

Onconova Therapeutics, Inc.
Form 10-Q
May 15, 2014
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UNITED STATES SECURITIES AND EXCHANGE

COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2014

Or

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

Commission file number: 001-36020

Onconova Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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Delaware

(State or other jurisdiction of
incorporation or organization)

22-3627252

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

375 Pheasant Run, Newtown, PA

(Address of principal executive offices)

18940

(Zip Code)

Registrant's telephone number, including area code: **(267) 759-3680**

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 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The number of outstanding shares of the registrant's common stock, par value \$0.01 per share, as of April 30, 2014 was 21,640,387.

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ONCONOVA THERAPEUTICS, INC.

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FOR THE QUARTER ENDED MARCH 31, 2014

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Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****Onconova Therapeutics, Inc.****Condensed Consolidated Balance Sheets**

	March 31, 2014 (unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 54,624,000	\$ 60,009,000
Marketable securities	29,999,000	39,994,000
Prepaid expenses and other current assets	4,401,000	4,387,000
Total current assets	89,024,000	104,390,000
Property and equipment, net	557,000	626,000
Restricted cash	125,000	125,000
Other non-current assets	12,000	12,000
Total assets	\$ 89,718,000	\$ 105,153,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,302,000	\$ 3,710,000
Accrued expenses and other current liabilities	7,795,000	5,820,000
Warrant liability	4,000	20,000
Deferred revenue	455,000	788,000
Total current liabilities	11,556,000	10,338,000
Deferred revenue, non-current	13,795,000	13,909,000
Other	3,000	6,000
Total liabilities	25,354,000	24,253,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000,000 authorized at March 31, 2014 and December 31, 2013, none issued and outstanding at March 31, 2014 and December 31, 2013		
Common stock, \$0.01 par value, 75,000,000 authorized at March 31, 2014 and December 31, 2013, 21,638,887 and 21,467,482 shares issued and outstanding at March 31, 2014 and December 31, 2013	217,000	215,000
Additional paid in capital	313,272,000	311,093,000
Accumulated other comprehensive income		1,000
Accumulated deficit	(249,575,000)	(230,896,000)
Total Onconova Therapeutics, Inc. stockholders' equity	63,914,000	80,413,000
Non-controlling interest	450,000	487,000
Total stockholders' equity	64,364,000	80,900,000
Total liabilities and stockholders' equity	\$ 89,718,000	\$ 105,153,000

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See accompanying notes to condensed consolidated financial statements.

Table of Contents**Onconova Therapeutics, Inc.****Condensed Consolidated Statements of Operations (unaudited)**

	Three Months Ended March 31,	
	2014	2013
Revenue	\$ 447,000	\$ 1,116,000
Operating expenses:		
General and administrative	4,932,000	3,346,000
Research and development	14,248,000	12,756,000
Total operating expenses	19,180,000	16,102,000
Loss from operations	(18,733,000)	(14,986,000)
Change in fair value of warrant liability	16,000	14,000
Other income, net	1,000	127,000
Net loss	(18,716,000)	(14,845,000)
Net loss attributable to non-controlling interest	37,000	
Net loss attributable to Onconova Therapeutics, Inc.	(18,679,000)	(14,845,000)
Accretion of redeemable convertible preferred stock		(1,019,000)
Net loss applicable to common stockholders	\$ (18,679,000)	\$ (15,864,000)
Net loss per share of common stock, basic and diluted	\$ (0.87)	\$ (6.08)
Basic and diluted weighted average shares outstanding	21,568,302	2,607,406

See accompanying notes to condensed consolidated financial statements.

Table of Contents**Onconova Therapeutics, Inc.****Condensed Consolidated Statements of Comprehensive Loss (unaudited)**

	Three Months Ended March 31,	
	2014	2013
Net loss	\$ (18,716,000)	\$ (14,845,000)
Other comprehensive income, before tax:		
Foreign currency translation adjustments, net	(1,000)	7,000
Other comprehensive income, net of tax	(1,000)	7,000
Comprehensive loss	(18,717,000)	(14,838,000)
Comprehensive loss attributable to non-controlling interest	37,000	
Comprehensive loss attributable to Onconova Therapeutics, Inc.	\$ (18,680,000)	\$ (14,838,000)

See accompanying notes to condensed consolidated financial statements.

Table of Contents**Onconova Therapeutics, Inc.****Consolidated Statement of Stockholders Equity (unaudited)**

	Common Stock		Additional		Stockholders Equity		Non-controlling		Total	
	Shares	Amount	Paid in	Capital	Accumulated	Accumulated	interest			
			Capital		deficit	other				
						comprehensive				
						income				
Balance at										
December 31, 2013	21,467,482	\$ 215,000	\$ 311,093,000	\$ (230,896,000)	\$ 1,000	\$ 487,000	\$ 80,900,000			
Net loss				(18,679,000)		(37,000)	(18,716,000)			
Other comprehensive										
income						(1,000)	(1,000)			
Exercise of stock										
options	171,405	2,000	851,000				853,000			
Stock-based										
compensation			1,328,000				1,328,000			
Balance at March 31,										
2014	21,638,887	\$ 217,000	\$ 313,272,000	\$ (249,575,000)	\$	\$ 450,000	\$ 64,364,000			

See accompanying notes to condensed consolidated financial statements.

Table of Contents**Onconova Therapeutics, Inc.****Condensed Consolidated Statements of Cash Flows (unaudited)**

	Three Months Ended March 31,	
	2014	2013
Operating activities:		
Net loss	\$ (18,716,000)	\$ (14,845,000)
Adjustment to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	141,000	98,000
Change in fair value of warrant liabilities	(16,000)	(14,000)
Treasury note discount amortization	(5,000)	
Stock compensation expense	1,328,000	2,465,000
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(14,000)	(941,000)
Accounts payable	(408,000)	(1,274,000)
Accrued expenses	1,975,000	1,634,000
Other liabilities	(3,000)	20,000
Deferred revenue	(447,000)	(1,092,000)
Net cash used in operating activities	(16,165,000)	(13,949,000)
Investing activities:		
Payments for purchase of property and equipment	(72,000)	(284,000)
Maturities of marketable securities	10,000,000	
Net cash provided by (used in) investing activities	9,928,000	(284,000)
Financing activities:		
Proceeds from the exercise of stock options	853,000	6,000
Net cash provided by financing activities	853,000	6,000
Effect of foreign currency translation on cash	(1,000)	7,000
Net decrease in cash and cash equivalents	(5,385,000)	(14,220,000)
Cash and cash equivalents at beginning of period	60,009,000	81,527,000
Cash and cash equivalents at end of period	\$ 54,624,000	\$ 67,307,000

See accompanying notes to condensed consolidated financial statements.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Nature of Business

The Company

Onconova Therapeutics, Inc. (the Company) was incorporated in the State of Delaware on December 22, 1998 and commenced operations on January 1, 1999. The Company's headquarters are located in Newtown, Pennsylvania. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer. Using its proprietary chemistry platform, the Company has created an extensive library of targeted anti-cancer agents designed to work against specific cellular pathways that are important to cancer cells. The Company believes that the drug candidates in its pipeline have the potential to be efficacious in a wide variety of cancers without causing harm to normal cells. The Company has three clinical-stage product candidates and six preclinical programs. To accelerate and broaden the development of rigosertib, the Company's most advanced product candidate, the Company entered into a collaboration and license agreement in 2012 with Baxter Healthcare SA (Baxter), a subsidiary of Baxter International Inc., to commercialize rigosertib in Europe. In 2011, the Company entered into a collaboration and license agreement with SymBio Pharmaceuticals Limited (SymBio) to commercialize rigosertib in Japan and Korea. The Company has retained development and commercialization rights to rigosertib in the rest of the world, including the United States. During 2012, Onconova Europe GmbH was established as a wholly owned subsidiary of the Company for the purpose of further developing business in Europe. In April 2013, GBO, LLC, a Delaware limited liability company, (GBO) was formed pursuant to a collaboration agreement with GVK Biosciences Private Limited, a private limited company located in India, (GVK BIO) to collaborate and develop two new clinical programs using the Company's technology platform.

Liquidity

The Company has incurred recurring operating losses since inception. For the three months ended March 31, 2014, the Company incurred a net loss of \$18,716,000 and as of March 31, 2014, the Company had generated an accumulated deficit of \$249,575,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of its product candidates and its preclinical programs, strategic alliances and the development of its administrative organization. The Company will require substantial additional financing to continue to fund its operations and execute its strategy.

Since its inception, the Company raised significant capital through the issuance of redeemable convertible preferred stock, par value \$0.01 per share, in ten series denominated as Series A through Series J (Series A Preferred Stock through Series J Preferred Stock, respectively, and collectively the Preferred Stock). On July 30, 2013, the Company completed its initial public offering (the IPO) of 5,941,667 shares of the Company's common stock, par value \$0.01 per share (Common Stock), at a price of \$15.00 per share, including 775,000 shares of Common Stock issued upon the exercise in full by the underwriters of their option to purchase additional shares at the same price to cover over-allotments. The Company received net proceeds of \$79,811,000 from the sale, net of underwriting discounts and commissions and other estimated offering expenses. Immediately prior to the consummation of the IPO, all outstanding shares of Preferred Stock automatically converted into shares of Common Stock at the applicable conversion ratio then in effect. As a result of the conversion, as of July 30, 2013, the Company had no shares

of Preferred Stock outstanding.

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company's ability to continue as a going concern is dependent on its ability to raise additional capital to fund its research and development and commercial programs and meet its obligations. Management intends to fund future operations through additional equity offerings, licensing revenue, grants, government contracts and, if any of the Company's product candidates receive marketing approval, future sales of its products. There can be no assurance, however, that the Company will be successful in obtaining financing at the level needed to sustain operations or on terms acceptable to the Company, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States (GAAP) for interim financial information. Certain information and footnotes normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). The financial statements include the consolidated accounts of the Company, its wholly-owned subsidiary, Onconova Europe GmbH and GBO. All significant intercompany transactions have been eliminated.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of March 31, 2014, the condensed consolidated statements of operations, the condensed consolidated statements of comprehensive loss, the condensed consolidated statement of stockholders' equity and the condensed consolidated statements of cash flows for the three months ended March 31, 2014 and 2013 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2014 and the results of its operations, and its cash flows for the three months ended March 31, 2014 and 2013. The financial data and other information disclosed in these notes related to the three months ended March 31, 2014 and 2013 are unaudited. The results for the three months ended March 31, 2014 are not necessarily indicative of results to be expected for the year ending December 31, 2014, any other interim periods, or any future year or period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2013 included in the Company's annual report on Form 10-K filed with the SEC on March 20, 2014.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment, which is the identification and development of oncology therapeutics.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2013 included in the Company's annual report on Form 10-K filed with the SEC on March 20, 2014. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

Foreign Currency Translation

The reporting currency of the Company and its U.S. subsidiary is the U.S. dollar. The functional currency of the Company's non-U.S. subsidiary is the local currency. Assets and liabilities of the foreign subsidiary are translated into U.S. dollars based on exchange rates at the end of the period. Revenues and expenses are translated at average exchange rates during the reporting period. Gains and losses arising from the translation of assets and liabilities are included as a component of accumulated other comprehensive income. Gains and losses resulting from foreign currency transactions are reflected within the Company's results of operations. The Company has not utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies (Continued)

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (the "FASB") issued guidance clarifying that an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax benefit is disallowed. In situations where a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction or the tax law of the jurisdiction does not require, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit should be presented in the financial statements as a liability and should not be netted with the deferred tax asset. The guidance was effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company adopted these new provisions during the quarter beginning January 1, 2014. The guidance did not have an impact on the Company's consolidated financial position, results of operations or cash flows.

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****3. Fair Value Measurements**

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The Company had no assets or liabilities classified as Level 1 or Level 2. The warrants (see Note 7) are classified as Level 3.

The Company has classified the warrants as a liability and has re-measured the liability to estimated fair value at March 31, 2014 and December 31, 2013, using the Black-Scholes option pricing model with the following assumptions: contractual life according to the remaining terms of the warrants, no dividend yield, weighted average risk-free interest rates of 0.13% and 0.34% at March 31, 2014 and December 31, 2013, respectively, and weighted average volatility of 72.11% and 74.40% at March 31, 2014 and December 31, 2013, respectively. The volatility was based on average historical share price trading data for a group of 11 comparable companies.

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2014 and December 31, 2013:

	Fair Value Measurement as of March 31, 2014				Fair Value Measurement as of December 31, 2013			
	Level 1	Level 2	Level 3	Balance	Level 1	Level 2	Level 3	Balance
Warrant liability	\$	\$	\$ 4,000	\$ 4,000	\$	\$	\$ 20,000	\$ 20,000
Total	\$	\$	\$ 4,000	\$ 4,000	\$	\$	\$ 20,000	\$ 20,000

The following table presents a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months ended March 31, 2014:

	Warrant Liability	
Balance at December 31, 2013	\$	20,000
Change in fair value upon re-measurement		(16,000)
Balance at March 31, 2014	\$	4,000

There were no transfers between Level 1 and Level 2 in any of the periods reported.

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****4. Marketable Securities**

Marketable securities with initial maturities longer than three months but that mature within one year from the balance sheet date are classified as current assets and are summarized as follows:

	March 31, 2014	December 31, 2013
U.S. Treasury obligations	\$ 29,999,000	\$ 39,994,000

As of March 31, 2014 and December 31, 2013, all of the Company's investments were classified as held-to-maturity.

5. Net Loss Per Share of Common Stock

The following potentially dilutive securities outstanding at March 31, 2014 and 2013 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	2014	March 31, 2013
Preferred Stock		12,838,127
Warrants	4,597	4,597
Stock options	4,252,171	2,792,169
	4,256,768	15,634,893

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****6. Balance Sheet Detail**

Prepaid expenses and other current assets:

	March 31, 2014	December 31, 2013
Research and development	\$ 2,435,000	\$ 2,242,000
Manufacturing	1,025,000	1,051,000
Insurance	421,000	645,000
Other	520,000	449,000
	\$ 4,401,000	\$ 4,387,000

Property and equipment:

	March 31, 2014	December 31, 2013
Property and equipment	\$ 2,471,000	\$ 2,402,000
Accumulated depreciation	(1,914,000)	(1,776,000)
	\$ 557,000	\$ 626,000

Accrued expenses and other current liabilities:

	March 31, 2014	December 31, 2013
Research and development	\$ 5,808,000	\$ 4,625,000
Employee compensation	1,383,000	509,000
Professional fees	329,000	310,000
Taxes	208,000	302,000
Other	67,000	74,000
	\$ 7,795,000	\$ 5,820,000

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

7. Warrants

In June 2009, the Company issued 6,128 Series G Preferred Stock warrants in connection with a Loan and Security Agreement. Additionally, the Company issued one Series G Preferred Stock warrant for every two shares of Series G Preferred Stock purchased in 2009 and 2010. The warrants were initially recorded at their fair value calculated using the Black-Scholes model. The warrants are classified as liabilities due to certain anti-dilution provisions, and the value of the warrants is adjusted to current fair value at each reporting period end. For the three months ended March 31, 2014 and 2013, the Company recorded \$16,000 and \$14,000, respectively, in the consolidated statements of operations related to the change in the fair value of the outstanding warrants.

Immediately prior to the consummation of the IPO, the 6,128 Series G Preferred Stock warrants outstanding were automatically converted into 4,597 Common Stock warrants (after giving effect to the one-for-1.333 reverse stock split that became effective on July 17, 2013 in connection with the IPO).

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****8. Stock-Based Compensation**

The Company recognized stock-based compensation expense as follows for the three months ended March 31, 2014 and 2013:

	Three Months Ended March 31,	
	2014	2013
General and administrative	\$ 647,000	\$ 1,307,000
Research and development	681,000	1,158,000
	\$ 1,328,000	\$ 2,465,000

Stock options may be granted with exercise prices of not less than the estimated fair value of the Common Stock on the date of grant and generally vest over a period of up to four years. Stock options granted under the 2013 Plan generally expire no later than ten years from the date of grant. A summary of stock option activity for the three months ended March 31, 2014 is as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)
Outstanding at December 31, 2013	4,344,365	\$ 11.05	7.91
Granted	132,500	7.63	
Exercised	(171,405)	4.95	
Forfeited	(53,289)	11.47	
Outstanding at March 31, 2014	4,252,171	\$ 11.19	8.02
Vested or expected to vest at March 31, 2014	4,180,309	\$ 11.19	8.02
Exercisable at March 31, 2014	2,352,446	\$ 9.39	7.00