CYTRX CORP Form 10-Q November 04, 2014

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2014

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 number 0-15327

CytRx Corporation (Exact name of Registrant as specified in its charter)

Delaware 58-1642740

(State or other jurisdiction of incorporation or

organization)

(I.R.S. Employer Identification No.)

11726 San Vicente Blvd., Suite 650

Los Angeles, CA

90049

(Address of principal executive offices) (Zip Code)

(310) 826-5648

(Registrant's telephone number, including area code)

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 R 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 during

the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes R No \pounds

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 R (Do not check if a smaller rep	Non-accelerated filer £ porting company)	Smaller reporting company £
Indicate by check mark wheth Act). Yes £ No R	her the Registrant is a shell con	npany (as defined in Rule 120	(b)-2 of the Exchange
Number of shares of CytRx (55,736,581 shares, exclusive	Corporation common stock, \$.0 of treasury shares.	01 par value, outstanding as	of November 4, 2014:

CYTRX CORPORATION

FORM 10-Q

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PART I — FINANCIAL INFORMATION

Item 1. — Financial Statements

CYTRX CORPORATION

CONDENSED BALANCE SHEETS

(Unaudited)

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$39,412,296	\$11,483,112
Short-term investments	50,621,593	27,084,980
Receivables	3,494,662	117,527
Interest receivable	75,543	8,464
Prepaid expenses and other current assets	2,076,164	2,329,742
Total current assets	95,680,258	41,023,825
Equipment and furnishings, net	824,491	175,452
Goodwill	183,780	183,780
Other assets	119,501	116,998
Total assets	\$96,808,030	\$41,500,055
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$5,419,228	\$3,853,531
Accrued expenses and other current liabilities	8,573,633	2,802,833
Warrant liability	4,621,974	24,182,324
Total current liabilities	18,614,835	30,838,688
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, \$0.01 par value, 5,000,000 shares authorized, including 25,000		
shares of Series A Junior Participating Preferred Stock; no shares issued and		
outstanding	_	_
Common stock, \$0.001 par value, 250,000,000 shares authorized; 55,921,986		
shares issued and outstanding at September 30, 2014; 42,116,964 shares issued and		
outstanding at December 31, 2013	55,924	42,118
Additional paid-in capital	373,782,442	289,426,100
Treasury stock, at cost (185,405 shares at September 30, 2014 and 143,796 shares		
at December 31, 2013)	(2,575,364)	(2,417,247)
Accumulated deficit	(293,069,807)	(276,389,604)
Total stockholders' equity	78,193,195	10,661,367
Total liabilities and stockholders' equity	\$96,808,030	\$41,500,055

The accompanying notes are an integral part of these condensed financial statements.

CYTRX CORPORATION CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue:				
License revenue	\$—	\$—	\$ —	\$200,000
Expenses:				
Research and development	10,637,963	4,013,572	28,054,935	11,828,575
General and administrative	2,412,848	1,987,512	8,453,048	5,775,767
	13,050,811	6,001,084	36,507,983	17,604,342
Loss before other income (loss)	(13,050,811)	(6,001,084)	(36,507,983)	(17,404,342)
Other income (loss):				
Interest income	78,735	31,068	238,750	106,890
Other income, net	20,779	822	28,680	202,520
Gain (loss) on warrant derivative liability	7,326,049	(4,010,811)	19,560,350	(3,172,324)
Net loss	\$(5,625,248)	\$(9,980,005)	\$(16,680,203)	\$(20,267,256)
Basic and diluted net loss per share	\$(0.10	\$(0.33)	\$(0.31)	\$(0.67)
_				
Basic and diluted weighted-average shares outstanding	55,703,715	30,443,293	53,918,141	30,426,460

The accompanying notes are an integral part of these condensed financial statements

CYTRX CORPORATION CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$(16,680,203)	\$(20,267,256)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	95,834	89,256
Loss on retirement of fixed assets	975	2,595
Stock compensation and warrant expense	3,402,706	1,336,667
Fair value adjustment on warrant liability	(19,560,350)	
Net foreign exchange gain	(29,131)	(140,780)
Changes in assets and liabilities:		
Receivables	(3,377,135)	107,351
Interest receivable	(67,079)	(51,443)
Prepaid expenses and other current assets	251,075	335,948
Accounts payable	1,409,926	(199,435)
Accrued expenses and other current liabilities	5,788,188	407,221
Net cash used in operating activities	(28,765,194)	(15,207,552)
Cash flows from investing activities:		
Purchase of short-term investments	(57,121,593)	_
Proceeds from the sale of short-term investments	33,584,980	7,000,000
Purchases of equipment and furnishings	(590,077)	(22,274)
Net cash provided by (used in) investing activities	(24,126,690)	6,977,726
Cash flows from financing activities:		
Net proceeds from public offering	80,535,401	
Proceeds from issuance of restricted stock to employee	100	
Repurchase of common stock for treasury	(146,374)	(78,975)
Net proceeds from exercise of warrants and stock options	431,941	933
Net cash provided by (used in) financing activities	80,821,068	(78,042)
Net increase (decrease) in cash and cash equivalents	27,929,184	(8,307,868)
Cash and cash equivalents at beginning of period	11,483,112	14,344,088
Cash and cash equivalents at end of period	\$39,412,296	\$6,036,220
Supplemental disclosure of cash flow information:		
Equipment and furnishings purchased on credit	\$155,771	\$4,535
Cashless warrant exercises	\$133	\$ —
Repurchase of Company's own stock for treasury	\$11,743	\$15,229

Cash paid for income taxes \$77,071 \$34,221

The accompanying notes are an integral part of these condensed financial statements.

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2014

(Unaudited)

1. Description of Company and Basis of Presentation

CytRx Corporation ("CytRx" or the "Company") is a biopharmaceutical research and development company specializing in oncology. The Company currently is focused on the clinical development of aldoxorubicin (formerly known as INNO-206), its modified version of the widely-used chemotherapeutic agent, doxorubicin. CytRx has initiated under a Special Protocol Assessment, or "SPA," granted by the U.S. Food and Drug Administration, or the "FDA," a pivotal Phase 3 global trial with aldoxorubicin as a therapy for patients with soft tissue sarcomas whose tumors have progressed following treatment with chemotherapy, and recently announced that it has received approval from the FDA to continue dosing patients with aldoxorubicin until disease progression in that clinical trial. CvtRx is currently evaluating aldoxorubicin in a global Phase 2b clinical trial in small cell lung cancer, a Phase 2 clinical trial in HIV-related Kaposi's sarcoma, a Phase 2 clinical trial in patients with late-stage glioblastoma (brain cancer), a Phase 1b trial in combination with ifosfamide in patients with soft tissue sarcoma, and a Phase 1b trial in combination with gemcitabine in subjects with metastatic solid tumors. CytRx has completed a global Phase 2b clinical trial with aldoxorubicin as a first-line therapy for soft tissue sarcomas, a Phase 1b/2 clinical trial primarily in the same indication, a Phase 1b clinical trial of aldoxorubicin in combination with doxorubicin in patients with advanced solid tumors and a Phase 1b pharmacokinetics clinical trial in patients with metastatic solid tumors. CytRx plans to expand its pipeline of oncology candidates at its new laboratory facilities in Freiburg, Germany, based on novel linker technologies that can be utilized with multiple chemotherapeutic agents and may allow for greater concentration of drug at tumor sites.

The accompanying condensed financial statements at September 30, 2014 and for the three-month and nine-month periods ended September 30, 2014 and 2013, respectively, are unaudited, but include all adjustments, consisting of normal recurring entries, that management believes to be necessary for a fair presentation of the periods presented. Prior period figures have been reclassified, wherever necessary, to conform to current presentation. Interim results are not necessarily indicative of results for a full year. Balance sheet amounts as of December 31, 2013 have been derived from the Company's audited financial statements as of that date.

The financial statements included herein have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to such rules and regulations. The financial statements should be read in conjunction with the Company's audited financial statements contained in its Annual Report on Form 10-K for the year ended December 31, 2013. The Company's operating results will fluctuate for the foreseeable future. Therefore, period-to-period comparisons should not be relied upon as predictive of the results in future periods.

2. Foreign Currency Remeasurement

The U.S. dollar has been determined to be the functional currency for the net assets of the CytRx German Branch. The transactions are recorded in the local currencies and are remeasured at each reporting date using the historical rates for nonmonetary assets and liabilities and exchange rates for monetary assets and liabilities at the balance sheet date. Exchange gains and losses from the remeasurement of monetary assets and liabilities are recognized in other income (loss). The Company recognized a gain of approximately \$9,501 and \$13,110 for the three-month and nine-month periods ended September 30, 2014, respectively, and zero for the comparative periods in 2013.

3. Recent Accounting Pronouncements

We have reviewed all of the recent accounting pronouncements and have determined that they have not or will not have a material impact on the Company's financial statements, or simply do not apply to the Company's operations.

4. Short-term Investments

The Company held \$50.6 million of short-term investments at September 30, 2014, as compared to \$27.1 million at December 31, 2013. The Company has classified these investments as available for sale. These investments are federally insured certificates of deposit in the following amounts and maturities: \$5.0 million with a maturity date of October 30, 2014; \$23.5 million with a maturity date of February 26, 2015; \$10.0 million with a maturity date of April 23, 2015; and \$12.1 million with a maturity date of April 30, 2015.

5. Investment in Mast Therapeutics, Inc.

On April 8, 2011, Mast Therapeutics, Inc. (formerly ADVENTRX Pharmaceuticals) completed its acquisition of SynthRx, Inc., in which the Company held a 19.1% interest. As a result of the transaction, the Company received approximately 126,000 shares of common stock of Mast Therapeutics, which it sold on October 11, 2011 for \$112,200. In June 2012, the Company received an additional 38,196 shares of common stock of Mast Therapeutics that had been held in an escrow established in connection with the acquisition, which it sold on June 6, 2012 for \$17,900. The Company received an additional 92,566 shares in January 2013 and an additional 47,745 shares in June 2013, all of which shares were sold in June 2013 for \$60,566. If all of the development milestones under the acquisition agreement were to be achieved, the Company would be entitled to receive up to 2.8 million additional Mast Therapeutics shares. The Company's former interest in SynthRx had a zero carrying value.

6. Basic and Diluted Net Income (Loss) Per Common Share

Basic and diluted net loss per common share is computed based on the weighted-average number of common shares outstanding. Common share equivalents (which consist of options, warrants and restricted stock) are excluded from the computation of diluted net income (loss) per common share where the effect would be anti-dilutive. Common share equivalents that could potentially dilute net income (loss) per share in the future, and which were excluded from the computation of diluted loss per share, totaled 14.6 million shares for each of the three-month and nine-month periods ended September 30, 2014, and 11.5 million shares for each of the three-month and nine-month periods ended September 30, 2013.

7. Warrant Liabilities

Liabilities measured at market value on a recurring basis include warrant liabilities resulting from the Company's past equity financings. In accordance with ASC 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity ("ASC 815-40"), the warrant liabilities are being marked to market until they are completely settled. The warrants are valued using the Black-Scholes method, using assumptions consistent with the Company's application of ASC 505-50, Equity-Based Payments to Non-Employees ("ASC 505-50"). The gain or loss resulting from the marked to market calculation is shown on the Condensed Statements of Operations as gain (loss) on warrant derivative liability. The Company recognized a gain (loss) of \$7.3 million and (\$4.0) million for the three-month periods ended September 30, 2014 and 2013, respectively, and a gain (loss) of \$19.6 million and (\$3.2) million for the nine-month periods ended September 30, 2014 and 2013, respectively. The following reflects the weighted-average assumptions for each of the nine-month periods indicated:

	Nine Mont	Nine Months Ended		
	Septem	September 30,		
	2014	2013		
Risk-free interest rate	0.54 %	0.59 %		
Expected dividend yield	0 %	0 %		
Expected lives	1.71	2.71		
Expected volatility	81.9 %	66.7 %		
Warrants classified as liabilities (in shares)	6,984,716	6,984,716		
Gain (loss) on warrant liability	\$19,560,350	\$(3,172,324)		

The Company's computation of expected volatility is based on the historical daily volatility of its publicly traded stock. The dividend yield assumption of zero is based upon the fact that the Company has never paid cash dividends and

presently has no intention to do so. The risk-free interest rate used for each warrant classified as a derivative is equal to the U.S. Treasury rates in effect at September 30 of each year presented. The expected lives are based on the remaining contractual lives of the related warrants at the valuation date.

8. Stock Based Compensation

The Company has a 2000 Long-Term Incentive Plan, which expired on August 6, 2010. As of September 30, 2014, there were approximately 0.8 million shares subject to outstanding stock options under this plan. No further shares are available for future grant under this plan.

The Company also has a 2008 Stock Incentive Plan. As of September 30, 2014, there were 5.9 million shares subject to outstanding stock options and 4.1 million shares available for future grant under this plan.

The Company follows ASC 718, Compensation-Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees.

For stock options and stock warrants paid in consideration of services rendered by non-employees, the Company recognizes compensation expense in accordance with the requirements of ASC 505-50.

Non-employee option grants that do not vest immediately upon grant are recorded as an expense over the vesting period. At the end of each financial reporting period, the value of these options, as calculated using the Black-Scholes option-pricing model, is determined, and compensation expense recognized or recovered during the period is adjusted accordingly. Since the fair market value of options granted to non-employees is subject to change in the future, the amount of the future compensation expense is subject to adjustment until the common stock options are fully vested.

The following table sets forth the total stock-based compensation expense resulting from stock options and warrants included in the Company's unaudited interim statements of operations:

		Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013	
Research and development — employee	\$213,180	\$52,492	\$622,818	\$156,247	