing to new territories and managed care contracting efforts.

General and administrative expenses increased \$2.9 million, or 17%, from \$16.8 million in fiscal 2008 to \$19.7 million in fiscal 2009. The increase was due to increased stock-based compensation charges of \$1.0 million and higher audit and legal fees associated with M&A activities.

The net loss from continuing operations for the fiscal year 2009 was \$123.7 million, which included items related to IPR&D expense of \$55.1 million associated with the recent acquisitions of Adenosine Therapeutics and Avalon, depreciation and amortization of \$1.7 million and stock based compensation charges of \$8.1 million. Excluding IPR&D and non-cash charges, the loss would have been approximately \$58.8 million. During the year, the Company funded research and development efforts primarily associated with the vilazodone clinical and safety trials totaling \$44.1 million.

At March 31, 2009, the Company had cash and marketable securities totaling \$56.4 million. This amount does not include \$13.1 million in proceeds received from the sale of the Cogenics division in April 2009, with an additional \$2.5 million held in escrow.

About Clinical Data, Inc.

Clinical Data is a biotechnology company focused on the discovery, development and commercialization of targeted therapeutics: From Targeted Science to Better Healthcare^(R). Clinical Data is leveraging advances in molecular discovery to provide tangible benefits for patients, healthcare professionals and payors worldwide. The Company is advancing its late-stage, first-in-class or potential best-in-category drug candidates including vilazodone, for the treatment of depression, and Stedivaze, a vasodilator used for cardiac stress testing, to be followed by promising drug candidates in other therapeutic areas such as inflammatory diseases and oncology. Coupled with its biomarker expertise and portfolio of intellectual property, Clinical Data plans to develop and commercialize targeted therapeutics, as well as genetic and pharmacogenomic tests to detect serious diseases and help predict drug safety, tolerability, and efficacy, thereby improving patient health while reducing costs. To learn more, please visit the Company's website at www.clda.com.

SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This press release contains certain forward-looking information and statements that are intended to be covered by the safe harbor for forward looking statements provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Words such as "expect(s)", "feel(s)", "believe(s)", "will", "may", "anticipate (s)" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements about our ability to obtain regulatory approval for, and successfully introduce vilazodone; our ability to expand our long-term business opportunities; and all other statements regarding future performance. All such information and statements are subject to certain risks and uncertainties, the effects of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to, whether vilazodone will advance further in the clinical trials process and whether and when, if at all, vilazodone will receive final approval from the U.S. Food and Drug Administration and equivalent foreign regulatory agencies and for which indications; whether vilazodone will be successfully marketed if approved; the extent to which genetic markers are predictive of clinical outcomes and drug efficacy and safety; the strength of our intellectual property rights; competition from pharmaceutical, biotechnology and diagnostics companies; the development of and our ability to take advantage of the market for pharmacogenetic and biomarker products and services; general economic downturns; and those risks identified and discussed by Clinical Data in its filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward looking statements that speak only as of the date hereof. Clinical Data does not undertake any obligation to republish revised forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Readers are also urged to carefully review and consider the various disclosures in Clinical Data's SEC periodic and interim reports, including but not limited to its Annual Report on Form 10-K for the fiscal year ended March 31, 2008, Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2008, and Current Reports on Form 8-K filed from time to time by the Company.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

Three Months Ended		Year Ended	
March 31,		March 31,	
2009	2008	2009	2008
(UNAUDITED)			

Revenues	\$ 3,224	\$ 1,592	\$ 10,442	\$ 5,107
Cost of revenues	<u>1,655</u>	<u>786</u>	<u>6,489</u>	<u>2,627</u>
Gross profit	1,569	806	3,953	2,480
Operating expenses:				
Research and development	12,792	5,328	44,134	16,889
Sales and marketing	2,109	1,508	7,764	3,612
General and administrative	4,996	5,734	19,730	16,806
Purchased in-process research and development	<u>2,000</u>	<u>-</u>	<u>55,100</u>	<u>-</u>
Total operating expenses	<u>21,897</u>	<u>12,570</u>	<u>126,728</u>	<u>37,307</u>
Operating loss	(20,328)	(11,764)	(122,775)	(34,827)
All other (expense) income, net	<u>(1,149)</u>	<u>650</u>	<u>(907)</u>	<u>2,249</u>
Loss from continuing operations before taxes	(21,477)	(11,114)	(123,682)	(32,578)
Benefit from income taxes	<u>-</u>	<u>122</u>	<u>-</u>	<u>230</u>
Loss from continuing operations	(21,477)	(10,992)	(123,682)	(32,348)
Loss from discontinued operations	<u>(2,409)</u>	<u>(3,694)</u>	<u>(8,756)</u>	<u>(2,982)</u>
Net loss	<u>\$ (23,886)</u>	<u>\$ (14,686)</u>	<u>\$ (132,438)</u>	<u>\$ (35,330)</u>
Loss per basic and diluted share:				
Continuing operations	\$ (0.94)	\$ (0.52)	\$ (5.63)	\$ (1.69)
Discontinued operations	<u>(0.11)</u>	<u>(0.18)</u>	<u>(0.40)</u>	<u>(0.16)</u>
Net loss	<u>\$ (1.05)</u>	<u>\$ (0.70)</u>	<u>\$ (6.03)</u>	<u>\$ (1.85)</u>
Weighted average shares: basic and diluted	22,742	21,130	21,962	19,081

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	March 31,	
	2009	2008
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 55,180	\$ 54,755
Marketable securities	1,175	-
Accounts receivable, net	2,471	1,243
Prepaid expenses and other current assets	1,240	678
Assets of discontinued operations	<u>18,541</u>	<u>6,903</u>
Total current assets	<u>78,607</u>	<u>63,579</u>
Marketable securities, at fair value	-	12,725
Property, plant and equipment, net	2,942	1,978
Goodwill & intangible assets, net	34,243	31,894
Other assets, net	4,405	257
Assets of discontinued operations	<u>-</u>	<u>19,015</u>
TOTAL ASSETS	<u>\$120,197</u>	<u>\$129,448</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Current portion of long-term debt and capital leases	\$ 7,067	\$ 954
Accounts payable, accrued expenses and other liabilities	11,693	7,775
liabilities of discontinued operations	<u>8,902</u>	<u>9,522</u>
Total current liabilities	<u>27,662</u>	<u>18,251</u>
Long-term debt and other liabilities	63,123	2,211
Long-term liabilities of discontinued operations	<u>-</u>	<u>2,911</u>
TOTAL LIABILITIES	<u>90,785</u>	<u>23,373</u>
Stockholders' equity	<u>29,412</u>	<u>106,075</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$120,197</u>	<u>\$129,448</u>

SOURCE: Clinical Data, Inc.

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