



Clinical Data, Inc. Reports Second Quarter Fiscal 2010 Results

- Recent Financing Provides Additional Capital to Advance Late-stage Drug Development Programs to Key Milestones -

NEWTON, Mass., Nov 09, 2009 (BUSINESS WIRE) -- Clinical Data, Inc. (NASDAQ: CLDA) today announced the Company's operational and financial results for its second fiscal quarter ended September 30, 2009.

Second Quarter and Recent Highlights

- Completed a public offering which generated approximately \$47.4 million in gross proceeds
- Hosted an investor day in New York City which focused on vilazodone and featured leading experts in the treatment of depression, antidepressants and related sexual dysfunction; Company on track to submit its new drug application (NDA) for vilazodone in the first quarter of calendar 2010
- Expanded the Board of Directors to include pharmaceutical industry leader, Scott Tarriff
- Generated proceeds from the sale of certain non-core assets from the Avalon Pharmaceuticals acquisition for \$1.5 million, with an estimated annual cost-savings of \$4.0 to \$5.0 million
- Established a collaboration and licensing agreement for A_{2A} agonist ATL313, with the potential to receive up to \$252.0 million in milestones, as well as royalties related to the commercialization of multiple myeloma and other B-cell cancer treatments
- Reported a 51% increase in *FAMILION* genetic testing gross revenue, as well as improved gross margins which rose from 36% to 47%, when compared to the same period a year ago

"The majority of our resources remain focused on driving our late-stage products toward key development milestones, several of which we anticipate over the next few quarters," said Drew Fromkin, Clinical Data's President and Chief Executive Officer. "We plan to submit our NDA for vilazodone for the treatment of depression in the first quarter of calendar 2010, and will initiate our Phase III program for Stedivaze for cardiac stress testing, shortly. During the quarter, we again demonstrated our ability to secure capital by selling non-core assets and executing transactions that will reduce overall expenses. More recently, we successfully obtained capital through the public markets, improving our stock's liquidity and significantly expanding our shareholder base. We believe that our ability to attract high-quality investors in this recent financing is further evidence of the value we are building for shareholders."

Financial Results for the Three Months Ended September 30, 2009

Gross revenue for the three months ended September 30, 2009 increased to \$3.7 million, or 47%, from \$2.5 million for the same period a year ago. This was primarily driven by an increase in gross sales from PGxHealth's *FAMILION* tests of \$1.2 million, or 51%, compared to the same period a year ago. The increase in gross revenue was partially offset by a rise in contractual allowances of \$542,000, which represents an increase from 5% to 18% of gross genetic testing revenues when compared to the second quarter of fiscal year 2009. This increase in contractual allowances is due to additional coverage policies, as well as the revenue mix from third-party payors. Management also noted that weakened economic conditions had negatively impacted revenue as well as higher than normal contractual allowances for the period. The Company anticipates that future revenue will continue to be driven by expanding genetic test offerings, driving greater test adoption and increasing insurance coverage from third-party payors.

For the three month period ended September 30, 2009, gross profit margins increased to 47% from 36% for the same period last year. The year-over-year improvement in gross margins was due to an increase in revenues coupled with the realization of significant investments the Company has made in infrastructure improvements. Gross margins are anticipated to improve as revenues and test volumes and reimbursement increases over time.

Research and development expenses for the three months ended September 30, 2009 increased to \$8.9 million, up from \$8.6 million for the same period last year. This modest increase was attributable primarily to the concluding activities related to the vilazodone safety trial, Phase III clinical program and initial preparations for the NDA submission, which is anticipated in the first quarter of calendar year 2010. Ongoing research and development expenses are expected to increase with continued activities focused on NDA preparations and the imminent start of the Phase III program for Stedivaze, the Company's potential best-in-

class vasodilator for use in cardiac stress testing.

In August 2009, the Company sold certain non-core assets from the Avalon acquisition, which is expected to result in future cost savings in Avalon research and development activities of approximately \$4.0 to \$5.0 million annually.

Sales and marketing expense of \$2.0 million was essentially flat when compared to the three months ended September 30, 2008. Expense in this area should continue at a similar rate for the next several quarters as the Company leverages a well-established *FAMILION* sales and marketing organization.

General and administrative expenses decreased to \$5.3 million, down from \$5.6 million in the second quarter of last fiscal year. The decrease was primarily driven by a reduction in stock-based compensation, however, this was partially offset by an increase in provisions for uncollectable accounts largely due to the current economic conditions.

Financial Results for the Six Months Ended September 30, 2009

Gross revenue for the six months ended September 30, 2009 increased to \$7.8 million, or 65%, from \$4.7 million for the six months ended September 30, 2008. This increase was mainly driven by the increase in gross sales of genetic tests of \$2.9 million, or 67%, compared to the same period a year ago. Revenue has risen as a result of continued expansion of the commercial sales and marketing team in fiscal 2009, and increased coverage policies from third-party payors, such as Blue Cross and Blue Shield, Aetna and Humana. As of September 30, 2009, PGxHealth was an approved Medicare provider and a Medicaid provider in certain states. These increases were partially offset by an increase in contractual allowances of \$762,000 from \$274,000, or 6% of gross genetic testing revenue, to \$1.0 million, or 14% of gross genetic testing revenue. This increase in contractual allowances was due to increased coverage from third-party payers, as well as the mix of revenue from third-party payers.

Gross profit margins increased from 32% for the six months ended September 30, 2008 to 51% for the six months ended September 30, 2009. The improvement in gross profit from fiscal 2009 to 2010 was due to the increase in revenue, as well as the realization of infrastructure improvements and lab efficiencies in fiscal 2009. Gross profit margins are expected to continue to improve as revenue increases, since costs, including personnel, equipment and facilities, are expected to remain essentially fixed.

Research and development expenses increased to \$20.4 million for the six months ended September 30, 2009, up from \$16.2 million for the same period in 2008. The increase is primarily related to the concluding stages of the vilazodone safety and Phase III confirmatory trials and the preparation of the NDA for vilazodone, and to a lesser extent, costs associated with advancing Stedivaze and preclinical programs. Ongoing research and development costs are expected to continue to increase with supportive NDA activities for vilazodone and the commencement of the Stedivaze Phase III program.

Sales and marketing expenses increased to \$4.1 million for the six months ended September 30, 2009, up from \$3.7 million for the same period in 2008. The increase was mainly due to expenses relating to the expanded sales and marketing team from the same period a year ago. 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 increased to \$10.5 million for the six months ended September 30, 2009, up from \$9.7 million for the same period in 2008. The increase was, in part, the result of a further provision for uncollectible accounts of \$576,000 largely due to the current economic conditions.

Cash, cash equivalents and marketable securities were \$37.2 million at September 30, 2009, which does not include the net proceeds of approximately \$44.1 million (net of underwriting and transaction costs) from the Company's public offering, which was completed November 2, 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 capable of combining its drug development and biomarker expertise to develop products with enhanced efficacy and tolerability, improving patient health and 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, 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. 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 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, 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		Six Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
	<u>(UNAUDITED)</u>			
Net revenues	\$ 3,042	\$ 2,400	\$ 6,737	\$ 4,437
Cost of revenues	1,609	1,544	3,278	3,017
Gross profit	1,433	856	3,459	1,420
Operating expenses:				
Research and development	8,940	8,590	20,422	16,209
Sales and marketing	2,034	1,973	4,118	3,654
General and administrative	5,319	5,631	10,511	9,701
Restructuring and lease exiting costs	1,783	-	1,783	-
Purchased in-process research and development	-	52,100	-	52,100
Avalon acquisition costs	-	-	1,978	-
Total operating expenses	18,076	68,294	38,812	81,664
Loss from operations	(16,643)	(67,438)	(35,353)	(80,244)
All other (expense) income, net	(2,019)	162	(3,555)	442
Loss from continuing operations	(18,662)	(67,276)	(38,908)	(79,802)
(Loss) income from discontinued operations	-	(2,734)	4,837	(5,072)
Net loss	\$ (18,662)	\$ (70,010)	\$ (34,071)	\$ (84,874)
(Loss) income per basic and diluted share:				
Continuing operations	\$ (0.79)	\$ (3.17)	\$ (1.66)	\$ (3.79)
Discontinued operations	-	(0.13)	0.20	(0.24)
Net loss	\$ (0.79)	\$ (3.30)	\$ (1.46)	\$ (4.03)
Weighted average shares: basic and diluted	23,728	21,233	23,412	21,070

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	September 30, 2009		March 31, 2009	
	<u>(UNAUDITED)</u>			
ASSETS				
Current Assets:				
Cash and cash equivalents	\$	37,219	\$	55,180
Marketable securities		-		1,175
Accounts receivable, net		2,181		2,471
Prepaid expenses and other current assets		2,264		1,240
Assets of discontinued operations		-		18,541

Total current assets	41,664	78,607
Property, plant and equipment, net	2,922	2,942
Goodwill & intangible assets, net	43,218	34,243
Other assets, net	350	4,405
TOTAL ASSETS	\$ 88,154	\$ 120,197
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Current portion of long-term debt and capital leases	\$ 6,899	\$ 7,067
Accounts payable, accrued expenses and other liabilities	13,438	11,693
Liabilities of discontinued operations	-	8,902
Total current liabilities	20,337	27,662
Long-term debt and other liabilities	59,945	63,123
TOTAL LIABILITIES	80,282	90,785
Stockholders' equity	7,872	29,412
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 88,154	\$ 120,197

SOURCE: Clinical Data, Inc.

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