



Clinical Data, Inc. Reports Third Quarter Fiscal 2010 Results

-Company on Track To Submit NDA For Vilazodone This Quarter for the Treatment of Depression

NEWTON, Mass., Feb 09, 2010 (BUSINESS WIRE) -- Clinical Data, Inc. (NASDAQ: CLDA) today announced the Company's operational and financial results for its third fiscal quarter ended December 31, 2009, confirming its plans to submit a new drug application (NDA) for vilazodone for the treatment of depression this quarter.

Third Quarter and Recent Highlights

- Completed a public offering which generated approximately \$47.4 million in gross proceeds
- Initiated the first Phase III trial of Stedivaze, a potential best-in-class coronary vasodilator for cardiac stress testing
- Increased *FAMILION*^(R) genetic testing gross revenue by 25% and improved gross margins from 35% to 53%, over the same period a year ago
- Launched the sixth *FAMILION* test used to diagnose or confirm familial heart disease and established a Scientific Advisory Board for cardiovascular genetics

"We have completed all of the clinical studies and related requirements to submit our NDA for vilazodone to the FDA this quarter," said Drew Fromkin, Clinical Data's President and Chief Executive Officer. "We are also advancing Stedivaze, our potential best-in-class coronary vasodilator, by enrolling patients in our first Phase III trial, and planning for the second Phase III study that we expect to begin later this year. Our preclinical programs are also moving forward, and we anticipate filing an investigational new drug application for at least one of these compounds in the next 12 to 18 months. We strengthened our financial resources in support of these programs and broadened our investor base through our successful public offering completed in November. We will also continue to pursue collaborative opportunities to advance our growing pipeline and supplement our financial resources."

Financial Results for the Three Months Ended December 31, 2009

Gross revenue for the three months ended December 31, 2009 increased to \$3.7 million, or 22%, up from \$3.0 million when compared to the same period a year ago. This was primarily driven by an increase in gross sales from PGxHealth's *FAMILION* tests of \$719,000, or 25%, compared to the same period a year ago. The increase in gross revenue was partially offset by a rise in contractual allowances of \$323,000, which represents an increase from 8% to 15% of gross genetic testing revenues, when compared to the third quarter of fiscal year 2009. This increase in contractual allowances is due to greater overall coverage policies, as well as the revenue mix of third-party payors and challenging macroeconomic conditions. The Company anticipates that future revenue will continue to be driven by expanding genetic test offerings, greater test adoption and increasing insurance coverage from third-party payors.

For the three-month period ended December 31, 2009, gross profit margins increased to 53%, up from 35% for the same period last year. The year-over-year improvement in gross margins was due to the increase in revenues, coupled with the realization of benefits from the significant investments the Company has made in infrastructure improvements. Gross margins are anticipated to continue to improve as revenues increase over time.

During the quarter, the Company expanded its genetic test offerings with the launch of its sixth genetic test, the *FAMILION* DCM Test for Dilated Cardiomyopathy (DCM). DCM is an inherited heart disease which is the leading cause of heart transplants and a possible cause of sudden cardiac death. The launch marked the third significant genetic test launched by PGxHealth, a division of Clinical Data, Inc., within the past 18 months.

Research and development expenses for the three months ended December 31, 2009 were \$9.7 million, down from \$15.1 million for the same period last year. This decrease was primarily attributable to the completion of the vilazodone safety trial and Phase III clinical program. These reductions were partially offset by costs incurred with advancing Stedivaze into the clinic, progressing preclinical programs, and commercial scale-up activities and preparations for the NDA submission for vilazodone. Ongoing research and development expenses are expected to increase due to the Stedivaze Phase III clinical trials and preparations for the commercialization of vilazodone.

During the quarter, the Company initiated a Phase III trial of Stedivaze (apadenoson) to evaluate its safety and efficacy for use

as a pharmacologic stress agent in myocardial perfusion imaging (MPI), a method for evaluating blood flow to the heart. The Phase III ASPECT Trial (A₁adenoson Single Photo Emission Computed Tomography) will also compare the tolerability of Stedivaze to adenosine, a standard pharmacologic stress agent used in MPI scans.

Sales and marketing expenses of \$1.9 million were essentially flat when compared to the three months ended December 31, 2008. Expense in this area should continue at a comparable rate for the next several quarters as the Company continues to leverage its well-established *FAMILION* sales and marketing organization.

General and administrative expenses were \$4.4 million, down from \$5.0 million in the third quarter of last fiscal year. The decrease was primarily driven by a reduction in stock-based compensation, partially offset by an increase in the provision for uncollectable accounts largely due to the current economic conditions.

Financial Results for the Nine Months Ended December 31, 2009

Gross revenue for the nine months ended December 31, 2009 was \$11.4 million, or 48%, an increase from \$7.7 million for the nine months ended December 31, 2008. This increase was mainly driven by the growth in genetic tests sales of \$3.7 million, up 51% when compared to the same period a year ago. Revenue has risen as a result of continued expansion of sales and marketing activities in fiscal 2009, the introduction of new and expanded tests and increased coverage policies from third-party payors. To date, third-party payor coverage for *FAMILION* tests is approximately 280 million lives in the U.S. As of December 31, 2009, PGxHealth was an approved Medicare provider and a Medicaid provider in most states. These increases in revenue were partially offset by an increase in contractual allowances of \$1.1 million from \$489,000, or 7% of gross genetic testing revenue, to \$1.6 million, or 14% of gross genetic testing revenue. The increase in contractual allowances was due to an increase in coverage from third-party payors, as well as the mix of revenue from third-party payors.

Gross margins increased from 33% for the nine months ended December 31, 2008 to 52% for the nine months ended December 31, 2009. The improvement in gross margins from fiscal 2009 to 2010 was due to an increase in revenues, as well as the realization of benefits from infrastructure improvements and lab efficiencies implemented by the Company in fiscal 2009. Gross margins are expected to continue to improve as revenues increase, while costs, including personnel, equipment and facilities expense, remain essentially flat.

Research and development expenses were \$30.1 million for the nine months ended December 31, 2009, down from \$31.3 million when compared to the same a year ago. The decrease is primarily attributable to the completion of the safety and Phase III confirmatory trials for vilazodone. These reductions were partially offset by costs incurred with advancing Stedivaze into the clinic, progressing preclinical programs and the preparation of the NDA submission for vilazodone, which is expected to be made in the first quarter of calendar year 2010. Ongoing research and development expenses are expected to increase as the Company expands Phase III clinical trials for Stedivaze and prepares for the commercialization of vilazodone.

Sales and marketing expenses were \$6.0 million for the nine months ended December 31, 2009, up from \$5.7 million for the same period a year ago. The increase was mainly due to expenses relating to expanded sales and marketing activities during the past year. Sales and marketing expenses are expected to remain flat over the next several quarters as the Company leverages its established sales organization.

General and administrative expenses remained essentially flat at \$14.9 million for the nine months ended December 31, 2009, compared to \$14.7 million for the same period a year ago.

Cash and cash equivalents at December 31, 2009, were \$70.2 million. This included net proceeds of \$44.2 million raised from a public offering of 2,750,000 shares of common stock at a price of \$17.25 per share completed in November 2009.

About Clinical Data, Inc.

Clinical Data develops first-in-class and best-in-category therapeutics. The Company is advancing its late-stage drug candidates for [central nervous system disorders](#) and [cardiovascular diseases](#), to be followed by promising drug candidates in other major therapeutic areas. Clinical Data is also combining its drug development and biomarker expertise to develop products with enhanced efficacy and tolerability to improve patient health and reduce 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, Stedivaze and our

other drug candidates; 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 contained in this press release. These risks and uncertainties include, but are not limited to, whether vilazodone or Stedivaze will advance further in the clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration and equivalent foreign regulatory agencies and for which indications; whether vilazodone and Stedivaze 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 conditions; 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 publish 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, 2009, its Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2009, 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 Nine Months Ended			
	December 31,		December 31,	
	2009	2008	2009	2008
	(UNAUDITED)			
Net revenues	\$ 3,128	\$ 2,781	\$ 9,865	\$ 7,218
Cost of revenues	1,478	1,817	4,756	4,834
Gross profit	1,650	964	5,109	2,384
Operating expenses:				
Research and development	9,710	15,133	30,132	31,342
Sales and marketing	1,889	2,000	6,007	5,654
General and administrative	4,381	5,034	14,892	14,735
Restructuring and lease exiting costs	-	-	1,783	-
Purchased in-process research and development	-	1,000	-	53,100
Avalon acquisition costs	-	-	1,978	-
Total operating expenses	15,980	23,167	54,792	104,831
Loss from operations	(14,330)	(22,203)	(49,683)	(102,447)
All other (expense) income, net	(1,854)	(200)	(5,409)	242
Loss from continuing operations	(16,184)	(22,403)	(55,092)	(102,205)
Income (loss) from discontinued operations	150	(1,275)	4,987	(6,347)
Net loss	\$ (16,034)	\$ (23,678)	\$ (50,105)	\$ (108,552)
(Loss) income per basic and diluted share:				
Continuing operations	\$ (0.63)	\$ (0.98)	\$ (2.28)	\$ (4.73)
Discontinued operations	-	(0.06)	0.21	(0.29)
Net loss	\$ (0.63)	\$ (1.04)	\$ (2.07)	\$ (5.02)
Weighted average shares: basic and diluted	25,642	22,742	24,158	21,629

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	December 31, 2009		March 31, 2009	
	(UNAUDITED)			
ASSETS				
Current Assets:				
Cash and cash equivalents	\$	70,189	\$	55,180
Marketable securities		-		1,175
Accounts receivable, net		2,580		2,471
Prepaid expenses and other current assets		2,076		1,240
Assets of discontinued operations		-		18,541
Total current assets		74,845		78,607

Property, plant and equipment, net	2,759	2,942
Goodwill & intangible assets, net	42,893	34,243
Other assets, net	50	4,405
TOTAL ASSETS	<u>\$ 120,547</u>	<u>\$ 120,197</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Current portion of long-term debt and capital leases	\$ 6,825	\$ 7,067
Accounts payable, accrued expenses and other liabilities	15,232	11,693
Liabilities of discontinued operations	-	8,902
Total current liabilities	<u>22,057</u>	<u>27,662</u>
Long-term debt and other liabilities	<u>58,779</u>	<u>63,123</u>
TOTAL LIABILITIES	<u>80,836</u>	<u>90,785</u>
Stockholders' equity	<u>39,711</u>	<u>29,412</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 120,547</u>	<u>\$ 120,197</u>

SOURCE: Clinical Data, Inc.

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