CYTRX CORP Form 425 August 12, 2008

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On August 12, 2008, CytRx Corporation issued the following press release:

CytRx Corporation Announces Second Quarter Results

Pending Acquisition of Innovive Pharmaceuticals to Add Attractive Oncology Portfolio to Business

LOS ANGELES August 12, 2008 CytRx Corporation (Nasdaq:CYTR), a biopharmaceutical company engaged in the development and commercialization of therapeutics based on molecular chaperone amplification, today reported financial results for the three months ended June 30, 2008 and other second quarter developments.

During the second quarter, we announced the signing of a definitive agreement to purchase Innovive Pharmaceuticals, Inc., said Steven A. Kriegsman, CytRx President and CEO. The acquisition is a compelling strategic fit for CytRx. The combined business will provide us with the opportunity for near-term revenue while maintaining our longer-term emphasis on our molecular chaperone technology. We look forward to completing the acquisition in the third quarter of 2008.

Steven Kriegsman continued, The drug candidate tamibarotene is a key asset in the Innovive portfiolio. It is currently in a pivotal Phase 2 clinical trial to evaluate the safety and efficiacy for the treatment of relapsed or refractory APL, a type of leukemia. Based on successful development of tamibarotene, a New Drug Application (NDA) could be filed as early as 2010. Also, tamibarotene may become a treatment for other hematologic cancers and solid tumors.

In 2008, we have continued to advance our molecular chaperone amplification compounds, including iroxanadine for diabetic foot ulcers, said Steven Kriegsman. In June, we reported that diabetic mice treated with iroxanadine healed nearly two times faster than untreated diabetic mice. These data suggest that iroxanadine may treat the underlying condition associated with diabetic foot ulcers by promoting wound healing through a molecular chaperone pathway. Our goal is to advance iroxanadine into a Phase 2 clinical trial in the first quarter of 2009.

Earlier in 2008, we successfully completed the partial spinoff of RXi Pharmaceuticals which began trading on Nasdaq as RXII, stated Steven Kriegsman. With the spinoff completed, we are focused on enhancing shareholder value through the planned integration of the Innovive oncology products into our pipeline and through the discovery and development of novel compounds produced at our San Diego laboratory using our molecular chaperone amplification platform.

REVIEW OF FINANCIAL RESULTS

CytRx reported a net loss for the three months ended June 30, 2008, of \$5.8 million, or \$0.06 per share, based on 90.8 million weighted average shares outstanding, compared with a net loss for the three months ended June 30, 2007, of \$6.3 million, or \$0.07 per share, based on 85.4 million shares outstanding. The increase in weighted average shares outstanding resulted primarily from the issuance of shares of common stock upon the exercise of stock options and warrants.

Revenue for the second quarter of 2008 was \$1.7 million, compared with the second quarter of 2007 revenue of \$2.4 million, and consisted primarily of service revenue recognized from CytRx s 2006 royalty transaction with the ALS Charitable Remainder Trust, or ALSCRT. CytRx will continue to recognize the balance of the deferred revenue recorded from the royalty transaction with the ALSCRT on a dollar-for-dollar basis for ALS-related research expenses incurred.

Research and development (R&D) expenses were \$2.5 million for the three months ended June 30, 2008, compared with \$6.9 million for the comparable period in 2007. R&D expenses incurred during the second quarter of 2008 related primarily to (i) the Company s Phase 2b clinical trial for arimoclomol in ALS, which currently is on clinical hold by the FDA, (ii) the molecular chaperone amplification research and development conducted at the Company s San Diego laboratory, and (iii) the ongoing development and manufacturing of iroxanadine in preparation for its Phase 2 clinical trial.

General and administrative (G&A) expenses were \$3.2 million for the second quarter of 2008, compared with \$4.1 million for the same period in the prior year. The decrease in G&A expenses in 2008 resulted primarily from a reduction of approximately \$700,000 in RXi expenses and approximately \$490,000 in professional fees which largely related to the partial spinoff of RXi.

Cash and cash equivalents totaled \$36.4 million as of June 30, 2008, compared to \$43.5 million as of March 31, 2008. CytRx s 45% ownership stake in RXi at June 30, 2008, had a market value of approximately \$50.2 million.

2008 SECOND QUARTER AND RECENT HIGHLIGHTS

Proposed Acquisition of Innovive Pharmaceuticals, Inc.

On June 9, 2008, CytRx announced the signing of a definitive agreement to acquire Innovive Pharmaceuticals. Included in the to-be-acquired pipeline are North American and European rights to tamibarotene, a drug currently being sold in Japan for the treatment of relapsed or refractory APL. Tamibarotene is presently in a pivotal Phase 2 clinical trial at sites in the United States and Europe for the treatment of APL. The Innovive pipeline also includes three additional oncology drug candidates, INNO-406, INNO-206 and INNO-305, for the treatment of chronic myelogenous leukemia, small cell lung cancer, and acute myelogenous leukemia, respectively.

The combined company will have an attractive and expanded portfolio of clinical development programs in oncology, diabetic foot ulcers, amyotrophic lateral sclerosis (ALS or Lou Gehrig s disease) and stroke recovery. CytRx anticipates that the acquisition will accelerate the time to its first potential NDA filing to 2010.

On Monday, August 11, 2008, CytRx announced that the registration statement relating to the Innovive transaction was declared effective by the Securities and Exchange Commission on August 9, 2008. The transaction is expected to close in the third quarter of 2008, subject to approval by Innovive stockholders at the special meeting of Innovive stockholders scheduled for September 19, 2008 and other customary closing conditions.

Molecular Chaperone Development

CytRx remains focused on advancing the development of arimoclomol, an oral drug candidate based on molecular chaperone technology in development for ALS and stroke recovery. In June, CytRx announced its plans to conduct additional preclinical toxicology studies of arimoclomol, which are expected to take up to one year to complete. Based on telephone discussions with the FDA and having received a formal determination letter from them regarding its clinical hold on arimoclomol for ALS, CytRx anticipates that the planned Phase 2b clinical trial of arimoclomol will require completion of this additional preclinical work. In addition, CytRx anticipates that the time frame for initiating the previously planned Phase 2 clinical trial of arimoclomol in stroke recovery will depend on the results of the new preclinical toxicology studies.

CytRx is expected to begin Phase 2 testing of iroxanadine for diabetic foot ulcers in the first quarter of 2009, subject to FDA clearance. During the second quarter of 2008, CytRx s Senior Vice President of Research and Development Shi Chung Ng, Ph.D., presented data for iroxanadine at the Third Congress of the World Union of Wound Healing Societies held in Toronto, Canada, reporting that diabetic mice treated with iroxanadine healed from diabetic wounds nearly two times faster than untreated diabetic mice. These results suggest that iroxanadine promotes healing by normalizing endothelial dysfunction through the molecular chaperone amplification pathway.

Furthermore, scientists at the Company s laboratory have identified possible next-generation chaperone-amplifying compounds. In the field of oncology, CytRx has adapted its proprietary

chaperone screening assay to identify inhibitors (rather than amplifiers) of chaperone activity. Because certain chaperones appear to be essential for cancer cell survival, CytRx s internal molecular chaperone-inhibiting drug candidates may form the basis of future oncology products.

RXi Pharmaceuticals Corporation (RXi)

In March 2008, CytRx completed its partial spin out of RXi by awarding a dividend of RXi common shares to holders of CytRx common stock as of March 6, 2008. At the same time, RXi common stock commenced trading on Nasdaq under the symbol RXII. CytRx continues to hold approximately 45% of RXi s outstanding common stock.

CytRx management presented at the following conferences during the second quarter:

GTCbio s Third Assay Development & Screening Technologies Conference

Risk-Reduced Models for the Biotech Industry Panel at BIO 2008 International Convention

Jefferies 2nd Annual Healthcare Conference

Third Congress of the World Union of Wound Healing Societies

CYTRX CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS

ASSETS	(1	June 30, 2008 Unaudited)	D	ecember 31, 2007
Current assets:				
Cash and cash equivalents	\$	36,382,744	\$	50,498,261
Short-term investments, at amortized cost		, ,		9,951,548
Accounts receivable		29,332		101,217
Loan receivable, net of reserve		1,600,000		,
Prepaid expense and other current assets		1,232,891		930,596
Total current assets		39,244,967		61,481,622
Equipment and furnishings, net		1,703,607		1,573,290
Molecular library, net		148,639		193,946
Investment in unconsolidated subsidiary (see Note 9)		1,344,373		
Goodwill		183,780		183,780
Other assets		238,387		713,398
Total assets	\$	42,863,753	\$	64,146,036
LIABILITIES AND STOCKHOLDERS EQUITY Current liabilities:				
Accounts payable	\$	520,363	\$	1,946,215
Accrued expenses and other current liabilities		2,262,637		3,700,866
Income taxes payable		342,000		
Deferred revenue, current portion		6,228,035		8,399,167
Total current liabilities		9,353,035		14,046,248
Deferred revenue, non-current portion		5,417,062		7,167,381
Total liabilities		14,770,097		21,213,629
Minority interest				2,708,368
Commitments and Contingencies				
Stockholders equity: Preferred Stock, \$.01 par value, 5,000,000 shares authorized, including 15,000 shares of Series A Junior Participating Preferred Stock; no shares issued and outstanding Common stock, \$.001 par value, 150,000,000 shares authorized; 91,404,269 and 90,397,867 shares issued at June 30, 2008 and December 31, 2007,		01.404		00.200
respectively Additional paid in capital		91,404		90,398
Additional paid-in capital		206,617,383 (2,279,238)		203,905,691 (2,279,238)

Treasury stock, at cost (633,816 shares held at June 30,2008 and

December 31, 2007, respectively)

Accumulated deficit (176,335,893) (161,492,812)

Total stockholders equity 28,093,656 40,224,039

Total liabilities and stockholders equity \$ 42,863,753 \$ 64,146,036

CYTRX CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended June 30,		
	2008	2007	
Revenue:			
Service revenue	\$ 1,740,362	\$ 2,369,513	
Grant revenue			
	1,740,362	2,369,513	
Expenses:			
Research and development	2,525,659	6,884,296	
General and administrative	3,192,082	4,106,597	
	5,717,741	10,990,893	
Loss before other income	(3,977,379)	(8,621,380)	
Other income: Interest income	294 204	650.062	
Other income, net	284,304 1,000	659,062 1,501,000	
Equity in loss of unconsolidated subsidiary	(2,133,956)	1,501,000	
Minority interest in losses of subsidiary	(2,133,730)	176,136	
Net loss before income taxes Provision for income taxes	(5,826,031)	(6,285,182)	
Net loss	(5,826,031)	(6,285,182)	
Deemed dividend for anti-dilution adjustment made to stock warrants			
Net loss applicable to common stockholders	\$ (5,826,031)	\$ (6,285,182)	
Basic and diluted loss per share	\$ (0.06)	\$ (0.07)	
Weighted average shares outstanding	90,768,145	85,379,769	

About Molecular Chaperone Amplification

CytRx is a leader in molecular chaperone amplification technology. The Company currently has three orally administered, clinical-stage small-molecule programs and recently discovered a series of additional compounds that provide pipeline leads for additional drug candidates. The Company s drug candidates are believed to function by stimulating a normal cellular protein repair pathway through the activation of molecular chaperones. Since damaged proteins are thought to play a role in many diseases, CytRx believes that activation of molecular chaperones that help to reduce the accumulation of mis-folded proteins may have therapeutic efficacy in a broad range of disease states.

About CytRx Corporation

CytRx Corporation is a biopharmaceutical research and development company engaged in the development of high-value human therapeutics. The Company owns three clinical-stage compounds based on its small-molecule molecular chaperone amplification technology. CytRx has a research and development facility in San Diego. CytRx currently owns a 45% equity interest in RXi Pharmaceuticals Corporation (NASDAQ:RXII). For more information on the Company, visit www.cytrx.com.

Forward-Looking Statements

This press release may contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Such statements involve risks and uncertainties that could cause actual events or results to differ materially from the events or results described in the forward-looking statements, including risks or uncertainties related to CytRx s business, including those related to the outcome or results of the additional pre-clinical testing of arimoclomol and any future clinical testing of arimoclomol for ALS and stroke recovery and of iroxanadine for diabetic foot ulcers, uncertainties related to the impact of the FDA s clinical hold on the Company s arimoclomol clinical trial for ALS on the timing and ability to resume clinical testing at the desired dosage of arimoclomol, and the impact of that clinical hold on the timing and ability to initiate the planned Phase 2 clinical trial of arimoclomol for stroke recovery, the risk that any requirements imposed on the Company s planned clinical trial designs for ALS or stroke recovery by the FDA as a result of the concerns expressed in their clinical hold of the Company s ALS program might adversely affect the Company s ability to demonstrate that arimoclomol is efficacious in treating ALS or stroke patients or cause the Company to cancel one or both of those trials, the potential need to conduct additional toxicology or human studies with arimoclomol or iroxanadine, which could result in substantial additional expenses and delay the initiation or resumption, as applicable, of the Company s planned clinical trials, uncertainties related to the outcome or results of any future identification, development or testing of product candidates based on new molecular chaperone amplification compounds, including their safety and efficacy, and CytRx s need for additional capital to fund its ongoing working capital needs. The statements in this press release also are subject to risks and uncertainties related to the proposed acquisition of Innovive Pharmaceuticals, Inc., including those related to CytRx s ability to achieve one or more of its objectives in undertaking the acquisition, the risk that secured loan amounts advanced by CytRx to Innovive cannot be repaid by Innovive if the acquisition is not completed, the risk that the added costs of CytRx s planned additional clinical trials of arimoclomol for the treatment of ALS and funding of Innovive s operating losses before and after the acquisition will be greater than CytRx anticipates and adversely affect CytRx s liquidity and require CytRx to obtain additional equity financing sooner than expected, and risks relating to clinical development of the Innovive product candidates if the acquisition is completed, as well as other risks and uncertainties described in CytRx s Form 10-Q for the quarter ended June 30, 2008 and other recently filed SEC documents, such as its most recent annual report on Form 10-K. The business and operations of RXi, as well as CytRx s ownership of RXi shares, also are subject to risks and uncertainties, including those set forth in RXi s filings with the SEC. All

forward-looking statements are based upon information available to CytRx on the date the statements are first published. CytRx undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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In connection with the proposed Innovive acquisition, CytRx has filed with the SEC a registration statement on Form S-4, which includes a prospectus/proxy statement of CytRx and Innovive relating to the merger. INVESTORS AND STOCKHOLDERS ARE STRONGLY ADVISED TO READ THE PROSPECTUS/PROXY STATEMENT, BECAUSE IT CONTAINS IMPORTANT INFORMATION. Investors and stockholders may obtain a free copy of the prospectus/proxy statement and other documents filed by us and Innovive at the SEC s website at http://www.sec.gov.

This communication does not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction. No offering of securities will be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

This communication is not a solicitation of a proxy from any stockholder of Innovive. However, CytRx, Innovive and their respective officers and directors may be deemed to be participants in the solicitation of proxies from Innovive stockholders in connection with the proposed Innovive acquisition. Information about the officers and directors of CytRx and their ownership of CytRx common stock is set forth in the proxy statement for CytRx s 2008 Annual Meeting of Stockholders, which was filed with the SEC on May 23, 2008. Information about the officers and directors of Innovive and their ownership of Innovive common stock is set forth in Innovive s most recent Annual Report on Form 10-K, which was filed with the SEC on March 31, 2008 and amended on April 29, 2008. Investors and stockholders may obtain additional information regarding the direct and indirect interests of CytRx, Innovive and their respective officers and directors in the proposed acquisition by reading the prospectus/proxy statement referred to above.

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