

Onconova Therapeutics, Inc.
Form 10-Q
May 15, 2018
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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, 2018

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, a smaller reporting company or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company and emerging growth company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>
	Emerging growth company <input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 May 7, 2018 was 77,607,812.

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ONCONOVA THERAPEUTICS, INC.

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FOR THE QUARTER ENDED MARCH 31, 2018

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Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements**

Onconova Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,264,000	\$ 4,024,000
Receivables	477,000	59,000
Prepaid expenses and other current assets	814,000	820,000
Total current assets	8,555,000	4,903,000
Property and equipment, net	48,000	64,000
Other non-current assets	12,000	12,000
Total assets	\$ 8,615,000	\$ 4,979,000
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 7,034,000	\$ 6,186,000
Accrued expenses and other current liabilities	3,063,000	3,335,000
Deferred revenue	455,000	455,000
Total current liabilities	10,552,000	9,976,000
Warrant liability	961,000	1,773,000
Deferred revenue, non-current	3,977,000	4,091,000
Total liabilities	15,490,000	15,840,000
Commitments and contingencies		
Stockholders (deficit) equity:		
Preferred stock, \$0.01 par value, 5,000,000 authorized at March 31, 2018 and December 31, 2017, none issued and outstanding at March 31, 2018 and December 31, 2017		
Common stock, \$0.01 par value, 100,000,000 and 25,000,000 authorized at March 31, 2018 and December 31, 2017, 19,426,163 and 10,771,163 shares issued and outstanding at March 31, 2018 and December 31, 2017	194,000	108,000
Additional paid in capital	359,496,000	350,514,000
Accumulated other comprehensive income	11,000	3,000
Accumulated deficit	(367,406,000)	(362,316,000)
Total Onconova Therapeutics, Inc. stockholders (deficit) equity	(7,705,000)	(11,691,000)
Non-controlling interest	830,000	830,000
Total stockholders (deficit) equity	(6,875,000)	(10,861,000)
Total liabilities and stockholders (deficit) equity	\$ 8,615,000	\$ 4,979,000

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,	
	2018	2017
Revenue	\$ 564,000	\$ 210,000
Operating expenses:		
General and administrative	1,889,000	2,116,000
Research and development	4,577,000	4,886,000
Total operating expenses	6,466,000	7,002,000
Loss from operations	(5,902,000)	(6,792,000)
Change in fair value of warrant liability	812,000	(1,549,000)
Net loss	(5,090,000)	(8,341,000)
Net loss attributable to non-controlling interest		
Net loss attributable to Onconova Therapeutics, Inc.	(5,090,000)	(8,341,000)
Net loss per share of common stock, basic and diluted	\$ (0.34)	\$ (1.23)
Basic and diluted weighted average shares outstanding	15,138,663	6,771,383

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,	
	2018	2017
Net loss	\$ (5,090,000)	\$ (8,341,000)
Other comprehensive income (loss), before tax:		
Foreign currency translation adjustments, net	8,000	5,000
Other comprehensive income (loss), net of tax	8,000	5,000
Comprehensive loss	(5,082,000)	(8,336,000)
Comprehensive loss attributable to non-controlling interest		
Comprehensive loss attributable to Onconova Therapeutics, Inc.	\$ (5,082,000)	\$ (8,336,000)

See accompanying notes to condensed consolidated financial statements.

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

	Stockholders Equity (Deficit)						
	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Non-controlling interest	Total
Balance at December 31, 2017	10,771,163	\$ 108,000	\$ 350,514,000	\$ (362,316,000)	\$ 3,000	\$ 830,000	\$ (10,861,000)
Net loss				(5,090,000)			(5,090,000)
Other comprehensive loss					8,000		8,000
Exercise of stock options							
Stock-based compensation			327,000				327,000
Issuance of common stock and pre-funded warrants, net	7,005,000	70,000	8,655,000				8,725,000
Issuance of common stock upon exercise of warrants	1,650,000	16,000					16,000
Issuance of common stock, net							
Balance at March 31, 2018	19,426,163	\$ 194,000	\$ 359,496,000	\$ (367,406,000)	\$ 11,000	\$ 830,000	\$ (6,875,000)

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,	
	2018	2017
Operating activities:		
Net loss	\$ (5,090,000)	\$ (8,341,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	16,000	23,000
Change in fair value of warrant liabilities	(812,000)	1,549,000
Stock compensation expense	278,000	458,000
Changes in assets and liabilities:		
Receivables	(418,000)	(95,000)
Prepaid expenses and other current assets	6,000	740,000
Accounts payable	848,000	84,000
Accrued expenses and other current liabilities	(223,000)	(361,000)
Deferred revenue	(114,000)	(113,000)
Net cash used in operating activities	(5,509,000)	(6,056,000)
Investing activities:		
Net cash provided by investing activities		
Financing activities:		
Proceeds from the sale of common stock and warrants, net of costs	8,725,000	40,000
Proceeds from the exercise of warrants	16,000	
Net cash provided by financing activities	8,741,000	40,000
Effect of foreign currency translation on cash	8,000	5,000
Net increase (decrease) in cash and cash equivalents	3,240,000	(6,011,000)
Cash and cash equivalents at beginning of period	4,024,000	21,400,000
Cash and cash equivalents at end of period	\$ 7,264,000	\$ 15,389,000

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 product candidates primarily 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 product candidates in its pipeline have the potential to be efficacious in a variety of cancers. The Company has three clinical-stage product candidates and several preclinical programs. In 2011, the Company entered into a license agreement, as subsequently amended, with SymBio Pharmaceuticals Limited ("SymBio"), which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. On March 2, 2018, the Company entered into a License, Development and Commercialization Agreement with Pint International SA (which, together with its affiliate Pint Pharma GmbH, are collectively referred to as "Pint"). Under the terms of the agreement, the Company granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product containing rigosertib in all uses of rigosertib in certain Latin America countries. In 2012, the Company entered into a development and license agreement with Baxter Healthcare SA, the predecessor in interest to Baxalta GmbH (together with its affiliates, "Baxalta"), pursuant to which the Company granted an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe. The Baxalta agreement terminated effective August 30, 2016, at which time the rights the Company licensed to Baxalta reverted to the Company at no cost. 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 an agreement with GVK Biosciences Private Limited, a private limited company located in India, ("GVK") to collaborate and develop two programs using the Company's technology platform. The two preclinical programs sublicensed to GBO have not been developed to clinical stage as initially hoped, and the Company is in discussions with GVK regarding the future of GBO.

On March 21, 2018, the Company amended its certificate of incorporation to increase the number of authorized shares of common stock par value \$0.01 per share from 25,000,000 to 100,000,000.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Liquidity

The Company has incurred recurring operating losses since inception. For the three months ended March 31, 2018, the Company incurred a net loss of \$5,090,000 and as of March 31, 2018 the Company had generated an accumulated deficit of \$367,406,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At March 31, 2018, the Company had cash and cash equivalents of \$7,264,000. The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy.

From its inception through July 2013, the Company raised capital through the private issuance of preferred stock. On July 30, 2013, the Company completed its initial public offering (the IPO) of 594,167 shares of Common Stock, at a price of \$150.00 per share. 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. From the IPO through December 31, 2016, the Company closed on several offerings which included Common Stock and warrants. Total net proceeds from these offerings was approximately \$24.9 million

On April 26, 2017 the Company closed on an underwritten public offering of 2,476,190 shares of Common Stock. On May 17, 2017, the Company sold an additional 363,580 shares as a result of the underwriter's exercise of its over-allotment option. Net proceeds from these transactions were approximately \$5.3 million. (See Note 13)

On November 14, 2017 the Company closed on a registered direct offering to select accredited investors of 920,000 shares of common stock. Net proceeds were approximately \$1.1 million. (See Note 13)

On February 12, 2018 the Company closed on an offering of units of common stock and warrants. The Company issued 7,005,000 shares of common stock, pre-funded warrants to purchase 2,942,500 share of common stock, and preferred stock warrants to purchase 1,044,487.5 shares of Series A convertible preferred stock. Each share of Series A convertible preferred stock is convertible into ten shares of common stock. Net proceeds were approximately \$8.7 million. (See Note 13)

On May 1, 2018 the Company closed on an offering of units of common stock and warrants. The Company issued 55,411,763 shares of common stock, pre-funded warrants to purchase 12,235,295 shares of common stock, and preferred stock warrants to purchase 1,691,176.450 shares of Series B convertible preferred stock. Each share of Series B convertible preferred stock is convertible into 40 shares of common stock. Net proceeds were approximately \$25.6 million. (See Note 13)

The Company has and may continue to delay, scale-back, or eliminate certain of its research and development activities and other aspects of its operations until such time as the Company is successful in securing additional funding. The Company continues to explore various dilutive and non-dilutive sources of funding, including equity financings, strategic alliances, business development and other sources. The future success of the Company is dependent upon its ability to obtain additional funding. There can be no assurance, however, that the Company will be successful in obtaining such funding in sufficient amounts, on terms acceptable to the Company, or at all. The Company currently anticipates that current cash and cash equivalents will be sufficient to meet its anticipated cash requirements into the fourth quarter of 2019.

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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 financi