ARQULE INC
Form 10-Q
May 07, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

Quarterly report pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

For the Quarter Ended March 31, 2014

Commission File No. 000-21429

ArQule, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	04-3221586
(State of Incorporation)	(I.R.S. Employer Identification Number)

19 Presidential Way, Woburn, Massachusetts 01801
(Address of Principal Executive Offices)

(781) 994-0300
(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 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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its 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 x No o

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

Number of shares outstanding of the registrant's Common Stock as of April 23, 2014:

Common Stock, par value $.01	62,723,543 shares outstanding

ARQULE, INC.

QUARTER ENDED MARCH 31, 2014

TABLE OF CONTENTS

ARQULE, INC.

CONDENSED BALANCE SHEETS (Unaudited)

	March 31, 2014	December 31, 2013
	(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)	
ASSETS		
Current assets:		
Cash and cash equivalents	$15,519	$ 15,579
Marketable securities-short term	56,209	59,116
Prepaid expenses and other current assets	922	941
Total current assets	72,650	75,636
Marketable securities-long term	14,030	20,391
Property and equipment, net	923	1,128
Other assets	971	1,024
Total assets	$88,574	$ 98,179
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$7,834	$ 8,470
Note payable	1,700	1,700
Current portion of deferred revenue	11,031	11,031
Current portion of deferred gain on sale leaseback	552	552
Total current liabilities	21,117	21,753
Deferred revenue, net of current portion	12,811	15,568
Deferred gain on sale leaseback, net of current portion	92	232
Total liabilities	34,020	37,553
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 1,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.01 par value; 100,000,000 shares authorized; 62,723,543 and 62,736,207 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	627	627
Additional paid-in capital	505,970	504,884
Accumulated other comprehensive income	50	67
Accumulated deficit	(452,093)	(444,952)
Total stockholders' equity	54,554	60,626
Total liabilities and stockholders' equity	$88,574	$ 98,179

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

ARQULE, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)

	THREE MONTHS ENDED MARCH 31,	
	2014	2013
	(IN THOUSANDS, EXCEPT PER SHARE DATA)	
Revenue:		
Research and development revenue	$ 2,676	$ 5,661
Costs and expenses:		
Research and development	6,731	8,181
General and administrative	3,250	3,400
Total costs and expenses	9,981	11,581
Loss from operations	(7,305)	(5,920)
Interest income	95	151
Interest expense	(7)	(4)
Other income (expense)	76	(2)
Net loss	(7,141)	(5, 775)
Unrealized gain (loss) on marketable securities	(17)	9
Comprehensive loss	$ (7,158)	$ (5,766)
Basic and diluted net loss per share:		
Net loss per share	$ (0.11)	$ (0.09)
Weighted average basic and diluted common shares outstanding	62,583	62,384

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

ARQULE, INC.

CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	THREE MONTHS ENDED March 31,	
	2014	2013
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	$ (7,141)	$ (5,775)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	205	235
Amortization of premium/(discount) on marketable securities	340	625
Amortization of deferred gain on sale leaseback	(140)	(140)
Non-cash stock compensation	1,086	1,365
Loss (gain) on auction rate securities	(76)	2
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	19	(481)
Other assets	53	81
Accounts payable and accrued expenses	(636)	(2,681)
Deferred revenue	(2,757)	(3,571)
Net cash used in operating activities	(9,047)	(10,340)
Cash flows from investing activities:		
Purchases of marketable securities	(10,635)	(616)
Proceeds from sale or maturity of marketable securities	19,622	11,603
Net cash provided by investing activities	8,987	10,987
Cash flows from financing activities	—	—
Net increase (decrease) in cash and cash equivalents	(60)	647
Cash and cash equivalents, beginning of period	15,579	14,327
Cash and cash equivalents, end of period	$ 15,519	$ 14,974

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

ARQULE, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

We are a clinical-stage biotechnology company organized as a Delaware corporation in 1993 engaged in the research and development of innovative cancer therapeutics. Our mission is to produce novel drugs with differentiated mechanisms of action that will extend the lives of our patients. These drugs target biological pathways implicated in a wide range of cancers. We employ technologies such as our ArQule Kinase Inhibitor Platform ("AKIP TM") to design and develop drugs that have the potential to fulfill this mission.

Our lead product candidate is tivantinib (ARQ 197), an orally administered, small molecule inhibitor of the c-Met receptor tyrosine kinase ("c-MET") and its biological pathway. C-MET is a promising target for cancer therapy, based on its multiple roles in cancerous cell proliferation, tumor spread, new blood vessel formation and resistance to certain drug therapies. We and our partners, Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") and Kyowa Hakko Kirin Co., Ltd. ("Kyowa Hakko Kirin"), are implementing a worldwide clinical development program designed to realize the broad potential of tivantinib. Our strategy is to focus on the most promising indications within our clinical programs based upon continually generated and updated clinical and pre-clinical data. Our lead indication is liver cancer ("hepatocellular carcinoma" or "HCC"). We have also completed earlier-stage combination therapy trials and pre-clinical experiments with tivantinib and other anti-cancer agents that may provide data to support later-stage trials in additional indications.

Our most advanced ongoing clinical trial, the METIV-HCC trial, is a pivotal Phase 3 randomized, double-blind, controlled study of tivantinib as single agent therapy in previously treated patients with MET diagnostic-high, inoperable HCC conducted by Daiichi Sankyo and us. A dose reduction in the METIV-HCC trial from 240 mg twice daily ("BID") tablets to 120 mg BID tablets was implemented in September 2013 following the observation of a higher incidence of neutropenia in the initial phase of the METIV-HCC trial than was observed in the Phase 2 trial in the same patient population, which employed a 240 mg BID capsule dose, and in other trials with tivantinib. Certain enhanced patient monitoring procedures were temporarily instituted to confirm the safety profile of the lower dose. Following a review of data analyses from a predefined number of patients who received this lower dose, the Data Monitoring Committee ("DMC") of the METIV-HCC trial recommended in January 2014 continuation of the ongoing trial, with patients receiving the lower dose.

Approximately 300 patients are planned to be enrolled in the METIV-HCC trial at approximately 120 clinical sites worldwide. Our current estimate of the time frame for completion of enrollment is mid-2016. This trial is being conducted under a Special Protocol Assessment ("SPA") agreement with the FDA. An SPA is an agreement establishing the design, endpoints and statistical analysis of a clinical trial intended to provide the necessary data, depending on the outcome of the trial, which could support the filing of a New Drug Application ("NDA"). Final marketing approval depends on the results of the trial. Because the METIV-HCC trial is enrolling patients with MET-diagnostic high HCC whom we believe are likely to benefit from treatment with tivantinib, the SPA also includes an immunohistochemistry ("IHC")-based companion diagnostic ("CDx") under development by Daiichi Sankyo and ourselves in collaboration with a third party provider of such tests. The CDx is being developed to enable the identification of the MET status of patients seeking to be enrolled in this trial. Our collaborator for the companion diagnostic test will need to submit a Premarket Approval ("PMA") application to FDA that establishes the predictive value of the CDx in connection with the registration and commercialization of the drug in the U.S., and additional

regulatory applications will need to be made in other geographic areas.

In addition to METIV-HCC, a second Phase 3 clinical trial in HCC with tivantinib is ongoing in Japan. On February 4, 2014, Kyowa Hakko Kirin, our partner for the development of tivantinib in Asian territories, announced the initiation of this trial in Japanese patients with MET diagnostic-high, inoperable HCC treated with one prior therapy with sorafenib. The trial is a randomized, double-blind placebo-controlled study to compare progression free survival ("PFS") in patients treated with tivantinib with those treated with placebo. Kyowa Hakko Kirin plans to enroll approximately 160 patients in this study. There are no milestone payments associated with the initiation of this trial.

On January 16, 2014, we reported that Kyowa Hakko Kirin provided us with top-line results of the amended Phase 3 randomized, double-blind ATTENTION clinical trial evaluating the combination of tivantinib and erlotinib in second-line patients with advanced or metastatic non-squamous non-small cell lung cancer ("NSCLC") with wild-type epidermal growth factor receptor ("EGFR") in Asia (Japan, Korea and Taiwan). Enrollment in ATTENTION had been originally planned at 460 patients. Recruitment of new patients was permanently suspended in October 2012 based on a recommendation by the trial's Safety Review Committee following an observed imbalance in interstitial lung disease ("ILD") cases as a drug-related adverse event. Patients recruited into ATTENTION as of October 2012 were allowed to continue thereafter in the trial after being re-consented, and including such patients, 307 patients in total were included in the final analysis.

We have licensed commercial rights to tivantinib for human cancer indications to Daiichi Sankyo in the U.S., Europe, South America and the rest of the world, excluding Japan and certain other Asian countries, where we have licensed commercial rights to Kyowa Hakko Kirin. Our agreements with these partners provide for possible future milestone payments, royalties on product sales, and development funding, in addition to significant payments that we have already received. During 2011, we received $25 million from Daiichi Sankyo resulting from the dosing of the first patient in the MARQUEE trial and $10 million from Kyowa Hakko Kirin resulting from dosing of the first patient in the ATTENTION trial. On January 31, 2013, we announced that the first patient had been enrolled in the pivotal Phase 3 METIV trial of tivantinib, entitling us to a $15 million milestone. That milestone was netted against our cumulative share of Phase 3 collaboration costs in 2013, and consequently we did not receive any cash proceeds from this milestone. The terms of our tivantinib licensing agreements with Daiichi Sankyo and Kyowa Hakko Kirin remain in effect following the recent developments in both of these trials.

Our proprietary pipeline of product candidates is directed toward molecular targets and biological processes with demonstrated roles in the development of human cancers. Our priorities within this pipeline include ARQ 092, an Akt inhibitor, and ARQ 087, an inhibitor of fibroblast growth factor receptor. We are also supporting an ongoing investigator-sponsored trial with ARQ 761, which is being investigated as a potential NQ01 inhibitor.

We have prepared the accompanying condensed financial statements pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to these rules and regulations. These condensed financial statements should be read in conjunction with our audited financial statements and footnotes related thereto for the year ended December 31, 2013 included in our annual report on Form 10-K filed with the SEC on March 5, 2014.

The unaudited condensed financial statements include, in our opinion, all adjustments (consisting only of normal recurring adjustments) necessary for a fair statement of our financial position as of March 31, 2014, and the results of our operations and cash flows for the three months ended March 31, 2014 and March 31, 2013. The results of operations for such interim periods are not necessarily indicative of the results to be achieved for the full year.

2. COLLABORATIONS AND ALLIANCES

Daiichi Sankyo ARQ 092 Agreement

We have regained worldwide rights for the development and commercialization of ARQ 092 and all other compounds included under our Akt collaboration with Daiichi Sankyo pursuant to their formal notice to terminate our license and commercialization agreement received on March 26, 2013. Termination of this agreement was effective 90 days from our receipt of the formal notice from Daiichi Sankyo, following which we became responsible for funding the remainder of the ongoing Phase 1 trial with ARQ 092 beyond the contractual termination period, as well as any future clinical development and commercialization of this compound. The license agreement had provided exclusive rights to Daiichi Sankyo for the development, manufacturing and marketing of ARQ 092 on a worldwide basis. Under this agreement, we received a $10 million upfront fee from Daiichi Sankyo in November 2011. Following the termination of this agreement, ARQ 092 has become our proprietary asset, and Daiichi Sankyo has no further financial or other obligations or rights related to this program.

On November 10, 2011, we and Daiichi Sankyo announced the execution of a license agreement for the development of ARQ 092. The license agreement provided exclusive rights to Daiichi Sankyo for the development, manufacturing and marketing of ARQ 092 on a worldwide basis. Revenue for this agreement was recognized using Financial

Accounting Standards Board Accounting Standards Update No. 2009-13, Multiple-Deliverable Revenue Arrangements ("ASU 2009-13"). Under ASU 2009-13 all undelivered items under an agreement are divided into separate units of accounting based on whether the deliverable provides stand-alone value to the licensee. The Company determined the best estimate selling price (BESP) for each unit of accounting based upon management's judgment and including factors such as discounted cash flows, estimated direct expenses and other costs and probability of successful outcome of clinical trials.

As the license granted under the agreement was delivered, the license had standalone value, and there were no further obligations related to the license, revenue of $10 million related to this accounting unit was recognized in 2011 based on the best estimate of selling price of the license. Revenue related to clinical trial costs and steering committee services were recognized ratably over the clinical trial as services were provided and costs were incurred, up to the amount of cash received for these deliverables based on the best estimate of selling price of each deliverable. The development period for this agreement concluded in June 2013 and accordingly we recognized no revenue for the quarter ended March 31, 2014. We recognized revenue of $0.6 million for the quarter ended March 31, 2013. At March 31, 2014 there was no remaining deferred revenue related to this agreement.

Daiichi Sankyo Tivantinib Agreement

On December 18, 2008, we entered into a license, co-development and co-commercialization agreement with Daiichi Sankyo to conduct research, clinical trials and the commercialization of tivantinib in human cancer indications in the U.S., Europe, South America and the rest of the world, excluding Japan, China (including Hong Kong), South Korea and Taiwan, where Kyowa Hakko Kirin has exclusive rights for development and commercialization. The terms of our tivantinib agreement with Daiichi Sankyo remain in effect following the recent developments in the trials described above.

The agreement provides for a $60 million cash upfront licensing payment from Daiichi Sankyo to us, which we received in December 2008, and an additional $560 million in potential development and sales milestone payments offset by our share of the Phase 3 costs. Upon commercialization, we will receive tiered, double-digit royalties from Daiichi Sankyo on net sales of tivantinib commensurate with the magnitude of the transaction. We retain the option to participate in the commercialization of tivantinib in the U.S. We and Daiichi Sankyo will share equally the costs of Phase 2 and Phase 3 clinical studies, with our share of Phase 3 costs payable solely from milestone and royalty payments by Daiichi Sankyo.

Under the terms of our tivantinib collaboration agreement with Daiichi Sankyo we share development costs equally with our share of Phase 3 costs funded solely from milestones and royalties. In each quarter the tivantinib collaboration costs we incur are compared with those of Daiichi Sankyo. If our costs for the quarter exceed Daiichi Sankyo's, we recognize revenue on the amounts due to us under the contingency adjusted performance model. Revenue is calculated on a pro-rata basis using the time elapsed from inception of the agreement over the estimated duration of the development period under the agreement. If our costs for the quarter are less than those of Daiichi Sankyo's, we report the amount due to Daiichi Sankyo as contra-revenue in that quarter. To the extent that our share of Phase 3 collaboration costs exceeds the amount of milestones and royalties received, that excess is netted against future milestones and royalties if and when earned and is not reported as contra-revenue.

Our cumulative share of the Daiichi Sankyo Phase 3 costs through March 31, 2014, totaled $84.2 million. We received a milestone of $25 million in February 2011 upon enrolling the first patient in the MARQUEE trial, the cash proceeds of which were subsequently applied to our share of Phase 3 collaboration costs. On January 31, 2013, we announced that the first patient had been enrolled in the pivotal Phase 3 METIV trial of tivantinib, entitling us to a $15 million milestone. That $15 million milestone was also netted against our cumulative share of Phase 3 collaboration costs in 2013, and consequently we did not receive any cash proceeds from this milestone. Our cumulative share of Phase 3 collaboration costs has exceeded the amount of milestones received through March 31, 2014 by $44.2 million which will be netted against future milestones and royalties, if any, when earned and has not been reported as contra-revenue.

For the quarter ended March 31, 2014 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo's by $82 which was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue.

For the quarter ended March 31, 2013 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo's by $216 which was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue.

The duration and termination of the agreement are tied to future events. Unless earlier terminated due to breach, insolvency or upon 90 days notice if prior to phase 3 clinical trials or 180 days notice if on or after the beginning of phase 3 clinical trials by Daiichi Sankyo, the agreement shall continue until the later of (i) such time as Daiichi Sankyo is no longer developing at least one licensed product or (ii) if Daiichi Sankyo has commercialized a licensed product or products, such time as all royalty terms for all licensed products have ended. The royalty term, on a country-by-country basis for a product, ends as of the later of (i) the expiration of the last valid claim under a patent covering the manufacture, use, or sale of a licensed product or (ii) a certain number of years from the date of the commercial sale of the licensed product in such country.

Revenue for this agreement is recognized using the contingency-adjusted performance model. Through September 30, 2012, revenue was recognized based upon an estimated development period through December 2013. As a result of

the October 2012 decision to discontinue the MARQUEE trial, the development period as of October 1, 2012 was extended to June 2015. Commencing with the fourth quarter of 2012 and through the third quarter of 2013 revenue was recognized over that development period. In the fourth quarter of 2013, following a recommendation by the Data Monitoring Committee that the METIV-HCC trial continue with patients receiving a lower dose of tivantinib than the dose originally employed in the trial, we reviewed the estimated development period and extended it to June 2016. For the quarters ended March 31, 2014 and 2013, $1.3 million and $1.9 million, respectively, were recognized as net revenue. At March 31, 2014, $12.0 million remains in deferred revenue.

Kyowa Hakko Kirin Licensing Agreement

On April 27, 2007, we entered into an exclusive license agreement with Kyowa Hakko Kirin to develop and commercialize tivantinib in Japan and parts of Asia. A $3 million portion of an upfront licensing fee was received by the Company under this agreement in the first quarter of 2007, and an additional $27 million in upfront licensing fees was received on May 7, 2007. The agreement includes $123 million in upfront and potential development milestone payments from Kyowa Hakko Kirin to ArQule, including the $30 million cash upfront licensing payments. In February 2008, we received a $3 million milestone payment from Kyowa Hakko Kirin. Upon commercialization, ArQule will receive tiered royalties in the mid-teen to low-twenty percent range from Kyowa Hakko Kirin on net sales of tivantinib. Kyowa Hakko Kirin will be responsible for all clinical development costs and commercialization of the compound in certain Asian countries, consisting of Japan, China (including Hong Kong), South Korea and Taiwan. In July 2010, we announced the initiation of a Phase 2 trial with tivantinib by Kyowa Hakko Kirin in gastric cancer, for which we received a $5 million milestone payment in September 2010. The terms of our tivantinib licensing agreement with Kyowa Hakko Kirin remain in effect following the recent 2013 developments in the Phase 3 ATTENTION trial in Asia described above.

In August 2011, Kyowa Hakko Kirin announced the initiation of the Phase 3 ATTENTION trial. Dosing of the first patient in this trial triggered a $10 million milestone payment, which we received in August 2011. The milestone payment was recorded as deferred revenue and is being recognized as revenue using the contingency-adjusted performance model with an estimated development period through April 2016.

In addition to the upfront and possible regulatory milestone payments totaling $123 million, the Company will be eligible for future milestone payments based on the achievement of certain levels of net sales. The Company will recognize the payments, if any, as revenue in accordance with the contingency-adjusted performance model. As of March 31, 2014, the Company had not recognized any revenue from these sales milestone payments, and there can be no assurance that it will do so in the future.

The duration and termination of the agreement are tied to future events. Unless earlier terminated due to breach, insolvency or upon 90 days notice by Kyowa Hakko Kirin, the agreement terminates on the date that the last royalty term expires in all countries in the territory. The royalty term ends as of the later of (i) the expiration of the last pending patent application or expiration of the patent in the country covering the manufacture, use, or sale of a licensed product or (ii) a certain number of years from the date of the commercial launch in such country of such license product.

Revenue for this agreement is recognized using the contingency-adjusted performance model with an estimated development period through April 2016. For each of the quarters ended March 31, 2014 and 2013, $1.4 million was recognized as revenue. At March 31, 2014, $11.8 million remains in deferred revenue.

Other Project Revenue

During the quarter ended March 31, 2013 we completed a one-time research project. In connection with this project we received a payment of $1.75 million which we recognized as revenue in the quarter ended March 31, 2013.

3. MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

We generally classify our marketable securities as available-for-sale at the time of purchase and re-evaluate such designation as of each balance sheet date. Since we generally intend to convert them into cash as necessary to meet our liquidity requirements our marketable securities are classified as cash equivalents if the original maturity, from the date of purchase, is ninety days or less and as short-term investments if the original maturity, from the date of purchase, is in excess of ninety days but less than one year. Our marketable securities are classified as long-term investments if the maturity date is in excess of one year of the balance sheet date.

We report available-for-sale investments at fair value as of each balance sheet date and include any unrealized gains and, to the extent deemed temporary, unrealized losses in stockholders' equity. Realized gains and losses are determined using the specific identification method and are included in other income (expense) in the statement of operations and comprehensive loss. Our auction rate securities are classified as trading securities and any changes in the fair value of those securities are recorded as other income (expense) in the statement of operations and comprehensive loss.

We conduct quarterly reviews to determine the fair value of our investment portfolio and to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. In the event that the cost basis of a security exceeds its fair value, we evaluate,

among other factors, the duration of the period that, and extent to which, the fair value is less than cost basis, the financial health of and business outlook for the issuer, including industry and sector performance, and operational and financing cash flow factors, overall market conditions and trends, our intent to sell the investment and if it is more likely than not that we would be required to sell the investment before its anticipated recovery. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded in accumulated other comprehensive income (loss).

For available-for-sale debt securities with unrealized losses, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is reflected in the statement of operations and comprehensive loss as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

We invest our available cash primarily in U.S. Treasury bill funds, money market funds, commercial paper, and U.S. federal and state agency backed certificates, including auction rate securities that have investment grade ratings. Auction rate securities are structured with short-term interest reset dates of generally less than 90 days, but with contractual maturities that can be well in excess of ten years. At the end of each reset period, which occurs every seven to twenty-eight days, investors can sell or continue to hold the securities at par value. If auction rate securities fail an auction, due to sell orders exceeding buy orders, the funds associated with a failed auction would not be accessible until a successful auction occurred, a buyer was found outside the auction process, the underlying securities matured or a settlement with the underwriter is reached.

The following is a summary of the fair value of available-for-sale marketable securities we held at March 31, 2014 and December 31, 2013:

March 31, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Corporate debt securities-short term	$ 56,174	$ 45	$ (10)	$ 56,209
Corporate debt securities-long term	12,093	19	(4)	12,108
Total available-for-sale marketable securities	$ 68,267	$ 64	$ (14)	$ 68,317

December 31, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Corporate debt securities-short term	$ 59,059	$ 62	$ (5)	$ 59,116
Corporate debt securities-long term	18,535	23	(13)	18,545
Total available-for-sale marketable securities	$ 77,594	$ 85	$ (18)	$ 77,661

Our available-for-sale marketable securities in a loss position at March 31, 2014 were in a continuous unrealized loss position for less than 12 months. The fair value of our available-for-sale marketable securities in a continuous unrealized loss position for more than 12 months was $2,377 at December 31, 2013. The unrealized loss on these marketable securities was $3 at December 31, 2013.

The following is a summary of the fair value of trading securities we held at March 31, 2014 and December 31, 2013:

March 31, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Auction rate securities	$ 2,100	$ —	$ (178)	$ 1,922
Total trading securities	$ 2,100	$ —	$ (178)	$ 1,922

December 31, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Auction rate securities	$ 2,100	$ —	$ (254)	$ 1,846
Total trading securities	$ 2,100	$ —	$ (254)	$ 1,846

The underlying collateral of our auction rate securities consists of student loans, supported by the federal government as part of the Federal Family Education Loan Program (FFELP).

At March 31, 2014 and December 31, 2013, the Company’s auction rate securities are included in marketable securities-long term and total $1,922 and $1,846, respectively. The net increase in value of our auction rate securities of $76 in the three months ended March 31, 2014 was recorded as a gain in other income (expense) in the statement of operations and comprehensive loss. The net decrease in value of our auction rate securities of $2 in the three months

ended March 31, 2013 was recorded as a loss in other income (expense) in the statement of operations and comprehensive loss.

The following tables present information about our assets that are measured at fair value on a recurring basis for the periods presented and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. We value our level 2 investments using quoted prices for identical assets in the markets where they are traded, although such trades may not occur daily. These quoted prices are based on observable inputs, primarily interest rates. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. There were no transfers in or out of Level 1 or Level 2 measurements for the periods presented:

	March 31, 2014	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$13,663	$13,663	$—	$—
Corporate debt securities-short term	56,209	—	56,209	—
Corporate debt securities-long term	12,108	—	12,108	—
Auction rate securities-long term	1,922	—	—	1,922
Total	$83,902	$13,663	$68,317	$1,922

	December 31, 2013	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$12,247	$12,247	$—	$—
Corporate debt securities-short term	59,116	—	59,116	—
Corporate debt securities-long term	18,545	—	18,545	—
Auction rate securities-long term	1,846	—	—	1,846
Total	$91,754	$12,247	$77,661	$1,846

Due to the lack of market quotes relating to our auction rate securities, the fair value measurements for our auction rate securities have been estimated using an income approach model (discounted cash flow analysis), which is exclusively based on Level 3 inputs. The model considers factors that reflect assumptions market participants would use in pricing including, among others, the collateralization underlying the investments, the creditworthiness of the counterparty, the expected future cash flows, liquidity premiums, the probability of successful auctions in the future, and interest rates. The assumptions used are subject to volatility and may change as the underlying sources of these assumptions and markets conditions change.

The following table rolls forward the fair value of our auction rate securities and put option, whose fair values are determined by Level 3 inputs for 2014:

	Amount
Balance at December 31, 2013	$ 1,846
Gain on auction rate securities	76
Balance at March 31, 2014	$ 1,922

The following table rolls forward the fair value of our auction rate securities and put option, whose fair values are determined by Level 3 inputs for 2013:

	Amount
Balance at December 31, 2012	$ 1,789
Loss on auction rate securities	(2)
Balance at March 31, 2013	$ 1,787

11

The following table provides quantitative information on the unobservable inputs of our fair value measurements for our Level 3 assets for the year ended March 31, 2014:

	Estimated Fair Value at March 31, 2014	Valuation Technique	Unobservable Inputs	Range
Auction rate securities	$ 1,922	Discounted cash flow		
			Maximum rate	1.56%
			Liquidity risk premium	3.00%–4.00%
			Probability of earning maximum rate until maturity	0.08%–0.13%
			Probability of principal returned prior to maturity	85.54%–87.70%
			Probability of default	12.23%–14.34%

A significant increase or decrease in the individual assumptions included above could result in a significantly lower or higher fair value measurement.

4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses include the following at March 31, 2014 and December 31, 2013:

	2014	2013
Accounts payable	$ 250	$ 146
Accrued payroll	1,051	2,556
Accrued outsourced pre-clinical and clinical fees	5,633	4,702
Accrued professional fees	537	660
Other accrued expenses	363	406
	$ 7,834	$ 8,470

5. NET LOSS PER SHARE

Net loss per share is computed using the weighted average number of common shares outstanding. Basic and diluted net loss per share amounts are equivalent for the periods presented as the inclusion of potential common shares in the number of shares used for the diluted computation would be anti-dilutive to loss per share. Potential common shares, the shares that would be issued upon the exercise of outstanding stock options, were 8,454,520 and 8,259,603 for the three months ended March 31, 2014 and 2013, respectively.

6. STOCK-BASED COMPENSATION AND STOCK PLANS

Our stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the employees' requisite service period (generally the vesting period of the equity grant). We estimate the fair value of stock options using the Black-Scholes valuation model. Key input assumptions used to estimate the fair value of stock options include the exercise price of the award, expected option term, expected

volatility of our stock over the option's expected term, risk-free interest rate over the option's expected term, and the expected annual dividend yield. We believe that the valuation technique and approach utilized to develop the underlying assumptions are appropriate in calculating the fair values of our stock options granted in the three months ended March 31, 2014 and 2013.

The following table presents stock-based compensation expense included in our Condensed Statements of Operations and Comprehensive Loss:

	Three Months Ended March 31,	
	2014	2013
Research and development	$ 405	$ 494
General and administrative	681	871
Total stock-based compensation expense	$ 1,086	$ 1,365

In the three months ended March 31, 2014 and 2013, no stock-based compensation expense was capitalized and there were no recognized tax benefits associated with the stock-based compensation expense.

Option activity under our stock plans for the three months ended March 31, 2014 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2013	7,511,814	$ 5.28
Granted	1,050,119	2.57
Cancelled	(107,413)	5.32
Outstanding as of March 31, 2014	8,454,520	$ 4.95
Exercisable as of March 31, 2014	5,787,047	$ 5.37

The aggregate intrinsic value of options outstanding at March 31, 2014 was zero related to exercisable options. The weighted average fair value of options granted in the three months ended March 31, 2014 and 2013 was $1.71and $1.67 per share, respectively. No options were exercised in the three months ended March 31, 2014 or 2013.

Shares vested, expected to vest and exercisable at March 31, 2014 are as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Vested and unvested expected to vest at March 31, 2014	8,300,915	$ 4.95	6.1	$ —
Exercisable at March 31, 2014	5,787,047	$ 5.37	4.8	$ —

The total compensation cost not yet recognized as of March 31, 2014 related to non-vested option awards was $6.6 million, which will be recognized over a weighted-average period of 2.5 years. During the three months ended March 31, 2014, 99,088 shares expired and 8,325 shares were forfeited. The weighted average remaining contractual life for options exercisable at March 31, 2014 was 4.8 years.

In 2013, we granted 242,697 shares of restricted stock to employees, vesting annually over a four year period. The weighted average fair value of the restricted stock at the time of grant in 2013 was $2.51 per share, and is being expensed ratably over the vesting period. Through March 31, 2014, 46,860 shares have been forfeited, and 50,239 shares have vested. We recognized share-based compensation expense related to restricted stock of $25 and $143 for the three months ended March 31, 2014 and 2013, respectively.

Restricted stock activity under the Plan for the three months ended March 31, 2014 was as follows:

Restricted Stock	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2013	195,777	$ 2.51
Vested	(49,041)	2.51
Cancelled	(1,138)	2.51
Unvested as of March 31, 2014	145,598	$ 2.51

The fair value of restricted stock that vested in the three months ended March 31, 2014 and 2013 was $101 and $203, respectively.

In July 2010, the Company amended its chief executive officer's (the "CEO's") employment agreement to grant the CEO 100,000 stock options, of which 25% vested upon grant and 25% vest annually over the next three years, and a maximum of 390,000 performance-based stock units that vest upon the achievement of certain performance and market based targets. In March 2013, the Company amended its CEO's employment agreement to modify the performance and market based targets.

In February 2012, the Company amended its chief medical officer's (the "CMO's") employment agreement to grant the CMO 50,000 performance-based stock units that vest upon the achievement of certain performance based targets.

In March 2013, the Company amended its chief operating officer's (the "COO's") employment agreement to grant the COO 125,000 performance-based stock units that vest upon the achievement of certain performance based targets. In March 2013, the Company amended its CMO's employment agreement to grant the CMO 120,000 performance-based stock units that vest upon the achievement of certain performance based targets.

Through March 31, 2014 no expense has been recorded for any performance-based stock units granted to the CEO, COO, or CMO.

7. RECENT ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In July 2013, the FASB issued an update, which is intended to eliminate the diversity that is in practice with regard to the financial statement presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective for our interim period ending March 31, 2014. We adopted this standard in the first quarter of fiscal year 2014. The adoption of this standard did not have a material impact on our financial condition or results of operations.

8. INCOME TAXES

As of December 31, 2013, we had federal NOL, state NOL, and research and development credit carryforwards of approximately $298,727, $118,695 and $27,067 respectively, expiring from 2014 to 2033, which can be used to offset future income tax liabilities. Federal capital loss carry forwards of approximately $571, expiring in 2015, can be used to offset future federal capital gain income. Approximately $15,006 of our federal NOL and $855 of our state NOL were generated from excess tax deductions from share-based awards, the tax benefit of which will be credited to additional paid-in-capital when the deductions reduce current taxes payable.

At March 31, 2014 and December 31, 2013, we had no unrecognized tax benefits. We do not expect that the total amount of unrecognized tax benefits will significantly increase in the next twelve months. Our policy is to recognize interest and penalties related to uncertain tax positions in income tax expense. As of March 31, 2014 and December 31, 2013, we had no accrued interest or penalties related to uncertain tax positions. Our U.S. federal tax returns for the tax years 2011 through 2013 and our state tax returns for the tax years 2010 through 2013 remain open to examination. Prior tax years remain open to the extent of net operating loss and tax credit carryforwards.

Utilization of NOL and research and development credit carryforwards may be subject to a substantial annual limitation in the event of an ownership change that has occurred previously or could occur in the future pursuant to Section 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. An ownership change may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income, and may, in turn, result in the expiration of a portion of those carryforwards before utilization. In general, an ownership change, as defined by Section 382, results from transactions that increase the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three year period. We undertook a detailed study of our NOL and research and development credit carryforwards through January 31, 2014, to determine whether such amounts are likely to be limited by Sections 382 or 383. As a result of this analysis, we currently do not believe any Sections 382 or 383 limitations will significantly impact our ability to offset income with available NOL and research and development credit carryforwards. However, future ownership changes under Section 382 may limit our ability to fully utilize these tax benefits.

9. NOTES PAYABLE

In October 2008, we entered into a margin loan agreement with a financial institution collateralized by $2.9 million of our auction rate securities and borrowed $1.7 million which is the maximum amount allowed under this facility. The

amount outstanding under this facility is $1.7 million at March 31, 2014 and 2013, collateralized by $2.1 million of auction rate securities at cost. Interest expense was $7 and $4 for the three months ended March 31, 2014 and 2013, respectively.

Management believes the carrying value of the note payable approximates its fair value for these borrowings and would be classified as a Level 2 measurement due to use of valuation inputs based on similar liabilities in the market.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our financial statements and related notes contained in this report.

We are a clinical-stage biotechnology company engaged in the research and development of innovative cancer therapeutics. Our mission is to produce novel drugs with differentiated mechanisms of action that will extend the lives of our patients. These drugs target biological pathways implicated in a wide range of cancers. We employ technologies such as our ArQule Kinase Inhibitor Platform ("AKIP TM") to design and develop drugs that have the potential to fulfill this mission.

Our product candidates and programs span a continuum of research and development ranging from drug discovery to advanced clinical testing. They are based on our understanding of biological processes that lead to the proliferation and metastasis of cancer cells, combined with our ability to generate product candidates possessing certain pre-selected, drug-like properties. We believe that these qualities, when present from the earliest stages of product development, increase the likelihood of producing safe, effective and marketable drugs. Our discovery and development efforts are also guided when possible by an understanding of the role of biomarkers, which are indicators of a particular biological condition or process and may predict the clinical benefit of our compounds in defined patient populations.

Our lead product candidate is tivantinib (ARQ 197), an orally administered, small molecule inhibitor of the c-Met receptor tyrosine kinase ("c-MET" or "MET") and its biological pathway. C-MET is a promising target for cancer therapy, based on its multiple roles in cancerous cell proliferation, tumor spread, new blood vessel formation and resistance to certain drug therapies. We and our partners, Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") and Kyowa Hakko Kirin Co., Ltd. ("Kyowa Hakko Kirin"), are implementing a worldwide clinical development program designed to realize the broad potential of tivantinib. Our strategy is to focus on the most promising indications within our clinical programs based upon continually generated and updated clinical and pre-clinical data. Our lead indication is liver cancer ("hepatocellular carcinoma" or "HCC"). We have also completed earlier-stage combination therapy trials and pre-clinical experiments with tivantinib and other anti-cancer agents that may provide data to support trials in additional indications.

Our most advanced ongoing clinical trial, the METIV-HCC trial, is a pivotal Phase 3 randomized, double-blind, controlled study of tivantinib as single agent therapy in previously treated patients with MET diagnostic-high, inoperable HCC conducted by Daiichi Sankyo and us. A dose reduction in the METIV-HCC trial from 240 mg twice daily ("BID") tablets to 120 mg BID tablets was implemented in September 2013 following the observation of a higher incidence of neutropenia in the initial phase of the METIV-HCC trial than was observed in the Phase 2 trial in the same patient population, which employed a 240 mg BID capsule dose, and in other trials with tivantinib. Certain enhanced patient monitoring procedures were temporarily instituted to confirm the safety profile of the lower dose. Following a review of data analyses from a predefined number of patients who received this lower dose, the DMC of the METIV-HCC trial recommended in January 2014 continuation of the ongoing trial, with patients receiving the lower dose. Pharmacokinetic analyses among a predefined number of patients treated with the 120 mg BID tablet dose showed that the incidence of neutropenia was reduced with this lower dose and that the plasma exposure of the lower dose was comparable to the 240 mg BID capsule dose in the Phase 2 trial with similar medians and overlapping ranges.

Approximately 300 patients are planned to be enrolled in the METIV-HCC trial at approximately 120 clinical sites worldwide. Our current estimate of the time frame for completion of enrollment is mid-2016. This trial is being conducted under a Special Protocol Assessment ("SPA") agreement with the FDA. An SPA is an agreement establishing the design, endpoints and statistical analysis of a clinical trial intended to provide the necessary data, depending on the outcome of the trial, which could support the filing of a New Drug Application ("NDA"). Final marketing approval depends on the results of the trial. Because the METIV-HCC trial is enrolling patients with MET-diagnostic high HCC whom we believe are likely to benefit from treatment with tivantinib, the SPA also includes an immunohistochemistry ("IHC")-based companion diagnostic ("CDx") under development by Daiichi Sankyo and ourselves in collaboration with a third party provider of such tests. The CDx is being developed to enable the identification of the MET status of patients seeking to be enrolled in this trial. Our collaborator for the companion diagnostic test will need to submit a Premarket Approval ("PMA") application to FDA that establishes the predictive value of the CDx in connection with the registration and commercialization of the drug in the U.S., and additional regulatory applications will need to be made in other geographic areas.

In addition to METIV-HCC, a second Phase 3 clinical trial in HCC with tivantinib is ongoing in Japan. On February 4, 2014, Kyowa Hakko Kirin, our partner for the development of tivantinib in Asian territories, announced the initiation of this trial in Japanese patients with MET diagnostic-high, inoperable HCC treated with one prior therapy with sorafenib. The trial is a randomized, double-blind placebo-controlled study to compare PFS in patients treated with tivantinib with those treated with placebo. Kyowa Hakko Kirin plans to enroll approximately 160 patients in this study. There are no milestone payments associated with the initiation of this trial.

On January 16, 2014, we reported that Kyowa Hakko Kirin provided us with top-line results of the amended Phase 3 randomized, double-blind ATTENTION clinical trial evaluating the combination of tivantinib and erlotinib in second-line patients with advanced or metastatic non-squamous non-small cell lung cancer ("NSCLC") with wild-type epidermal growth factor receptor ("EGFR") in Asia (Japan, Korea and Taiwan). Enrollment in ATTENTION had been originally planned at 460 patients. Recruitment of new patients was permanently suspended in October 2012 based on a recommendation by the trial's Safety Review Committee following an observed imbalance in interstitial lung disease ("ILD") cases as a drug-related adverse event. Patients who received treatment as of October 2012 were allowed to continue thereafter in the trial after being re-consented, and including such patients, 307 patients in total were included in the final analysis.

In the intent to treat ("ITT") population of ATTENTION, OS favored the treatment arm of tivantinib plus erlotinib compared to the erlotinib only control arm, but it was not statistically significant (median OS of 12.9 months vs. 11.2 months, hazard ratio = 0.89, p = 0.4). PFS and overall response rate ("ORR") results also showed a trend toward improvement favoring the treatment arm. The safety profile observed in ATTENTION was in line with what was previously observed in other NSCLC trials with tivantinib, with the exception of ILD, which is a known adverse event observed in Japanese patients treated with EGFR inhibitors such as erlotinib.

On September 30, 2013 at the European Cancer Congress, we and our partner Daichii Sankyo, presented final data from MARQUEE, a randomized, double-blind, controlled pivotal Phase 3 trial conducted under an SPA to evaluate tivantinib in combination with erlotinib, an approved anti-cancer agent, in previously treated patients with locally advanced or metastatic, non-squamous NSCLC. Of the 1048 patients in the trial, 445 were evaluable for MET status. Patients with MET-high NSCLC numbered 211, and the number with MET-low disease was 234. These data demonstrated clinical benefits in patients with non-squamous, NSCLC whose tumors expressed high levels of MET protein. The overall safety profile among patients receiving tivantinib (360 milligrams BID) and erlotinib (150 milligrams daily) was consistent with findings at a previous planned interim analysis announced on October 2, 2012. Unlike the ATTENTION trial, no imbalance was observed in the incidence of ILD between treatment and control arms, with one case (0.2%) reported in the treatment arm and four cases (0.8%) in the control arm.

At the time of the interim analysis of MARQUEE, the independent DMC recommended that the study be discontinued early after concluding that it would not meet its primary endpoint of improved OS. Although the interim analysis showed a statistically significant improvement in PFS in the ITT population, this benefit did not carry over to OS. There were no safety concerns identified by the DMC during this analysis. We and our partners are evaluating data from the MARQUEE and ATTENTION trials to determine whether the potential exists for further trials in patient sub-populations within this disease category who may benefit from treatment that includes tivantinib.

On January 11, 2013, we announced the top-line results of a randomized Phase 2 signal generation trial of tivantinib used in combination with irinotecan and cetuximab in patients with refractory or relapsed colorectal cancer ("CRC"). The trial did not meet its primary endpoint of PFS. The PFS and ORR results obtained in both the control arm and the treatment arm were longer than expected compared to previously published historical norms. Additional data and analyses from this trial were presented at the American Society of Clinical Oncology ("ASCO") Annual Meeting in June 2013, showing that the median PFS in the treatment arm was 8.3 months, compared with 7.3 months in the control arm. Median OS in the treatment arm was 19.8 months, compared with 16.9 months in the control arm. ORR in the treatment arm was 45 percent versus 33 percent in the control arm. Adverse events were reported at similar rates in the treatment and control arms of the trial, except for increased neutropenia observed in the treatment arm, with no discontinuations of treatment for this reason. Tivantinib was generally well tolerated in combination with the approved doses of irinotecan and cetuximab studied in this trial.

We have licensed commercial rights to tivantinib for human cancer indications to Daiichi Sankyo in the U.S., Europe, South America and the rest of the world, excluding Japan and certain other Asian countries, where we have licensed commercial rights to Kyowa Hakko Kirin. Our agreements with these partners provide for possible future milestone payments, royalties on product sales, and development funding, in addition to significant payments that we have already received. During 2011, we received $25 million from Daiichi Sankyo resulting from the dosing of the first patient in the MARQUEE trial, and we received $10 million from Kyowa Hakko Kirin resulting from dosing of the first patient in the ATTENTION trial. The terms of our tivantinib licensing agreements with Daiichi Sankyo and Kyowa Hakko Kirin remain in effect following the recent developments in both of these trials.

Our proprietary pipeline of product candidates is directed toward molecular targets and biological processes with demonstrated roles in the development of human cancers. Our priorities within this pipeline include ARQ 092, an Akt inhibitor, and ARQ 087, an inhibitor of fibroblast growth factor receptor. We are also supporting an ongoing investigator-sponsored trial with ARQ 761, which is being investigated as a potential NQ01 inhibitor.

Our drug discovery efforts are focused primarily on AKIP TM, which we are using to generate novel kinase inhibitors that are potent and selective against their targets. We have assessed the potential of AKIP TM to target multiple kinases in oncology and other therapeutic areas, and we are generating and validating compounds that inhibit these kinase targets. We utilize our proprietary kinase-focused libraries that are enriched with chemical matter to enhance the efficiency and effectiveness of these efforts. During 2011, Daiichi Sankyo licensed ARQ 092, an inhibitor of the Akt protein kinase discovered under our AKIP TM oncology drug discovery collaboration that terminated in November 2012. ARQ 092 is the first clinical-stage compound to emerge from this collaboration. As a result of our license agreement for this compound, we received a $10 million payment from Daiichi Sankyo in November 2011.

We have incurred a cumulative deficit of approximately $452 million from inception through March 31, 2014. We recorded a net loss for 2011, 2012 and 2013 and expect a net loss for 2014.

Our revenue consists primarily of development funding from our alliances with Daiichi Sankyo and Kyowa Hakko Kirin. Revenue and expenses fluctuate from quarter to quarter based upon a number of factors, notably the timing and extent of our cancer-related research and development activities together with the length and outcome of our clinical trials.

On December 18, 2008, we entered into a license, co-development and co-commercialization agreement with Daiichi Sankyo to conduct research, clinical trials and commercialization of tivantinib in human cancer indications. The agreement provides for a $60 million cash upfront licensing payment from Daiichi Sankyo to us, which we received in December 2008, and an additional $560 million in potential development and sales milestone payments offset by our share of the Phase 3 costs. Upon commercialization, we will receive tiered, double-digit royalties from Daiichi Sankyo on net sales of tivantinib commensurate with the magnitude of the transaction. We retain the option to participate in the commercialization of tivantinib in the U.S. We and Daiichi Sankyo will share equally the costs of Phase 2 and Phase 3 clinical studies, with our share of Phase 3 costs payable solely from milestone and royalty payments by Daiichi Sankyo.

The dosing of the first patient in the Phase 3 MARQUEE clinical trial of tivantinib in NSCLC, announced in January 2011, triggered the payment of a $25 million development milestone from Daiichi Sankyo that was received in February 2011. Revenue for this agreement is recognized using the contingency-adjusted performance model. Through September 30, 2012, revenue was recognized based upon an estimated development period through December 2013. As a result of the October 2012 decision to discontinue the MARQUEE trial, the development period as of October 1, 2012 was extended to June 2015. Commencing with the fourth quarter of 2012 and through the third quarter of 2013 revenue was recognized over that development period.

In the fourth quarter of 2013, following a recommendation by the Data Monitoring Committee that the METIV-HCC trial continue with patients receiving a lower dose of tivantinib than the dose originally employed in the trial, we reviewed the estimated development period and extended it to June 2016.

Under the terms of our tivantinib collaboration agreement with Daiichi Sankyo we share development costs equally with our share of Phase 3 costs funded solely from milestones and royalties. In each quarter the tivantinib collaboration costs we incur are compared with those of Daiichi Sankyo. If our costs for the quarter exceed Daiichi Sankyo’s, we recognize revenue on the amounts due to us under the contingency adjusted performance model. Revenue is calculated on a pro-rata basis using the time elapsed from inception of the agreement over the estimated duration of the development period under the agreement. If our costs for the quarter are less than those of Daiichi Sankyo’s, we report the amount due to Daiichi Sankyo as contra-revenue in that quarter. To the extent that our share of Phase 3 collaboration costs exceeds the amount of milestones and royalties received, that excess is netted against future milestones and royalties if and when earned and is not reported as contra-revenue.

Our cumulative share of the Daiichi Sankyo Phase 3 costs through March 31, 2014, totaled $84.2 million. We received a milestone of $25 million in February 2011 upon enrolling the first patient in the MARQUEE trial, the cash proceeds of which were subsequently applied to our share of Phase 3 collaboration costs. On January 31, 2013, we announced that the first patient had been enrolled in the pivotal Phase 3 METIV trial of tivantinib, entitling us to a $15 million milestone. That $15 million milestone was also netted against our cumulative share of Phase 3 collaboration costs in 2013, and consequently we did not receive any cash proceeds from this milestone. Our cumulative share of Phase 3 collaboration costs has exceeded the amount of milestones received through March 31, 2014 by $44.2 million which will be netted against future milestones and royalties, if any, when earned and has not been reported as contra-revenue.

For the quarter ended March 31, 2014 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo's by $82 thousand which was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue.

For the quarter ended March 31, 2013 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo's by $216 thousand which was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue.

In November 2012, we completed our research collaboration with Daiichi Sankyo under a research collaboration, exclusive license and co-commercialization agreement entered into on November7, 2008, that was focused on applications of our proprietary AKIP TM technology and know-how for the discovery of therapeutic compounds that selectively inhibit certain kinases in the field of oncology. The agreement provided for a $15 million upfront payment, which we received in November 2008, research support payments for the first two years of the collaboration (which was extended for an additional two years in 2010), licensing fees for compounds discovered as a result of this research, milestone payments related to clinical development, regulatory review and sales, and royalty payments on net sales of compounds from the collaboration. Daiichi Sankyo's obligation to provide further research funding to ArQule under this agreement terminated in November 2012.

We have regained worldwide rights for the development and commercialization of ARQ 092 and all other compounds included under our Akt collaboration with Daiichi Sankyo pursuant to their formal notice to terminate our license and commercialization agreement received on March 26, 2013. Termination of this agreement was effective 90 days from our receipt of the formal notice from Daiichi Sankyo, following which we became responsible for funding the remainder of the ongoing Phase 1 trial with ARQ 092 beyond the contractual termination period, as well as any future clinical development and commercialization of this compound. The license agreement had provided exclusive rights to Daiichi Sankyo for the development, manufacturing and marketing of ARQ 092 on a worldwide basis. Under this agreement, we received a $10 million upfront fee from Daiichi Sankyo in November 2011. Following the termination of this agreement, ARQ 092 has become our proprietary asset, and Daiichi Sankyo has no further financial or other obligations or rights related to this program.

On April 27, 2007, we entered into an exclusive license agreement with Kyowa Hakko Kirin to develop and commercialize tivantinib in Japan and parts of Asia. A $3 million portion of an upfront licensing fee was received by the Company under this agreement in the first quarter of 2007, and an additional $27 million in upfront licensing fees was received on May 7, 2007. The agreement includes $123 million in upfront and potential development milestone payments from Kyowa Hakko Kirin to ArQule, including the $30 million cash upfront licensing payments. In February 2008, we received a $3 million milestone payment from Kyowa Hakko Kirin, and in September 2010, we received a $5 million milestone payment. Upon commercialization, ArQule will receive tiered royalties in the mid-teen to low-twenty percent range from Kyowa Hakko Kirin on net sales of tivantinib. Kyowa Hakko Kirin will be responsible for all clinical development costs and commercialization of the compound in certain Asian countries, consisting of Japan, China (including Hong Kong), South Korea and Taiwan. In addition to the upfront and possible regulatory milestone payments totaling $123 million, the Company will be eligible for future milestone payments based on the achievement of certain levels of net sales.

The Company will recognize the payments, if any, as revenue in accordance with its revenue recognition policies. As of March 31, 2014, the Company has not recognized any revenue from these potential sales milestone payments, and there can be no assurance that it will do so in the future. Revenue for this agreement is recognized using the contingency-adjusted performance model with an estimated development period through April 2016.

LIQUIDITY AND CAPITAL RESOURCES

	March 31, 2014	December 31, 2013	Increase (decrease) $	Increase (decrease) %
		(in millions)		
Cash, cash equivalents and marketable securities-short term	$ 71.7	$ 74.7	(3.0)	(4)%
Marketable securities-long term	14.0	20.4	(6.4)	(31)%
Notes payable	1.7	1.7	—	—
Working capital	51.5	53.9	(2.4)	(4)%

	Q1 2014	Q1 2013	Increase (decrease)
	(in millions)		
Cash flow from:			
Operating activities	$ (9.0)	$ (10.3)	$ 1.3
Investing activities	9.0	11.0	(2.0)
Financing activities	—	—	—

Cash flow from operating activities. Our uses of cash for operating activities have primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices and laboratories, fees paid in connection with preclinical and clinical studies, laboratory supplies and materials, and professional fees. The sources of our cash flow from operating activities have consisted primarily of payments received from our collaborators for services performed or upfront payments for future services. For the quarters ended March 31, 2014 and 2013, our net use of cash was primarily driven by payments for operating expenses which resulted in net cash outflows of $9.0 million and $10.3 million, respectively.

Cash flow from investing activities. Our net cash provided by investing activities of $9.0 million and $11.0 million for the quarters ended March 31, 2014 and 2013, respectively, was comprised of net sales of marketable securities. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of the Company's constant evaluation of conditions in financial markets, the maturity of specific investments, and our near term liquidity needs.

Our cash equivalents and marketable securities typically include U.S. Treasury bill funds, money market funds, commercial paper, and U.S. federal and state agency backed certificates, including auction rate securities that have investment grade ratings. Our cash equivalents and our portfolio of marketable securities are subject to market risk due to changes in interest rates. Fixed rate interest securities may have their market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates. ArQule's marketable securities portfolio includes $2.1 million (at cost) at March 31, 2014 and December 31, 2013, invested in auction rate securities.

Our cash requirements may vary materially from those now planned depending upon the results of our drug discovery and development strategies, our ability to enter into additional corporate collaborations and the terms of such collaborations, results of research and development, unanticipated required capital expenditures, competitive and technological advances, acquisitions and other factors. We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product. It is likely we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on financial, economic and market conditions, and due to global capital and credit market conditions or for other reasons, we may be unable to raise capital when needed, or on terms favorable to us. If necessary funds are not available, we may have to delay, reduce the scope of, or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates.

In July 2013, we implemented a focused reduction in our workforce of 26 positions, resulting in a remaining workforce of approximately 68 employees. This action was intended to align human and financial resources with our primary focus on clinical-stage development, while retaining our core discovery capabilities. The costs associated with this action were comprised of severance payments of $422 thousand and benefits continuation costs of $89 thousand all of which were paid by December 31, 2013. We also incurred non-cash charges of $139 thousand in 2013 related to the modification of employee stock options. The restructuring actions for which charges were incurred in the year ended December 31, 2013 are expected to result in annual cost savings of approximately $3.5 to $4.0 million commencing in 2014.

We anticipate that our cash, cash equivalents and marketable securities on hand at March 31, 2014, financial support from our collaboration agreements, and savings from our workforce reduction described above, will be sufficient to finance our working capital and capital requirements into 2016.

Our contractual obligations were comprised of the following as of March 31, 2014 (in thousands):

	Payment due by period				
Contractual Obligations	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Note payable	$ 1,700	$ 1,700	$ —	$ —	$ —
Operating lease obligations	3,457	3,190	267	—	—
Purchase obligations	5,739	5,739	—	—	—
Total	$ 10,896	$ 10,629	$ 267	$ —	$ —

Purchase obligations are comprised primarily of outsourced preclinical and clinical trial expenses and payments to license certain intellectual property to support the Company’s research efforts. Interest on notes payable is variable and is excluded from the table above. Notes payable currently bears interest at LIBOR plus 125 basis points. Under our tivantinib collaboration with Daiichi Sankyo, our share of Phase 3 costs are payable solely from future milestones and royalties. As of March 31, 2014 our portion of these costs was $44.2 million and is excluded from the table above. These costs are netted against any future milestones and royalties due to us. Daiichi Sankyo has the right to offset future milestone and royalty payments by this amount.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

A “critical accounting policy” is one which is both important to the portrayal of the Company’s financial condition and results and requires management’s most difficult, subjective or complex judgments, often as a result of the need to

make estimates about the effect of matters that are inherently uncertain. For additional information, please see the discussion of our significant accounting policies in Note 2 to the Financial Statements included in our Annual Report for the fiscal year ended December 31, 2013 on Form 10-K filed with the SEC on March 5, 2014.

RESULTS OF OPERATIONS

The following are the results of operations for the three months ended March 31, 2014 and 2013:

Revenue

			Increase (decrease)	
	2014	2013	$	%
	(in millions)			
For the three months ended March 31:				
Research and development revenue	$2.7	$5.7	$(3.0)	(53)%

Research and development revenue in the three months ended March 31, 2014 is comprised of revenue from the Daiichi Sankyo tivantinib development agreement and the Kyowa Hakko Kirin exclusive license agreement. Research and development revenue in the three months ended March 31, 2013 is comprised of revenue from the Daiichi Sankyo tivantinib development agreement, the license agreement with Daiichi Sankyo for the development of ARQ 092 that ended in June 2013, and the Kyowa Hakko Kirin exclusive license agreement. In addition, during the three months ended March 31, 2013 we completed a one-time research project. In connection with this project we received a payment of $1.8 million which we recognized as revenue in the quarter ended March 31, 2013.

Under the terms of our tivantinib collaboration agreement with Daiichi Sankyo we share development costs equally with our share of Phase 3 costs funded solely from milestones and royalties. In each quarter the tivantinib collaboration costs that we incur are compared with those of Daiichi Sankyo. If our costs for the quarter exceed Daiichi Sankyo's, we recognize revenue on the amounts due to us under the contingency adjusted performance model. Revenue is calculated on a pro-rata basis using the time elapsed from inception of the agreement over the estimated duration of the development period under the agreement. If our costs for the quarter are less than those of Daiichi Sankyo's, we report the amount due to Daiichi Sankyo as contra-revenue in that quarter. To the extent that our share of Phase 3 collaboration costs exceeds the amount of milestones and royalties received, that excess is netted against future milestones and royalties if and when earned and is not reported as contra-revenue.

Revenue for this agreement is recognized using the contingency-adjusted performance model. Through September 30, 2012, revenue was recognized based upon an estimated development period through December 2013. As a result of the October 2012 decision to discontinue the MARQUEE trial, the development period as of October 1, 2012 was extended to June 2015. Commencing with the fourth quarter of 2012 and through the third quarter of 2013 revenue was recognized over that development period. In the fourth quarter of 2013, following a recommendation by the Data Monitoring Committee that the METIV-HCC trial continue with patients receiving a lower dose of tivantinib than the dose originally employed in the trial, we reviewed the estimated development period and extended it to June 2016.

Our cumulative share of the Daiichi Sankyo Phase 3 costs through March 31, 2014, totaled $84.2 million. We received a milestone of $25 million in February 2011 upon enrolling the first patient in the MARQUEE trial, the cash proceeds of which were subsequently applied to our share of Phase 3 collaboration costs. On January 31, 2013, we announced that the first patient had been enrolled in the pivotal Phase 3 METIV trial of tivantinib, entitling us to a $15 million milestone. That $15 million milestone was also netted against our cumulative share of Phase 3 collaboration costs in 2013, and consequently we did not receive any cash proceeds from this milestone. Our cumulative share of Phase 3 collaboration costs has exceeded the amount of milestones received through March 31, 2013 by $44.2 million which will be netted against future milestones and royalties, if any, when earned and has not been reported as contra-revenue.

For the quarter ended March 31, 2014 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo's by $82 thousand which was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue.

For the quarter ended March 31, 2013 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo's by $216 thousand which was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue.

The $3.0 million revenue decrease in the quarter ended March 31, 2014 is primarily due to revenue decreases of $0.6 million from our Daichii Sankyo tivantinib program, $0.6 million from our Daiichi Sankyo ARQ 092 agreement that ended in June 2013, and $1.8 million of other revenue related to a one-time research project in the quarter ended March 31, 2013. The $0.6 million revenue decrease in the quarter ended March 31, 2014 from our Daichii Sankyo tivantinib program consisted of a $0.7 million decrease in revenue due to the changes in the estimated development period, partially offset by lower contra-revenue of $0.1 million.

Research and development

			Increase (decrease)	
	2014	2013	$	%

	(in millions)			
For the three months ended March 31:				
Research and development	$ 6.7	$ 8.2	$ (1.5)	(18)%

Research and development expense in the quarter ended March 31, 2014 decreased by $1.5 million primarily due to lower labor related costs of $0.5 million from attrition and $0.7 million from the July 2013 restructuring and reduced lab expenses of $0.4 million. These cost decreases were partially offset by $0.3 million higher outsourced clinical and product development costs related to our pipeline programs. At March 31, 2014 we had 43 employees dedicated to our research and development program compared to 72 at March 31, 2013.

Overview

Our research and development expense consists primarily of salaries and related expenses for personnel, costs of contract manufacturing services, costs of facilities and equipment, fees paid to professional service providers in conjunction with our clinical trials, fees paid to research organizations in conjunction with pre-clinical animal studies, costs of materials used in research and development, consulting, license, and sponsored research fees paid to third parties and depreciation of associated laboratory equipment. We expect our research and development expense to increase as we continue to develop our portfolio of oncology programs.

We have not accumulated and tracked our internal historical research and development costs or our personnel and personnel-related costs on a program-by-program basis. Our employee and infrastructure resources are allocated across several projects, and many of our costs are directed to broadly applicable research endeavors. As a result, we cannot state the costs incurred for each of our oncology programs on a program-by-program basis.

The expenses incurred by us to third parties for pre-clinical and clinical trials in the current quarter and since inception of our lead clinical stage program were as follows (in millions):

Oncology program	Current status	Three Months Ended March 31, 2014	Program-to-date
c-Met program—tivantinib	Phase 3	$ 0.7	$ 82.8

Under the terms of our tivantinib collaboration agreement with Daiichi Sankyo we share development costs equally with our share of Phase 3 costs funded solely from milestones and royalties. Our cumulative share of Phase 3 collaboration costs has exceeded the amount of milestones received through March 31, 2014 by $44.2 million and is not reflected in the above table.

Our future research and development expenses in support of our current and future oncology programs will be subject to numerous uncertainties in timing and cost to completion. We test potential products in numerous pre-clinical studies for safety, toxicology, and efficacy. We may conduct multiple clinical trials for each product. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty, and intended use of a product. It is not unusual for the pre-clinical and clinical development of each of these types of products to take nine years or more, and for total development costs to exceed $500 million for each product.

We estimate that clinical trials of the type generally needed to secure new drug approval are typically completed over the following timelines:

Clinical Phase	Estimated Completion Period
Phase 1	1 – 2 years
Phase 2	2 – 3 years
Phase 3	2 – 4 years

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others, the following:

the number of clinical sites included in the trials;

the length of time required to enroll suitable patients;

the number of patients that ultimately participate in the trials;

the duration of patient follow-up to ensure the absence of long-term product-related adverse events; and

the efficacy and safety profile of the product.

An element of our business strategy is to pursue the research and development of a broad pipeline of products. This is intended to allow us to diversify the risks associated with our research and development expenditures. As a result, we believe our future capital requirements and future financial success do not substantially depend on any one product. To the extent we are unable to build and maintain a broad pipeline of products, our dependence on the success of one or a few products increases.

Our strategy includes entering into alliance arrangements with third parties to participate in the development and commercialization of our products, such as our collaboration agreements with Daiichi Sankyo and Kyowa Hakko Kirin. In the event that third parties have control over the clinical trial process for a product, the estimated completion date would be under control of that third party rather than under our control. We cannot forecast with any degree of certainty whether our products will be subject to future collaborative arrangements or how such arrangements would affect our development plans or capital requirements.

As a result of the uncertainties discussed above, we make significant estimates in determining the duration and completion costs of our oncology programs or when and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our oncology programs in a timely manner or our failure to enter into appropriate collaborative agreements could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time-to-time in order to continue with our product development strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

General and administrative

			Increase (decrease)	
	2014	2013	$	%
	(in millions)			
For the three months ended March 31:				
General and administrative	$ 3.3	$ 3.4	$ (0.1)	(4)%

General and administrative expense decreased in the first quarter of 2013 principally due to lower non-cash stock compensation costs. General and administrative headcount was 20 at March 31, 2014, compared to 25 at March 31, 2013.

Interest income, interest expense and other income (expense)

			Increase (decrease)	
	2014	2013	$	%
	(in thousands)			
For the three months ended March 31:				
Interest income	$ 95	$ 151	$ (56)	(37)%
Interest expense	(7)	(4)	3	75 %
Other income (expense)	76	(2)	78	3900 %

Interest income is derived from our portfolio of cash, cash equivalents and investments and decreased in the first quarter of 2014 primarily due to a decrease in our portfolio balance. Interest expense was incurred on our notes payable and increased in the first quarter of 2014 due to higher interest rates. Other income (expense) in the first quarter of 2014 includes a gain of $76 thousand from the increase in fair value of our auction rate securities. Other income (expense) in the first quarter of 2013 includes a loss of $2 thousand from the decrease in fair value of our auction rate securities.

RECENT ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In July 2013, the FASB issued an update, which is intended to eliminate the diversity that is in practice with regard to the financial statement presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax

loss, or a tax credit carryforward exists. The guidance is effective for our interim period ending March 31, 2014. We adopted this standard in the first quarter of fiscal year 2014. The adoption of this standard did not have a material impact on our financial condition or results of operations.

FORWARD LOOKING STATEMENTS

In addition to historical information, this report contains forward-looking statements. You can identify these forward-looking statements by their use of words such as “anticipate,” “assume,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “project,” “target,” “will” and other words and terms of similar meaning. You also can identify them b the fact that they do not relate strictly to historical or current facts. All statements which address operating performance, events or developments that the Company expects or anticipates will occur in the future, such as projections about its future results of operations, its financial condition, research, development and commercialization of its products and anticipated trends in its business are forward-looking statements.

In this report we make forward-looking statements regarding our drug development pipeline and our clinical trials involving tivantinib. Additional forward-looking statements relate to our agreements with Kyowa Hakko Kirin and Daiichi Sankyo, including potential future milestones and royalty payments that could result from the future development of tivantinib.

Drug development involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. For example, pre-clinical efforts associated with our product pipeline may fail or prove disappointing because our technology platform did not produce candidates with the desired characteristics. Animal xenograft pre-clinical studies may be unpredictive of human response. Positive information about early stage clinical trial results will not ensure that later stage or larger scale clinical trials will be successful.

Furthermore, our drugs may not demonstrate promising therapeutic effects; in addition, they may not demonstrate appropriate safety profiles in ongoing or later stage or larger scale clinical trials as a result of known or as yet unidentified side effects. The results achieved in later stage trials may not be sufficient to meet applicable regulatory standards. Problems or delays may arise during clinical trials or in the course of developing, testing or manufacturing our drugs that could lead us or our partner to discontinue development.

Even if later stage clinical trials are successful, the risk exists that unexpected concerns may arise from analysis of data or from additional data or that obstacles may arise or issues be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with the Company's view of the data or require additional data or information or additional studies. Also, the planned timing of initiation of clinical trials and the duration and conclusion of such trials for our drugs are subject to the ability of the company to enroll patients, enter into agreements with clinical trial sites and investigators, and other technical hurdles and issues that may not be resolved.

We also make forward-looking statements regarding the adequacy of our financial resources. Our capital resources may not be adequate because our cash requirements may vary materially from those now planned depending upon the results of our drug discovery and development strategies, the outcomes of our clinical trials, our ability to enter into additional corporate collaborations in the future and the terms of such collaborations, results of research and development, the need for currently unanticipated capital expenditures, competitive and technological advances, acquisitions, financial market conditions, our ability to liquidate our investments in auction rate securities and other factors. Additionally, our corporate collaborators may terminate their agreements with us, thereby eliminating that source of funding, because we may fail to satisfy the prescribed terms of the collaborations or for other reasons.

We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product generating revenues. If we experience increased losses, we may have to seek additional financing from public and private sales of our securities, including equity securities. There can be no assurance that additional funding will be available when needed or on acceptable terms.

The factors, risks and uncertainties referred to above and others are more fully described under the heading "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 filed with the SEC on March 5, 2014, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The forward-looking statements contained herein represent the judgment of the Company as of the date of this report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We own financial instruments that are sensitive to market risk as part of our investment portfolio. We have implemented policies regarding the amount and credit ratings of investments. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. Our investments are evaluated quarterly to determine the fair value of the portfolio.

Our cash and marketable securities include US Treasury bill funds, money market funds, and U.S. federal and state agency backed certificates, including auction rate securities that have strong credit ratings. Our cash equivalents and our portfolio of marketable securities are subject to market risk due to changes in interest rates. Fixed rate interest securities may have their market value adversely impacted due to a rise in interest rates, while floating rate securities

may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates.

Auction rate securities are securities that are structured with short-term interest reset dates of generally less than 90 days, but with contractual maturities that can be well in excess of ten years. At the end of each reset period, which occurs every seven to twenty-eight days, investors can sell or continue to hold the securities at par value. If any of our auction rate securities were to fail an auction, due to sell orders exceeding buy orders, the funds associated with a failed auction would not be accessible until a successful auction occurred, a buyer was found outside the auction process, the underlying securities matured or a settlement with the underwriter is reached. ArQule’s marketable securities portfolio at March 31, 2014 and December 31, 2013 included $2.1 million (at cost) invested in auction rate securities that have not successfully auctioned since February 12, 2008.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer (Principal Executive Officer) and President and Chief Operating Officer (Principal Financial Officer), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2014. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2014, our Chief Executive Officer (Principal Executive Officer) and President and Chief Operating Officer (Principal Financial Officer) concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

There have been no changes in the Company's internal control over financial reporting during the most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. — LEGAL PROCEEDINGS. None.

ITEM 1A. — RISK FACTORS. For information regarding factors that could affect the Company's results of operations, financial condition and liquidity, see the risk factors discussion provided under "Risk Factors" in Item 1A of ArQule's Annual Report on Form 10-K for the year ended December 31, 2013 filed with the SEC on March 5, 2014, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. See also, "Forward-Looking Statements" included in this Quarterly Report on Form 10-Q.

ITEM 2. — UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS. None.

ITEM 3. — DEFAULTS UPON SENIOR SECURITIES. None.

ITEM 4. — MINE SAFETY DISCLOSURES. Not applicable.

ITEM 5. — OTHERS INFORMATION. None.

ITEM 6. — EXHIBITS.

EXHIBIT NO.	DESCRIPTION
31.1	Rule 13a-14(a) Certificate of Chief Executive Officer, filed herewith.
31.2	Rule 13a-14(a) Certificate of Principal Financial Officer, filed herewith.
32	Rule 13a-14(b) Certificate of Chief Executive Officer and Chief Financial Officer, filed herewith.

101	Interactive Data File

24

ARQULE, INC.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ArQule, Inc.

Date: May 7, 2014

/s/ PETER S. LAWRENCE
Peter S. Lawrence
President and Chief Operating Officer
(Principal Financial Officer)

/s/ ROBERT J. WEISKOPF
Robert J. Weiskopf
Vice President of Finance,
Corporate Controller and Treasurer
(Principal Accounting Officer)