ARQULE INC
Form 10-Q
July 30, 2013

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 June 30, 2013

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 July 22, 2013:

Common Stock, par value $.01	62,723,048 shares outstanding

ARQULE, INC.

QUARTER ENDED JUNE 30, 2013

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ARQULE, INC.

CONDENSED BALANCE SHEETS (Unaudited)

	June 30, 2013	December 31, 2012
	(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,263	$ 14,327
Marketable securities-short term	66,833	64,944
Prepaid expenses and other current assets	960	344
Total current assets	81,056	79,615
Marketable securities-long term	31,018	51,328
Property and equipment, net	1,541	1,992
Other assets	1,130	1,258
Total assets	$ 114,745	$ 134,193
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 8,186	$ 10,163
Note payable	1,700	1,700
Current portion of deferred revenue	14,072	14,232
Current portion of deferred gain on sale leaseback	552	552
Total current liabilities	24,510	26,647
Deferred revenue, net of current portion	18,794	25,733
Deferred gain on sale leaseback, net of current portion	506	784
Total liabilities	43,810	53,164
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; 62,723,048 and 62,399,827 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively	627	624
Additional paid-in capital	503,177	500,655
Accumulated other comprehensive income	44	102
Accumulated deficit	(432,913)	(420,352)
Total stockholders' equity	70,935	81,029
Total liabilities and stockholders' equity	$ 114,745	$ 134,193

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 June 30,		SIX MONTHS ENDED June 30,	
	2013	2012	2013	2012
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Research and development revenue	$ 4,436	$ 11,829	$ 10,097	$ 20,327
Costs and expenses:				
Research and development	8,082	9,271	16,263	18,574
General and administrative	3,198	3,514	6,598	7,113
Total costs and expenses	11,280	12,785	22,861	25,687
Loss from operations	(6,844)	(956)	(12,764)	(5,360)
Interest income	132	79	283	144
Interest expense	(6)	(6)	(10)	(12)
Other income (expense)	(68)	(2)	(70)	83
Net loss	(6,786)	(885)	(12,561)	(5,145)
Unrealized loss on marketable securities	(67)	(126)	(58)	(107)
Comprehensive loss	$ (6,853)	$ (1,011)	$ (12,619)	$ (5,252)
Basic and diluted net loss per share:				
Net loss per share	$ (0.11)	$ (0.01)	$ (0.20)	$ (0.09)
Weighted average basic and diluted common shares outstanding	62,473	60,891	62,429	57,351

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

ARQULE, INC.

CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	SIX MONTHS ENDED JUNE 30,	
	2013	2012
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	$(12,561)	$(5,145)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	451	557
Amortization of premium/discount on marketable securities	1,180	550
Amortization of deferred gain on sale leaseback	(278)	(277)
Non-cash stock compensation	2,312	2,212
Loss (gain) on auction rate securities	70	(83)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(616)	2,748
Other long-term assets	128	29
Accounts payable and accrued expenses	(1,977)	(1,523)
Deferred revenue	(7,099)	(17,495)
Net cash used in operating activities	(18,390)	(18,427)
Cash flows from investing activities:		
Purchases of marketable securities	(9,063)	(95,620)
Proceeds from sale or maturity of marketable securities	26,176	74,186
Purchases of property and equipment	—	(117)
Net cash provided by (used in) investing activities	17,113	(21,551)
Cash flows from financing activities:		
Proceeds from stock offering, net	—	56,256
Proceeds from stock option exercises and employee stock plan purchases	213	1,287
Net cash provided by financing activities	213	57,543
Net increase (decrease) in cash and cash equivalents	(1,064)	17,565
Cash and cash equivalents, beginning of period	14,327	11,095
Cash and cash equivalents, end of period	$13,263	$28,660

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 ("AKIPTM") 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 clinical development program designed to realize the broad potential of tivantinib as a single agent and in combination with other anti-cancer therapies in a number of disease indications. Our strategy is to focus on the most promising indications within our clinical programs based upon continually generated and updated data. Our most advanced indication is liver cancer ("hepatocellular carcinoma" or "HCC"). We are also completing earlier-stage combination therapy trials with tivantinib and other anti-cancer agents that may provide data to support later-stage trials in additional indications.

On January 31, 2013, we announced that the first patient had been enrolled in the pivotal Phase 3 METIV trial of tivantinib for patients diagnosed with HCC who have received one or two prior systemic anti-cancer therapies. The METIV trial is a randomized, double-blind, controlled study of previously treated patients with MET-high inoperable HCC who will receive tivantinib as a single agent or placebo. The primary endpoint of this trial is overall survival ("OS"), and the secondary endpoint is progression-free survival ("PFS"). Approximately 300 patients are planned to be enrolled at approximately 120 clinical sites worldwide. This trial is being conducted under a Special Protocol Assessment ("SPA") agreement with the U.S. Food and Drug Administration ("FDA"). The METIV trial builds upon the results of a randomized, double-blind, placebo controlled, Phase 2 trial in HCC announced in January 2012 demonstrating that treatment with tivantinib as single agent therapy produced a statistically significant improvement in the primary endpoint of time-to-progression ("TTP") in previously treated patients. Patients with higher levels of MET who were treated with tivantinib in this Phase 2 trial experienced pronounced benefit in prolonged TTP. Additional data from this trial, presented at the Annual Meeting of the American Society of Clinical Oncology ("ASCO") in June 2012, demonstrated significant improvements in median OS and PFS in these MET-high patients.

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 objective response rate ("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 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.

On October 2, 2012, we and Daiichi Sankyo announced that the independent Data Monitoring Committee ("DMC") of 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) recommended the study be discontinued early following a planned interim analysis, when they concluded that the study would not meet its primary endpoint of improved OS. Although the interim analysis showed a statistically significant improvement in PFS in the intent-to-treat ("ITT") population, this benefit did not carry over to OS. There were no safety concerns identified by the DMC during this interim analysis.

Daiichi Sankyo recently provided us with the final data set from the MARQUEE trial (with a cut-off date of December 15, 2012), including analyses of the pre-specified sub-groups prescribed in the statistical analysis plan ("SAP") for the trial. These latest data analyses confirm a statistically significant improvement in PFS in the ITT population (approximately 1000 patients) for patients receiving tivantinib, but the PFS benefit did not carry over to OS.

These analyses included an exploratory analysis of the MET IHC (immunohistochemistry) sub-group comprised of 445 evaluable patients. Of these, 211 patients were confirmed to be MET-high as defined in the SAP. The MET high tivantinib group showed a substantial improvement in OS relative to the control group, a benefit which was not seen in the ITT population. By comparison, 234 patients were confirmed to be MET low, and in this cohort of patients, no difference in OS was observed. PFS in MET-high and MET-low populations were similar. Complete data from these analyses are planned for presentation at the European Cancer Congress in the fall of 2013.

We and Daiichi Sankyo have provided information regarding the study discontinuation to health authorities and those clinical investigators participating in studies of tivantinib. Our analysis of data from the MARQUEE trial and other studies will inform our decisions regarding potential further development in NSCLC or in certain biomarker-defined sub-groups within this disease population. In NSCLC, we are also conducting a Phase 2, randomized trial of tivantinib and erlotinib in patients with a mutated form of the KRAS gene.

On October 30, 2012, we reported that we had been informed by Kyowa Hakko Kirin that it would permanently suspend enrollment in its ongoing Phase 3 ATTENTION (Asian Trial of Tivantinib plus Erlotinib for NSCLC without EGFR Mutation) trial following the recommendation of an independent Safety Review Committee ("SRC") in Japan after the reporting of cases of interstitial lung disease ("ILD") in the study as a drug-related adverse event. It is our understanding that patients who were enrolled in the ATTENTION trial at the time of the safety finding can continue to receive treatment with the combination of tivantinib and erlotinib upon request from the patient and investigator and after providing new informed consent. Data from the trial are expected in late 2013 or early 2014. The ATTENTION trial is investigating the use of tivantinib and erlotinib versus erlotinib and placebo in second line non-squamous NSCLC patients with the wild-type form of the EGFR gene. This trial is being conducted by Kyowa Hakko Kirin in Japan, South Korea and Taiwan.

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 milestone payments of $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 the 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 the six months ended June 30, 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.

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 co-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 are 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 related to this program.

ARQ 092 is part of our proprietary pipeline of product candidates directed toward molecular targets and biological processes with demonstrated roles in the development of human cancers. These product candidates also include ARQ 087, an inhibitor of fibroblast growth factor receptor, ARQ 621, an inhibitor of the Eg5 kinesin motor protein, and ARQ 736, an inhibitor of the RAF kinases, all of which are undergoing or have completed Phase 1 clinical testing.

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, 2012 included in our annual report on Form 10-K filed with the SEC on March 14, 2013.

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 June 30, 2013, the results of our operations for the three and six months ended June 30, 2013 and 2012, and cash flows for the six months ended June 30, 2013 and 2012. 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 Kinase Inhibitor Discovery Agreement

In November 2012, we completed our research collaboration with Daiichi Sankyo under a research collaboration, exclusive license and co-commercialization agreement entered into on November 7, 2008, that was focused on applications of our proprietary AKIPTM technology and know-how for the discovery of therapeutic compounds that selectively inhibit certain kinases in the field of oncology. The agreement provides 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.

Revenue for this agreement was recognized using the contingency-adjusted performance model with an estimated performance period through November 2012. The agreement was terminated in 2012 and accordingly no revenue was recognized in the three or six months ended June 30, 2013. For the three and six months ended June 30, 2012, revenues recognized were $4.9 million and $9.8 million, respectively.

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 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 are 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 related to this program.

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 the agreement were divided into separate units of accounting based on whether the deliverable provides stand-alone value to the licensee. These units of accounting consist of (i) the license to develop and commercialize ARQ 092, (ii) committed future clinical trial services, (iii) committed future clinical trial costs and (ii) steering committee services. 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 estimated development period for this agreement was through June 2013. We recognized revenue of $0.6 million and $1.3 million, and $0.8 million and $1.6 million related to this agreement for the three and six months ended June 30, 2013 and 2012, respectively. At June 30, 2013, there was no balance remaining in deferred revenue.

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 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 inception to date through June 30, 2013, totaled $73.4 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. In 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 netted against our cumulative share of Phase 3 collaboration costs in the six months ended June 30, 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 earned through June 30, 2013 by $33.4 million which will be netted against future milestones and royalties, if any, when earned and has not been reported as contra-revenue.

For the three months ended June 30, 2013, our non-Phase 3 tivantinib collaboration costs incurred exceeded those of Daiichi Sankyo's and we recognized $0.3 million as research and development revenue under the contingency adjusted performance model. Through the six months ended June 30, 2013 we recognized a net of $0.1 million of research and development revenue related to our non-Phase 3 tivantinib collaboration costs which included contra-revenue of $0.2 million and $0.3 million of revenue.

For the three months ended June 30, 2012 our non-Phase 3 tivantinib collaboration costs incurred were equal to those of Daiichi Sankyo's. For the six months ended June 30, 2012 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo's and $0.9 million was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue. Our non-refundable share of advance drug purchases is recognized as contra-revenue as the related drugs are administered to patients. For the three and six months ended June 30, 2012, zero and $2.5 million of these advance drug purchases, respectively were also recognized as contra-revenue. There were no advance drug purchases in the six months ended June 30, 2012.

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. Therefore, since the fourth quarter of 2012, revenue has been recognized over this revised development period. For the three and six months ended June 30, 2013 and 2012, $2.3 million and $4.2 million, and $4.7 million and $6.0 million, respectively, were recognized as net revenue. At June 30, 2013, $16.7 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. In August 2011, Kyowa Hakko Kirin announced the initiation of the Phase 3 ATTENTION trial in Asia of tivantinib and erlotinib in non-squamous NSCLC patients with wild type EGFR. 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 June 30, 2013, 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 the three and six months ended June 30, 2013 and 2012 $1.4 million and $2.8 million, and $1.4 million and $2.8 million, respectively were recognized as revenue. At June 30, 2013, $16.1 million remains in deferred revenue.

Other Project Revenue

During the six months ended June 30, 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 six months ended June 30, 2013. No such revenue was recognized in the three months ended June 30, 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 June 30, 2013 and December 31, 2012:

June 30, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Corporate debt securities-short term	$ 66,811	$ 31	$ (9)	$ 66,833
Corporate debt securities-long term	29,277	37	(15)	29,299
Total available-for-sale marketable securities	$ 96,088	$ 68	$ (24)	$ 96,132

December 31, 2012	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Corporate debt securities-short term	$ 64,921	$ 45	$ (22)	$ 64,944
Corporate debt securities-long term	49,460	93	(14)	49,539
Total available-for-sale marketable securities	$ 114,381	$ 138	$ (36)	$ 114,483

The Company's available-for-sale marketable securities in a loss position at June 30, 2013 and December 31, 2012, were in a continuous unrealized loss position for less than 12 months.

The following is a summary of the fair value of trading securities we held at June 30, 2013 and December 31, 2012:

June 30, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Auction rate securities	$ 2,100	$ —	$ (381)	$ 1,719
Total trading securities	$ 2,100	$ —	$ (381)	$ 1,719

December 31, 2012	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Auction rate securities	$ 2,100	$ —	$ (311)	$ 1,789
Total trading securities	$ 2,100	$ —	$ (311)	$ 1,789

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 June 30, 2013 and December 31, 2012, the Company's auction rate securities are included in marketable securities-long term and total $1,719 and $1,789, respectively. The net decrease in value of our auction rate securities of $68 and $70 in the three and six months ended June 30, 2013, respectively, was recorded as a loss in other income (expenses) in the statement of operations and comprehensive loss. The net decrease in fair value of our auction rate securities of $2 in the three months ended June 30, 2012 was recorded as a loss in other income (expense) in the statement of operations and comprehensive loss. The net increase in fair value of our auction rate securities of $83 in the six months ended June 30, 2012, was recorded as a gain 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:

	June 30, 2013	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$10,541	$ 10,541	$—	$ —
Corporate debt securities-short term	66,833	—	66,833	—
Corporate debt securities-long term	29,298	—	29,298	—
Auction rate securities-long term	1,719	—	—	1,719
Total	$108,391	$ 10,541	$96,131	$ 1,719

	December 31, 2012	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$11,754	$ 11,754	$—	$ —
Corporate debt securities-short term	64,944	—	64,944	—
Corporate debt securities-long term	49,539	—	49,539	—
Auction rate securities-long term	1,789	—	—	1,789
Total	$128,026	$ 11,754	$114,483	$ 1,789

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 2013:

	Amount
Balance at December 31, 2012	$ 1,789
Loss on auction rate securities	(70)
Balance at June 30, 2013	$ 1,719

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 2012:

	Amount
Balance at December 31, 2011	$ 1,676
Gain on auction rate securities	83
Balance at June 30, 2012	$ 1,759

The following table provides quantitative information on the unobservable inputs of our fair value measurements for our Level 3 assets for the six months ended June 30, 2013:

	Quantitative Information about Level 3 Fair Value Measurements			
	Estimated Fair Value at June 30, 2013	Valuation Technique	Unobservable Inputs	Range
Auction rate securities	$ 1,719	Discounted cash flow		
			Maximum rate	1.8%

Liquidity risk premium	3.5% - 4.5%
Probability of earning maximum rate until maturity	0.04% - 0.05%
Probability of principal returned prior to maturity	74.7%–77.2%
Probability of default	22.8%–25.3%

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 June 30, 2013 and December 31, 2012:

	2013	2012
Accounts payable	$ 533	$ 560
Accrued payroll	2,098	2,872
Accrued outsourced pre-clinical and clinical fees	5,058	5,501
Accrued professional fees	369	641
Other accrued expenses	128	589
	$ 8,186	$ 10,163

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 8,293,690 and 7,553,383 for the three and six months ended June 30, 2013 and 2012, 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 and six months ended June 30, 2013 and 2012.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Research and development	$343	$414	$837	$874
General and administrative	604	600	1,475	1,338
Total stock-based compensation expense	$947	$1,014	$2,312	$2,212

In the three months and six months ended June 30, 2013 and 2012, 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 six months ended June 30, 2013 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2012	7,157,458	$ 5.70
Granted	1,220,910	2.53
Exercised	—	—
Cancelled	(84,678)	4.15
Outstanding as of June 30, 2013	8,293,690	5.25
Exercisable as of June 30, 2013	5,339,950	$ 5.35

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The aggregate intrinsic value of options outstanding at June 30, 2013 was $0. The weighted average grant date fair value of options granted in the six months ended June 30, 2013 and 2012 was $1.68 and $4.67 per share, respectively. The intrinsic value of options exercised in the six months ended June 30, 2012 was $485. No options were exercised in the six months ended June 30, 2013.

Shares vested, expected to vest and exercisable at June 30, 2013 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 June 30, 2013	8,145,494	$ 5.25	6.2	$ —
Exercisable at June 30, 2013	5,339,950	$ 5.35	4.9	$ —

The total compensation cost not yet recognized as of June 30, 2013 related to non-vested option awards was $8.2 million, which will be recognized over a weighted-average period of 2.6 years. During the six months ended June 30, 2013 40,913 shares were forfeited. The weighted average remaining contractual life for options exercisable at June 30, 2013 was 4.9 years.

In 2013, we granted 242,697 shares of restricted stock to employees, vesting annually over a four year period. No restricted stock was granted in 2012. 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. We recognized share-based compensation expense related to restricted stock of $148 and $138 for the six months ended June 30, 2013 and 2012, respectively.

Restricted stock activity under the Plan for the six months ended June 30, 2013 was as follows:

Restricted Stock	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2012	79,795	$ 3.54
Granted	242,697	2.51
Vested	(79,795)	3.54
Cancelled	(5,449)	2.51
Unvested as of June 30, 2013	237,248	$ 2.51

The fair value of restricted stock vested in the six months ended June 30, 2013 and 2012 was $203 and $749, respectively.

Through June 30, 2013, 74,944 shares have been forfeited, and 571,021 shares have vested under the plan.

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 following 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 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 June 30, 2013, no expense has been recorded for any of these performance-based stock units.

7. STOCK OFFERING

On April 16, 2012, we sold 8,222,500 shares of common stock at $7.30 per share for aggregate net proceeds of approximately $56.3 million after commissions and other estimated offering expenses.

8. 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 February 2013, the Financial Accounting Standards Board ("FASB") issued an amendment to the accounting guidance on reporting amounts reclassified out of accumulated other comprehensive income. The guidance requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassed is required under United States Generally Accepted Accounting Principles ("GAAP") to be reclassified in its entirety to net income. For other amounts that are not required under United States GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under United States GAAP that provide additional detail about those amounts. The guidance is effective prospectively for reporting periods beginning after December 15, 2012. The adoption of this standard on January 1, 2013 did not impact our financial position or results of operations.

9. INCOME TAXES

As of December 31, 2012, we had federal NOL, state NOL, and research and development credit carryforwards of approximately $265,004, $113,262 and $24,885 respectively, expiring from 2013 to 2032, which can be used to offset future income tax liabilities. Federal capital loss carryforwards of approximately $571, expiring in 2015, can be used to offset future federal capital gain income. Approximately $15,003 of our federal NOL and $907 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 June 30, 2013 and December 31, 2012, 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 June 30, 2013 and December 31, 2012, we had no accrued interest or penalties related to uncertain tax positions. Our U.S. federal tax returns for the tax years 2010 through 2012 and our state tax returns for the tax years 2009 through 2012 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, 2013, to determine whether such amounts are likely to be limited by Section 382. 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.

10. 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 June 30, 2013 and 2012, collateralized by $2.1 million of auction rate securities at cost. Interest expense was $6 and $10 and $6 and $12 for the three and six months ended June 30, 2013 and 2012, 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.

11. SUBSEQUENT EVENT

In July 2013, the Company implemented a focused reduction in its workforce of approximately 25 positions, resulting in a remaining workforce of approximately 67 employees. This action is intended to align human and financial resources with the Company's primary focus on clinical-stage development, while retaining our core discovery capabilities. The Company estimates the costs associated with this action will be comprised principally of severance payments of approximately $525 and benefits continuation costs of approximately $100, all of which are expected to be paid by December 31, 2013. In addition, in the third quarter of 2013 the Company expects to incur non-cash charges of approximately $150 related to the modification of employee stock options.

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 ("AKIPTM") 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 ("MET") and its biological pathway. 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 clinical development program designed to realize the broad potential of tivantinib as a single agent and in combination with other anti-cancer therapies in a number of disease indications. Our strategy is to focus on the most promising indications within our clinical programs based upon continually generated and updated data. Our most advanced indication is hepatocellular carcinoma ("HCC"). We are also completing earlier-stage combination therapy trials with tivantinib and other anti-cancer agents that may provide data to support later-stage trials in additional indications.

On January 31, 2013, we announced that the first patient had been enrolled in the pivotal Phase 3 METIV trial of tivantinib for patients diagnosed with HCC who have received one or two prior systemic anti-cancer therapies. The METIV trial is a randomized, double-blind, controlled study of previously treated patients with MET-high inoperable HCC who will receive tivantinib as a single agent or placebo. The primary endpoint of this trial is overall survival ("OS"), and the secondary endpoint is progression-free survival ("PFS"). Approximately 300 patients are planned to be enrolled at approximately 120 clinical sites worldwide. This trial is being conducted under a Special Protocol Assessment ("SPA") agreement with the U.S. Food and Drug Administration ("FDA"). The METIV trial builds upon the results of a randomized, double-blind, placebo controlled, Phase 2 trial in HCC announced in January 2012 demonstrating that treatment with tivantinib as single agent therapy produced a statistically significant improvement in the primary endpoint of time-to-progression ("TTP") in previously treated patients. Patients with higher levels of MET who were treated with tivantinib in this Phase 2 trial experienced pronounced benefit in prolonged TTP. Additional data from this trial, presented at the Annual Meeting of the American Society of Clinical Oncology ("ASCO") in June 2012, demonstrated significant improvements in median OS and PFS in these MET-high patients.

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 objective response rate ("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 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 (hazard ratio = 0.85, 95% CI: 0.55, 1.33, stratified log-rank p = 0.38). Median OS in the treatment arm was 19.8 months, compared with 16.9 months in the control arm (hazard ratio = 0.70, 95% CI: 0.42, 1.17, stratified log-rank p = 0.25). ORR in the treatment arm was 45 percent versus 33 percent in the control arm. Patients pre-treated with oxaliplatin in the treatment arm experienced favorable PFS and OS results. Among these patients, median PFS was 8.3 months compared with 7.2 months in the oxaliplatin-treated control arm (hazard ratio = 0.66 CI: 0.41, 1.09, stratified log-rank p=0.10), and median OS was 22.3 months compared with 14.1 months (hazard ratio = 0.58, 95% CI: 0.33, 1.02, stratified log-rank p = 0.06). ORR in oxaliplatin pre-treated patients who received tivantinib was 42.6

percent, compared with 27.1 percent in the placebo arm. Efficacy observations in a small MET-high sub-group were inconclusive and would require further assessment with a larger sample size. Adverse events were reported at similar rates in the experimental and control arms, except for increased neutropenia observed in the experimental arm, with no discontinuations of treatment for this reason. No treatment-emergent adverse events leading to death were assessed as related to study treatment. Tivantinib was generally well tolerated in combination with the doses of cetuximab and irinotecan studied in this trial.

On October 2, 2012, we and Daiichi Sankyo announced that the independent Data Monitoring Committee ("DMC") of 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) recommended the study be discontinued early following a planned interim analysis, when they concluded that the study would not meet its primary endpoint of improved OS. Although the interim analysis showed a statistically significant improvement in PFS in the intent-to-treat ("ITT") population, this benefit did not carry over to OS. There were no safety concerns identified by the DMC during this interim analysis.

Daiichi Sankyo recently provided us with the final data set from the MARQUEE trial (with a cut-off date of December 15, 2012), including analyses of the pre-specified sub-groups prescribed in the statistical analysis plan ("SAP") for the trial. These latest data analyses confirm a statistically significant improvement in PFS in the ITT population (approximately 1000 patients) for patients receiving tivantinib, but the PFS benefit did not carry over to OS.

These analyses included an exploratory analysis of the MET IHC (immunohistochemistry) sub-group comprised of 445 evaluable patients. Of these, 211 patients were confirmed to be MET-high as defined in the SAP. The MET high tivantinib group showed a substantial improvement in OS relative to the control group, a benefit which was not seen in the ITT population. By comparison, 234 patients were confirmed to be MET low, and in this cohort of patients, no difference in OS was observed. PFS in MET-high and MET-low populations were similar. Complete data from these analyses are planned for presentation at the European Cancer Congress in the fall of 2013.

We and Daiichi Sankyo have provided information regarding the study discontinuation to health authorities and those clinical investigators participating in studies of tivantinib. Our analysis of data from the MARQUEE trial and other studies will inform our decisions regarding potential further development in NSCLC or in certain biomarker-defined sub-groups within this disease population. In NSCLC, we are also conducting a Phase 2, randomized trial of tivantinib and erlotinib in patients with a mutated form of the KRAS gene.

On October 30, 2012, we reported that we had been informed by Kyowa Hakko Kirin that it would permanently suspend enrollment in its ongoing Phase 3 ATTENTION (Asian Trial of Tivantinib plus Erlotinib for NSCLC without EGFR Mutation) trial following the recommendation of an independent Safety Review Committee (“SRC”) in Japan after the reporting of cases of interstitial lung disease (“ILD”) in the study as a drug-related adverse event. It is our understanding that patients who were enrolled in the ATTENTION trial at the time of the safety finding can continue to receive treatment with the combination of tivantinib and erlotinib upon request from the patient and investigator and after providing new informed consent. Data from the trial are expected in late 2013 or early 2014. The ATTENTION trial is investigating the use of tivantinib and erlotinib versus erlotinib and placebo in second line non-squamous NSCLC patients with the wild-type form of the EGFR gene. This trial is being conducted by Kyowa Hakko Kirin in Japan, South Korea and Taiwan.

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.

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 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 are 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 related to this program.

ARQ 092 is part of our proprietary pipeline of product candidates directed toward molecular targets and biological processes with demonstrated roles in the development of human cancers. These product candidates also include ARQ 087, an inhibitor of fibroblast growth factor receptor ARQ 621, an inhibitor of the Eg5 kinesin motor protein, and

ARQ 736, an inhibitor of the RAF kinases, all of which are undergoing or have completed Phase 1 clinical testing.

Our drug discovery efforts are focused primarily on AKIPTM, which we are using to generate compounds designed to inhibit kinases without competing with adenosine triphosphate ("ATP") for binding to the target kinase, as well as other types of kinase inhibitors. ATP is a chemical found in all living cells and is the energy source involved in a variety of physiological processes. We have assessed the potential of AKIPTM to target multiple kinases in oncology and other therapeutic areas, and we are generating and validating compounds that inhibit these kinase targets. During 2011, Daiichi Sankyo licensed ARQ 092, an inhibitor of the AKT protein kinase discovered under our AKIPTM 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. On April 1, 2013, we announced that we had regained worldwide rights for ARQ 092 pursuant to Daiichi Sankyo's decision to terminate this license agreement. We are responsible for funding the remainder of the ongoing Phase 1 trial beyond the contractual termination period, as well as any future clinical development and commercialization of this compound.

We have incurred a cumulative deficit of approximately $433 million from inception through June 30, 2013. We expect research and development costs to increase during the course of 2013, due to clinical testing of our lead product candidates. We recorded a net loss for 2010, 2011 and 2012 and expect a net loss for 2013.

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. Therefore, since the fourth quarter of 2012, revenue has been recognized over this revised development period.

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 inception to date through June 30, 2013, totaled $73.4 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. In 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 netted against our cumulative share of Phase 3 collaboration costs in the six months ended June 30, 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 earned through June 30, 2013 by $33.4 million which will be netted against future milestones and royalties, if any, when earned and has not been reported as contra-revenue.

For the three months ended June 30, 2013, our non-Phase 3 tivantinib collaboration costs incurred exceeded those of Daiichi Sankyo’s and we recognized $0.3 million as research and development revenue under the contingency adjusted performance model. Through the six months ended June 30, 2013 we recognized a net of $0.1 million of research and development revenue related to our non-Phase 3 tivantinib collaboration costs which included contra-revenue of $0.2

million and $0.3 million of revenue.

For the three months ended June 30, 2012 our non-Phase 3 tivantinib collaboration costs incurred were equal to those of Daiichi Sankyo's. For the six months ended June 30, 2012 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo's and $0.9 million was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue. Our non-refundable share of advance drug purchases is recognized as contra-revenue as the related drugs are administered to patients. For the three and six months ended June 30, 2012, zero and $2.5 million of these advance drug purchases, respectively were also recognized as contra-revenue. There were no advance drug purchases in the six months ended June 30, 2012

In November 2012, we completed our research collaboration with Daiichi Sankyo under an agreement entered into in 2008 that was focused on applications of our proprietary AKIPTM technology and know-how. 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. Revenue for this agreement was recognized using the contingency-adjusted performance model with a performance period through November 2012.

In November 2011, we and Daiichi Sankyo announced the execution of a license agreement for the development of ARQ 092, the first compound to emerge from the companies' AKIPTM collaboration. The license agreement provides 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 payment from Daiichi Sankyo in November 2011. On April 1, 2013, we announced that we had regained worldwide rights for ARQ 092 pursuant to Daiichi Sankyo's decision to terminate this license agreement. Following Daiichi Sankyo's termination of the license agreement for ARQ 092, we are responsible for funding the remainder of the ongoing Phase 1 trial beyond the contractual termination period, as well as any future clinical development and commercialization of this compound.

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 June 30, 2013, the Company has not recognized any revenue from these 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

	June 30, 2013	December 31, 2012	Increase (decrease) $	Increase (decrease) %
		(in millions)		
Cash, cash equivalents and marketable securities-short term	$ 80.1	$ 79.3	$ 0.8	1 %
Marketable securities-long term	31.0	51.3	(20.3)	(40)%
Notes payable	1.7	1.7	—	—
Working capital	56.5	53.0	3.5	7 %

	Six Months Ended June 30, 2013	June 30, 2012	Increase (decrease)
		(in millions)	
Cash flow from:			
Operating activities	$ (18.4)	$ (18.4)	$ —
Investing activities	17.1	(21.6)	38.7
Financing activities	0.2	57.5	(57.3)

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 six months ended June 30, 2013 and 2012, our net use of cash was primarily driven by the difference between cash receipts from our collaborators and payments for operating expenses which resulted in a net cash outflow of $18.4 million.

Cash flow from investing activities. Our net cash provided by investing activities of $17.1 million for the six months ended June 30, 2013 was comprised of net sales of marketable securities. Our net cash used by investing activities of $21.6 million for the six months ended June 30, 2012 was comprised of purchases 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 June 30, 2013 and December 31, 2012, invested in auction rate securities.

Cash flow from financing activities. 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.

Our net cash provided by financing activities was $0.2 million for the quarter ended June 30, 2013 from employee stock plan purchases. Our net cash provided by financing activities for the six months ended June 30, 2012 consisted of $56.3 million from the net proceeds of our April 2012 stock offering and $1.3 million from the issuance of common stock from the exercise of stock options and employee stock plan purchases.

In July 2013, the Company implemented a focused reduction in its workforce of approximately 25 positions, resulting in a remaining workforce of approximately 67 employees. This action is intended to align human and financial resources with the Company's primary focus on clinical-stage development, while retaining our core discovery capabilities. The Company estimates the costs associated with this action will be comprised principally of severance payments of approximately $525,000 and benefits continuation costs of approximately $100,000, all of which are expected to be paid by December 31, 2013. In addition, in the third quarter of 2013 the Company expects to incur non-cash charges of approximately $150,000 related to the modification of employee stock options.
We anticipate that our cash, cash equivalents and marketable securities on hand at June 30, 2013, financial support from our collaboration agreements, and savings from our workforce reduction described above, will be sufficient to finance the Company's working capital and capital requirements into 2016.

Our contractual obligations were comprised of the following as of June 30, 2013 (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	5,790	3,129	2,661	—	—
Purchase obligations	5,052	5,052	—	—	—
Total	$ 12,542	$ 9,881	$ 2,661	$ —	$ —

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 June 30, 2013 our portion of these costs was $33.4 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, 2012 on Form 10-K filed with the SEC on March 14, 2013.

RESULTS OF OPERATIONS

The following are the results of operations for the three and six months ended June 30, 2013 and 2012:

Revenue

	2013	2012	Increase (decrease) $	%
	(in millions)			
For the three months ended June 30:				
Research and development revenue	$4.4	$11.8	$(7.4)	(62)%
For the six months ended June 30:				
Research and development revenue	$10.1	$20.3	$(10.2)	(50)%

Research and development revenue for the three and six months ended June 30, 2013 and 2012 is comprised of revenue from the Daiichi Sankyo tivantinib development agreement, the license agreement with Daiichi Sankyo for the development of ARQ 092, and the Kyowa Hakka Kirin exclusive license agreement. In addition, during the six months ended June 30, 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 six months ended June 30, 2013. Research and development revenue for the three and six months ended June 30, 2012 also included revenue from our November 2008 Daiichi Sankyo AKIPTM agreement that ended in November 2012.

Under the terms of our tivantinib collaboration agreement with Daiichi Sankyo we share development costs equally with our share of Phase 3 costs funded 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 inception to date through June 30, 2013, totaled $73.4 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. In 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 netted against our cumulative share of Phase 3 collaboration costs in the six months ended June 30, 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 earned through June 30, 2013 by $33.4 million which will be netted against future milestones and royalties, if any, when earned and has not been reported as contra-revenue.

For the three months ended June 30, 2013, our non-Phase 3 tivantinib collaboration costs incurred exceeded those of Daiichi Sankyo's and we recognized $0.3 million as research and development revenue under the contingency adjusted performance model. Through the six months ended June 30, 2013 we recognized a net of $0.1 million of research and development revenue related to our non-Phase 3 tivantinib collaboration costs which included contra-revenue of $0.2

million and $0.3 million of revenue.

For the three months ended June 30, 2012 our non-Phase 3 tivantinib collaboration costs incurred were equal to those of Daiichi Sankyo's. For the six months ended June 30, 2012 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo's and $0.9 million was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue. Our non-refundable share of advance drug purchases is recognized as contra-revenue as the related drugs are administered to patients. For the three and six months ended June 30, 2012, zero and $2.5 million of these advance drug purchases, respectively were also recognized as contra-revenue. There were no advance drug purchases in the six months ended June 30, 2012.

The $7.4 million revenue decrease in the three months ended June 30, 2013 is primarily due to revenue decreases of $4.9 million from our Daiichi Sankyo AKIPTM agreement that ended in November 2012, and $2.3 million from our Daiichi Sankyo tivantinib program.

The $10.2 million revenue decrease in the six months ended June 30, 2013 was primarily due to revenue decreases of $9.8 million from our Daiichi Sankyo AKIPTM agreement that ended in November 2012, $0.4 million from our Daiichi Sankyo ARQ 092 agreement that ended in June 2013 and $1.8 million from our Daiichi Sankyo tivantinib program. These decreases were partially offset by $1.8 million of other revenue related to a one-time research project.

Research and development

			Increase (decrease)	
	2013	2012	$	%
	(in millions)			
For the three months ended June 30:				
Research and development	$8.1	$9.3	$(1.2)	(13)%
For the six months ended June 30:				
Research and development	$16.3	$18.6	$(2.3)	(12)%

Research and development expense in the three months ended June 30, 2013 decreased by $1.2 million primarily due to $0.3 lower outsourced clinical and product development costs related to our phase 1 and 2 programs for tivantinib and pipeline programs, $0.5 million lower labor related costs.

Research and development expense in the six months ended June 30, 2013 decreased by $2.3 million primarily due to $0.8 million lower outsourced clinical and product development costs related to our phase 1 and 2 programs for tivantinib and pipeline programs, and $1.0 million lower labor related costs. At June 30, 2013 we had 69 employees dedicated to our research and development program compared to 75 at June 30, 2012.

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	Six Months Ended June 30, 2013	Program-to-date
c-Met program—tivantinib	Phase 3	$ 2.0	$ 81.2

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 product candidates, 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 candidate, 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 product candidates 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)	
	2013	2012	$	%
	(in millions)			
For the three months ended June 30:				
General and administrative	$ 3.2	$ 3.5	$ (0.3)	(9)%
For the six months ended June 30:				
General and administrative	$ 6.6	$ 7.1	$ (0.5)	(7)%

General and administrative expense decreased in the three and six-month periods ended June 30, 2013 principally due to lower professional fees. General and administrative headcount was 25 at June 30, 2013, compared to 26 at June 30, 2012.

Interest income, interest expense and other income (expense)

			Increase (decrease)	
	2013	2012	$	%

	(in thousands)			
For the three months ended June 30:				
Interest income	$ 132	$ 79	$ 53	67 %
Interest expense	(6)	(6)	—	—
Other income (expense)	(68)	(2)	66	3,300 %
For the six months ended June 30:				
Interest income	$ 283	$ 144	$ 139	97 %
Interest expense	(10)	(12)	(2)	(17)%
Other income (expense)	(70)	83	(153)	(184)%

Interest income is derived from our portfolio of cash, cash equivalents and investments and increased in the three and six-month periods ended June 30, 2013 primarily due to an increase in our portfolio balance. Interest expense was incurred on our notes payable. Other income (expense) in the three and six-month periods ended June 30, 2013 includes a loss of $68 thousand and a loss of $70 thousand, from the decrease in fair value of our auction rate securities, respectively Other income (expense) in the three and six-month periods ended June 30, 2012 includes a loss of $2 thousand from the decrease in fair value of our auction rate securities, and a gain of $83 thousand from the increase in fair value of our auction rate securities, respectively.

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 February 2013, the Financial Accounting Standards Board ("FASB") issued an amendment to the accounting guidance on reporting amounts reclassified out of accumulated other comprehensive income. The guidance requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassed is required under United States Generally Accepted Accounting Principles ("GAAP") to be reclassified in its entirety to net income. For other amounts that are not required under United States GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under United States GAAP that provide additional detail about those amounts. The guidance is effective prospectively for reporting periods beginning after December 15, 2012. The adoption of this standard on January 1, 2013 did not impact our financial position 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 product candidates 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, 2012 filed with the SEC on March 14, 2013, 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 U.S. 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 June 30, 2013 and December 31, 2012 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 June 30, 2013. 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 June 30, 2013, 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, 2012 filed with the SEC on March 14, 2013, 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

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: July 30, 2013

/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)