ARQULE INC
Form 10-Q
November 09, 2010
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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 September 30, 2010

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 o 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 November 1, 2010:

Common Stock, par value $.01 44,949,693 shares outstanding

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ARQULE, INC.

QUARTER ENDED SEPTEMBER 30, 2010

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ARQULE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	September 30, 2010	December 31, 2009
	(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,742	$ 36,551
Marketable securities-short term	65,539	118,126
Prepaid expenses and other current assets	564	2,476
Total current assets	86,845	157,153
Marketable securities-long term	2,200	8,814
Property and equipment, net	3,761	4,585
Other assets	1,338	1,328
Total assets	$ 94,144	$ 171,880
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	$ 12,903	$ 12,360
Notes payable	1,700	46,100
Current portion of deferred revenue	26,637	24,572
Current portion of deferred gain on sale leaseback	552	552
Total current liabilities	41,792	83,584
Deferred revenue, net of current portion	60,073	74,321
Deferred gain on sale leaseback, net of current portion	2,025	2,440
Total liabilities	103,890	160,345
Commitments and contingencies		
Stockholders equity (deficit):		
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; 44,892,330 and 44,772,945 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	449	448
Additional paid-in capital	382,748	379,621
Accumulated other comprehensive income	19	55
Accumulated deficit	(392,962)	(368,589)
Total stockholders equity (deficit)	(9,746)	11,535
Total liabilities and stockholders equity (deficit)	$ 94,144	$ 171,880

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

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ARQULE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	THREE MONTHS ENDED September 30,		NINE MONTHS ENDED September 30,	
	2010	2009	2010	2009
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Research and development revenue	$ 8,270	$ 6,436	$ 21,701	$ 17,912
Costs and expenses:				
Research and development	11,475	11,347	36,237	35,359
General and administrative	3,173	3,134	10,028	9,997
Total costs and expenses	14,648	14,481	46,265	45,356
Loss from operations	(6,378)	(8,045)	(24,564)	(27,444)
Interest income	47	174	574	841
Interest expense	(12)	(169)	(267)	(505)
Other income (expense)	(51)	352	(666)	1,240
Net loss before taxes	(6,394)	(7,688)	(24,923)	(25,868)
Income tax benefit (provision)		(400)	550	(400)
Net loss	$ (6,394)	$ (8,088)	$ (24,373)	$ (26,268)
Basic and diluted net loss per share:				
Net loss per share	$ (0.14)	$ (0.18)	$ (0.55)	$ (0.60)
Weighted average basic and diluted common shares outstanding	44,570	44,322	44,498	44,126

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

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ARQULE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	NINE MONTHS ENDED September 30,	
	2010	2009
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	$ (24,373)	$ (26,268)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	1,088	1,289
Amortization of premium/discount on marketable securities	809	589
Amortization of deferred gain on sale leaseback	(415)	(415)
Non-cash stock compensation	2,655	2,761
Loss (gain) on auction rate securities put option	5,074	(2,019)
Loss (gain) on auction rate securities	(4,408)	779
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,912	(178)
Other assets	(10)	377
Accounts payable and accrued expenses	543	(499)
Restructuring accrual, net of current portion		(78)
Deferred revenue	(12,183)	(5,087)
Net cash used in operating activities	(29,308)	(28,749)
Cash flows from investing activities:		
Purchases of marketable securities	(75,086)	(58,610)
Proceeds from sale or maturity of marketable securities	132,776	13,687
Additions to property and equipment	(264)	(427)
Net cash provided by (used in) investing activities	57,426	(45,350)
Cash flows from financing activities:		
Proceeds from issuance of common stock	473	456
Payment of notes payable	(44,400)	
Net cash provided by (used in) financing activities	(43,927)	456
Net decrease in cash and cash equivalents	(15,809)	(73,643)
Cash and cash equivalents, beginning of period	36,551	141,890
Cash and cash equivalents, end of period	$ 20,742	$ 68,247

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

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ARQULE, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED 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 and engaged in the research and development of innovative cancer therapeutics. Our mission is to produce novel medicines with differentiated mechanisms of action that target the specific biological pathways implicated in a wide range of cancers.

Our lead product is ARQ 197, an orally administered inhibitor of the c-Met receptor tyrosine kinase. ARQ 197 is currently being evaluated as monotherapy and in combination therapy in a clinical development program that includes trials in non-small cell lung cancer (NSCLC), hepatocellular carcinoma, c-Met associated soft tissue sarcomas, pancreatic adenocarcinoma, colorectal cancer and germ cell tumors. We have licensed commercial rights to ARQ 197 for human cancer indications to Daiichi Sankyo Co., Ltd. (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 Co., Ltd. (Kyowa Hakko Kirin).

On June 5, 2010, data from a Phase 2, double-blind, randomized signal generation trial with ARQ 197 in non-small cell lung cancer (NSCLC) were presented at the 2010 Annual Meeting of the American Society of Clinical Oncology (ASCO). Final data from this trial were presented on October 9, 2010 at the annual meeting of the European Society for Medical Oncology (ESMO). We believe the data from this trial provide a clear signal of efficacy with a safety profile showing that ARQ 197 was well tolerated. We and Daiichi Sankyo have decided to move forward with a Phase 3 registration clinical trial of ARQ 197 in NSCLC. In October, 2010, we reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for the design of this trial, which will be conducted by Daiichi Sankyo and is planned for initiation later this year.

Our proprietary pipeline is directed toward molecular targets and biological processes with demonstrated roles in the development of human cancers. The most advanced candidates in this pipeline are ARQ 621, an inhibitor of the Eg5 kinesin motor protein that is in Phase 1 clinical testing, and ARQ 736, a small molecule inhibitor of the RAF kinase that is in pre-clinical development. Our drug design efforts are focused primarily on the ArQule Kinase Inhibitor Platform (AKIP), which we are using to generate compounds designed to inhibit a variety of kinases without competing with adenosine triphosphate (ATP) for binding to the target kinase, as well as other types of kinase inhibitors. With the AKIP technology, we have discovered and optimized a series of small molecule inhibitors of fibroblast growth factor receptor that are in pre-clinical development.

We have prepared the accompanying condensed consolidated 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. The December 31, 2009 condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States. These condensed consolidated financial statements should be read in conjunction with our audited financial statements and footnotes related thereto for the year ended December 31, 2009 included in our annual report on Form 10-K filed with the SEC on March 2, 2010.

The interim financial data as of September 30, 2010 and for the nine months ended September 30, 2010 and September 30, 2009 is unaudited; in the opinion of management, the interim data includes all adjustments, consisting only of normal recurring adjustments, necessary to a fair statement of the results for the interim periods.

2. COLLABORATIONS AND ALLIANCES

Daiichi Sankyo Kinase Inhibitor Discovery Agreement

On November 7, 2008, we entered into a research collaboration, exclusive license and co-commercialization agreement with Daiichi Sankyo under which we are applying our proprietary technology and know-how using our AKIP technology for the discovery of therapeutic compounds that selectively inhibit certain kinases in the field of oncology. The agreement defines two such kinase targets, and Daiichi Sankyo will have an option to license compounds directed to these targets following the completion of certain pre-clinical studies. The agreement provides for a $15 million upfront payment, which we received in November 2008, research support payments for the first and second years of the collaboration, 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

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compounds from the collaboration. We retain the option to co-commercialize licensed products developed under this agreement in the U.S. In May 2009, we entered into an agreement with Daiichi Sankyo related to potential future milestones and royalties for our AKIP collaboration, under which we could receive up to $265 million in potential development and sales milestone payments for each product selected for clinical development. Upon commercialization of a licensed product, we would also receive tiered, double-digit royalties on its net sales.

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 Daiichi Sankyo, the agreement terminates on the later of (i) the expiration of the research collaboration period, or (ii) various periods specified in the agreement for development and commercialization of products. If Daiichi Sankyo has commercialized a licensed product or products, the agreement will continue in force until 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 with an estimated performance period through November 2012. For the three and nine months ended September 30, 2010, $2.7 million and $8.0 million, respectively were recognized as revenue. For the three and nine months ended September 30, 2009, $1.9 million and $5.0 million, respectively were recognized as revenue. At September 30, 2010, $17.5 million remains in deferred revenue.

On October 12, 2010, we and Daiichi Sankyo announced the expansion of this agreement, establishing a third target, with an option for a fourth, in oncology, and including a two-year extension.

Daiichi Sankyo ARQ 197 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 market launch of ARQ 197 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. 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. Upon commercialization, we will receive tiered, double-digit royalties from Daiichi Sankyo on net sales of ARQ 197 commensurate with the magnitude of the transaction. We retain the option to participate in the commercialization of ARQ 197 in the U.S.

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 with an estimated development period through December 2013. For the three and nine months ended September 30, 2010, $2.7 million and $8.9 million, respectively were recognized as revenue. For the three and nine months ended September 30, 2009, $3.5 million and $9.8 million, respectively were recognized as revenue. At September 30, 2010, $44.5 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 ARQ 197, a small molecule, selective inhibitor of the c-Met receptor tyrosine kinase, 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 ARQ 197. Kyowa Hakko Kirin

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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 ARQ 197 by Kyowa Hakko Kirin in gastric cancer, which triggered a $5 million milestone payment to us from Kyowa Hakko Kirin. This milestone payment was received in September 2010. We determined that the milestone is not considered substantive under FASB guidance related to multiple element arrangements. Accordingly, 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. For the three and nine months ended September 30, 2010, $1.9 million was recognized as revenue from the milestone.

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 September 30, 2010, 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 nine months ended September 30, 2010, $2.9 million and $4.8 million, respectively, were recognized as revenue. For the three and nine months ended September 30, 2009, $1.0 million and $3.1 million, respectively, were recognized as revenue. At September 30, 2010, $24.7 million remains in deferred revenue.

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 consolidated 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. Certain of our marketable 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.

Investments are considered to be impaired when a decline in fair value below cost basis is determined to be other-than-temporary. We evaluate whether a decline in fair value below cost basis is other-than-temporary using available evidence regarding our investments. 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. Once a decline in fair value is determined to be other-than-temporary, a write-down is recorded in the consolidated statements of operations and a new cost basis in the security is established.

We invest our available cash primarily in U.S. Treasury bill funds, money market funds, commercial paper fully guaranteed by the FDIC under the Temporary Liquidity Guarantee Program, 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.

ArQule s marketable securities portfolio included $59.5 million (at cost) at December 31, 2009 and $2.6 million (at cost) at September 30, 2010, invested in auction rate securities. Beginning in the first quarter of 2008 and through the third quarter of 2010,

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certain auction rate securities failed at auction due to sell orders exceeding buy orders. On November 3, 2008, the Company received a put option from UBS AG to repurchase auction rate securities owned by the Company at par value at any time during the period from June 30, 2010 through July 2, 2012 (the Put Option). The Company accounted for the Put Option as a freestanding financial instrument and elected to record the value under the fair value option for financial assets and financial liabilities.

During the three and nine months ended September 30, 2010, $22.9 million and $56.6 million, respectively, in auction rate securities were redeemed at par value by UBS AG. On June 30, 2010, the company exercised the Put Option, and in July 2010, UBS AG redeemed at par value all $22.9 million of the Company s auction rate securities held by UBS AG that were outstanding at June 30, 2010. In July 2010, the Company used a portion of these proceeds to retire the remaining $14.5 million of notes payable outstanding at June 30, 2010 under its revolving credit line agreement with UBS AG. On July 2, 2010, the credit line at UBS AG was cancelled.

The following is a summary of the fair value of available-for-sale marketable securities we held at September 30, 2010 and December 31, 2009.

September 30, 2010	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Security type				
U.S. Federal Treasury and U.S. government agencies securities	$ 23,468	$ 4	$ (2)	$ 23,470
Corporate debt securities-short term	42,052	33	(16)	42,069
Total available-for-sale marketable securities	$ 65,520	$ 37	$ (18)	$ 65,539

December 31, 2009	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Security type				
U.S. Federal Treasury and U.S. government agencies securities	$ 42,034	$ 26	$ (2)	$ 42,058
Corporate debt securities-short term	18,770	14	(1)	18,783
	60,804	40	(3)	60,841
Corporate debt securities-long term	6,236	23	(5)	6,254
Total available-for-sale marketable securities	$ 67,040	$ 63	$ (8)	$ 67,095

The following is a summary of the fair value of trading securities we held at September 30, 2010 and December 31, 2009:

September 30, 2010	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Security type				
Auction rate securities	$ 2,600	$	$ (400)	$ 2,200
Total trading securities	$ 2,600	$	$ (400)	$ 2,200

December 31, 2009	**Amortized Cost**	**Gross Unrealized**	**Gross Unrealized**	**Fair Value**

			Gains	Losses	
Security type					
Auction rate securities	$	59,579	$	$ (4,808)	$ 54,771
Auction rate put option			5,074		5,074
Total trading securities	$	59,579	$ 5,074	$ (4,808)	$ 59,845

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

At September 30, 2010, the Company s auction rate securities are included in marketable securities-long term and total $2.2 million. At December 31, 2009, the Company s marketable securities-short term include auction rate securities and auction rate put option totaling $57.2 million and marketable securities-long term include auction rate securities of $2.6 million. The auction rate securities and put option were classified as trading securities and accordingly gains and losses were recorded as other income (expense) in the statement of operations. The net decrease in value of our auction rate securities totaling $0.1 million in the three

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months ended September 30, 2010 and the net decrease in value of our Put Option and auction rate securities totaling $0.7 million in the nine months ended September 30, 2010 was recorded as a loss in other income (expense) in the statement of operations.

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:

	September 30, 2010	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 17,013	$ 17,013	$	$
U.S. Federal Treasury and U.S. government agencies securities	23,470		23,470	
Corporate debt securities	42,069		42,069	
Auction rate securities	2,200			2,200
Total	$ 84,752	$ 17,013	$ 65,539	$ 2,200

	December 31, 2009	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 35,044	$ 35,044	$	$
U.S. Federal Treasury and U.S. government agencies securities	42,058		42,058	
Corporate debt securities	25,037		25,037	
Auction rate securities and put option	59,845			59,845
Total	$ 161,984	$ 35,044	$ 67,095	$ 59,845

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.

Due to the lack of market quotes relating to our Put Option, the fair value measurements for our Put Option have been estimated using a valuation approach commonly used for forward contracts in which one party agrees to sell a financial instrument (generating cash flows) to another party at a particular time for a predetermined price, which is based on Level 3 inputs. In this approach the present value of all expected future cash flows is subtracted from the current fair value of the security, and the resulting value is calculated as a future value at an interest rate reflective of counterparty risk. The assumptions used are subject to volatility and may change as the underlying sources of these assumptions and

markets conditions change. On June 30, 2010, the company exercised the Put Option and in July 2010, UBS AG redeemed at par value all $22.9 million of the Company s auction rate securities held by UBS AG that were outstanding at June 30, 2010.

The following tables roll forward the fair value of our auction rate securities and put option, whose fair values are determined by Level 3 inputs for the periods presented:

		Amount ($ in millions)
Balance at December 31, 2009	$	59.8
Loss on auction rate securities and put option		(0.7)
Settlements		(56.9)
Balance at September 30, 2010	$	2.2

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	Amount ($ in millions)
Balance at June 30, 2010	$ 25.3
Loss on auction rate securities and put option	(0.1)
Settlements	(23.0)
Balance at September 30, 2010	$ 2.2

	Amount ($ in millions)
Balance at December 31, 2008	$ 64.2
Gain on auction rate securities and put option	1.2
Settlements	(1.5)
Balance at September 30, 2009	$ 63.9

	Amount ($ in millions)
Balance at June 30, 2009	$ 64.7
Gain on auction rate securities and put option	0.4
Settlements	(1.2)
Balance at September 30, 2009	$ 63.9

4. COMPREHENSIVE LOSS

Comprehensive loss is comprised of net loss and other comprehensive gain (loss). Other comprehensive gain (loss) includes unrealized gains (losses) on our available-for-sale securities that are excluded from net loss. Total comprehensive loss for the three and nine months ended September 30, 2010 and 2009 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net loss	$ (6,394)	$ (8,088)	$ (24,373)	$ (26,268)
Unrealized gain (loss) on marketable securities		11	(36)	66
Comprehensive loss	$ (6,394)	$ (8,077)	$ (24,409)	$ (26,202)

5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses include the following at September 30, 2010 and December 31, 2009:

	September 30, 2010	December 31, 2009
Accounts payable	$ 308	$ 277
Accrued payroll	2,457	2,709

Accrued outsourced pre-clinical and clinical fees		8,912		8,019
Accrued professional fees		481		552
Other accrued expenses		745		803
	$	12,903	$	12,360

6. 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 6,302,452 and 5,279,389 at September 30, 2010 and 2009, respectively.

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7. 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 nine months ended September 30, 2010 and 2009.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development	$ 307	$ 348	$ 971	$ 1,102
General and administrative	442	419	1,684	1,659
Total stock-based compensation expense	$ 749	$ 767	$ 2,655	$ 2,761

In the three and nine months ended September 30, 2010 and 2009, 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 nine months ended September 30, 2010 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2009	5,215,189	$ 6.04
Granted	1,455,650	3.66
Exercised	(60,148)	3.14
Cancelled	(308,239)	10.25
Outstanding as of September 30, 2010	6,302,452	$ 5.31
Exercisable as of September 30, 2010	4,013,424	$ 6.07

The aggregate intrinsic value of options outstanding at September 30, 2010 was $4,319 of which $1,304 related to exercisable options. The weighted average fair value of options granted in the nine months ended September 30, 2010 and 2009 was $2.20 and $2.29 per share, respectively. The intrinsic value of options exercised in the nine months ended September 30, 2010 and 2009 was $178 and $53, respectively.

The total compensation cost not yet recognized as of September 30, 2010 related to non-vested option awards was $4.3 million, which will be recognized over a weighted-average period of 2.9 years. During the nine months ended September 30, 2010, there were 13,375 shares forfeited with a weighted average grant date fair value of $2.12 per share. The weighted average remaining contractual life for options exercisable at September 30, 2010 was 5.0 years.

In January 2009 and 2008, we granted 412,200 and 103,316 shares, respectively, of restricted stock to employees, vesting annually over a four year period. Through September 30, 2010, 40,358 shares were forfeited, and 140,944 shares have vested. The shares of restricted stock were issued at no cost to the recipients. The fair value of the restricted stock at the time of grant in January 2009 and 2008 was $3.54 and $4.75, respectively, per share, and is being expensed ratably over the vesting period. We recognized share-based compensation expense related to restricted stock of $318 and $334 for the nine months ended September 30, 2010 and 2009, respectively.

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

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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.

Recently Issued Accounting Standards

In October 2009, the FASB issued an accounting standards update (ASU) on Multiple-Deliverable Revenue Arrangements. This standards update amends existing revenue recognition accounting pronouncements and provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately. Revenue from our existing multiple-deliverable arrangements is recognized over the estimated development period using the contingency adjusted performance model. Under the new approach, revenue for new contracts will be recognized based upon the estimated selling price of each element in the arrangement. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which for ArQule means no later than January 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011, will require us to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships.

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition Milestone Method*. This ASU provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. Under the milestone method of revenue recognition, consideration that is contingent upon achievement of a milestone in its entirety can be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. This standard provides the criteria to be met for a milestone to be considered substantive which includes that: a) performance consideration earned by achieving the milestone be commensurate with either performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from performance to achieve the milestone; and b) relate to past performance and be reasonable relative to all deliverables and payment terms in the arrangement. This standard is effective on a prospective basis for milestones in fiscal years beginning on or after June 15, 2010. We are still evaluating the impact of this standard. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships.

9. INCOME TAXES

The Company recorded a $0.6 million income tax benefit in the nine months ended September 30, 2010 attributable to an election it made in the second quarter of 2010 under recent legislation that allowed net operating losses to offset 100% of alternative minimum tax (AMT). Prior to this legislation, only 90% of AMT could be offset by net operating losses. The Company received a refund in July 2010 of the $0.6 million AMT paid in 2009.

We adopted the authoritative guidance on accounting for uncertainty in income taxes on January 1, 2007. As a result, we recorded no adjustment for unrecognized income tax benefits. At the adoption date of January 1, 2007 and at December 31, 2008 and 2009, 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. We recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2009, we had no accrued interest or penalties related to uncertain tax positions. The tax years 2005 through 2009 remain open to examination by the major taxing jurisdictions to which we are subject, which is primarily the U.S. 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 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 tax, and may, in turn, result in the expiration of a portion of those carryforwards before utilization. In general, an ownership change, as defined by

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Section 382, results from transactions that increase the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three year period. We recently undertook a detailed study of our NOL and research and development credit carryforwards in the fourth quarter of 2009 to determine whether such amounts are likely to be limited by Section 382. As a result of this analysis, we currently do not believe Sections 382 s 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

On July 8, 2008, we entered into a collateralized, revolving credit line agreement for up to $47.5 million with UBS Bank USA, secured by a first priority lien and security interest in the auction rate securities held by us in an account with UBS Financial Services Inc., an affiliate of UBS Bank USA. During 2009 and through the first six months of 2010 certain of our auction rate securities were redeemed, and the note payable balance under the Facility was reduced to $44.4 million at December 31, 2009 and $14.5 million at June 30, 2010. On June 30, 2010, the company exercised the Put Option, and in July 2010, UBS AG redeemed at par value all $22.9 million of the Company s remaining auction rate securities held by UBS AG. In July 2010, the Company used a portion of these proceeds to retire the remaining $14.5 million of notes payable that were outstanding at June 30, 2010 under its revolving credit line agreement with UBS AG. On July 2, 2010, the credit line at UBS AG was cancelled.

In October 2008, we entered into a margin loan agreement with another 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 September 30, 2010 and is collateralized by $2.6 million of auction rate securities.

Interest expense under our loan agreements totaled $12 and $267 for the three and nine months ended September 30, 2010, respectively. Interest expense under our loan agreements totaled $169 and $505 for the three and nine months ended September 30, 2009, respectively.

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

OVERVIEW

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

Our products 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 and designed to act specifically against cancer cells. 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 lead product is ARQ 197, a non-adenosine triphosphate (ATP) - competitive inhibitor of the c-Met receptor tyrosine kinase (c-Met). C-Met is a promising target for cancer therapy, as evidence suggests that it plays a key role in cancerous cell proliferation, tumor spread, new blood vessel formation and drug resistance. Our ongoing clinical development program with ARQ 197 encompasses six tumor types, including non-small cell lung cancer, hepatocellular carcinoma, c-Met-associated soft tissue sarcomas, pancreatic adenocarcinoma, colorectal cancer and germ cell tumors. We believe the trials within the Phase 2 program for ARQ 197 offer the potential for proof-of-principle data that can be generated in one or more indications beginning in 2010 through 2011.

On June 5, 2010, data from a Phase 2, double-blind, randomized signal generation trial with ARQ 197 in non-small cell lung cancer (NSCLC) were presented at the 2010 Annual Meeting of the American Society of Clinical Oncology (ASCO). Key findings included consistent improvements in overall survival and progression-free survival among patients who received the combination of ARQ 197 and erlotinib compared to those who received placebo and erlotinib. These improvements were particularly evident and reached statistical significance in patients with non-squamous histology when adjusting for randomization imbalances in key prognostic factors. Final data from this trial were presented on October 9, 2010 at the annual meeting of the European Society for Medical Oncology (ESMO). We believe these data provide a clear signal of efficacy with a safety profile showing that ARQ 197 was well tolerated.

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One hundred sixty-seven patients participated in the Phase 2 trial. All patients were epidermal growth factor receptor (EGFR) inhibitor-naïve, but had progressed after at least one prior chemotherapy regimen. Patients were randomized one-to-one to receive either the combination of ARQ 197 plus erlotinib or placebo plus erlotinib in second and third line settings. The primary endpoint of the study was comparison of progression-free survival between treatment arms; secondary endpoints included progression-free survival in pre-defined patient subsets, overall survival, overall response rate, and safety. Erlotinib, marketed as Tarceva , is an inhibitor of the EGFR tyrosine kinase.

In the pre-defined sub-group of patients with non-squamous cell carcinoma histology (n = 117), median overall survival was 43.1 weeks in the treatment arm, compared with 29.4 weeks in the placebo arm, an improvement of 47 percent (unadjusted hazard ratio = 0.72, p = 0.19). Based on an exploratory Cox regression analysis, the difference in median overall survival achieved statistical significance ($p < 0.05$) in this sub-group when adjusting for imbalances in key prognostic factors that favored the placebo arm.

The ARQ 197 plus erlotinib combination also demonstrated a 66 percent improvement in the primary endpoint of this trial, median progression-free survival, although the difference in progression-free survival between the two arms did not achieve statistical significance (p = 0.24, hazard ratio = 0.81) by applying a log-rank test. Improvement in median progression-free survival was more pronounced in the pre-defined sub-group of patients with non-squamous histology (n = 117).

There were no clinically relevant differences in adverse event rates between the treatment and control arms. The majority of adverse events were mild in intensity and included rash, diarrhea and fatigue.

Exploratory data analyses related to the anti-metastatic effect of ARQ 197 were also presented at ESMO and showed that patients treated with ARQ 197 plus erlotinib had a median time to develop new metastases of 7.3 months, compared to 3.6 months for patients treated with erlotinib plus placebo. This effect was more pronounced among patients with non-squamous cell histology, among whom the median time to develop new metastases was 11.0 months for patients treated with ARQ 197 plus erlotinib, compared with 3.6 months for those treated with erlotinib plus placebo. The ESMO meeting also included an initial presentation of data from a randomized Phase 2 trial comparing the combination treatment of a monoclonal antibody specific for c-Met and erlotinib to placebo and erlotinib in patients with NSCLC. We believe that these and other data on c-Met inhibition reflect what is an evolving understanding of the biology of this target. We continue to investigate and expand our understanding of the profile of ARQ 197. As part of these efforts we have incorporated into the ARQ 197 Phase 3 Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) a broad genotyping and biomarker program.

Following a comprehensive review of these data, discussions with key opinion leaders world wide, and an end-of-Phase 2 meeting with the FDA, we and Daiichi Sankyo decided to move forward with a Phase 3 registration clinical trial of ARQ 197 in NSCLC. In October, 2010, we reached agreement with the FDA on an SPA for the design of this trial, which will be conducted by Daiichi Sankyo and is planned for initiation later this year.

The Phase 3 trial will be a randomized, double-blinded study of erlotinib plus ARQ 197 in patients with locally advanced or metatstatic NSCLC of non-squamous histology. The primary endpoint is overall survival in the intent-to-treat population. Key secondary objectives include overall survival in the epidermal growth factor receptor wild-type sub-population and progression-free survival in the intent-to-treat population.

We have licensed commercial rights to ARQ 197 for human cancer indications to Daiichi Sankyo Co., Ltd. (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 Co., Ltd. (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.

Our proprietary pipeline is directed toward molecular targets and biological processes with demonstrated roles in the development of human cancers. The most advanced candidate in this pipeline is ARQ 621, an inhibitor of the Eg5 kinesin motor protein that is in Phase 1 clinical testing. We are also pursuing pre-clinical development of ARQ 736, a small molecule inhibitor of the RAF kinase.

Our drug design efforts are focused primarily on AKIP , 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 involved in a variety of physiological processes. We have assessed AKIP s potential to target multiple kinases in oncology and other therapeutic areas, and we are generating and validating compounds that inhibit these kinase targets. With the AKIP technology, we have discovered and optimized a series of small molecule inhibitors of fibroblast growth factor receptor that are in pre-clinical development, with the potential submission of an IND for a lead product candidate in 2011. We are also pursuing a drug discovery collaboration with Daiichi Sankyo that utilizes the capabilities of the AKIP technology to discover compounds that inhibit two kinase targets in the field of oncology.

We have incurred a cumulative deficit of $393.0 million from inception through September 30, 2010. We expect research and development costs to increase during the course of 2010, due to clinical testing of our lead product candidates. We recorded a net loss for 2007, 2008, 2009 and expect a net loss for 2010.

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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 ARQ 197 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. 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. Upon commercialization, we will receive tiered, double-digit royalties from Daiichi Sankyo on net sales of ARQ 197 commensurate with the magnitude of the transaction. We retain the option to participate in the commercialization of ARQ 197 in the U.S. Revenue for this agreement is recognized using the contingency-adjusted performance model with an estimated development period through December 2013.

On November 7, 2008, we entered into a research collaboration, exclusive license and co-commercialization agreement with Daiichi Sankyo under which we are applying our proprietary know-how from our AKIP technology for the discovery of therapeutic compounds that selectively inhibit certain kinases in the field of oncology. The agreement defines two such kinase targets, and Daiichi Sankyo will have an option to license compounds directed to these targets following the completion of certain pre-clinical studies. 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, 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. In May 2009, we entered into an agreement with Daiichi Sankyo related to potential future milestones and royalties for our AKIP collaboration, under which we could receive up to $265 million in potential development and sales milestone payments for each product selected for clinical development. Upon commercialization of a licensed product, we would also receive tiered, double-digit royalties on its net sales. On October 12, 2010, we and Daiichi Sankyo announced the expansion of this agreement, establishing a third target, with an option for a fourth, in oncology, and including a two-year extension. We retain the option to co-commercialize licensed products developed under this agreement in the U.S. Revenue for this agreement is recognized using the contingency-adjusted performance model with an estimated performance period through November 2012.

On April 27, 2007, we entered into an exclusive license agreement with Kyowa Hakko Kirin to develop and commercialize ARQ 197, a small molecule, selective inhibitor of the c-Met receptor tyrosine kinase, 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. In July 2010, we announced the initiation of a Phase 2 trial with ARQ 197 by Kyowa Hakko Kirin in gastric cancer, which triggered a $5 million milestone payment to us from Kyowa Hakko Kirin. This milestone payment was received in September 2010.

Upon commercialization, ArQule will receive tiered royalties in the mid-teen to low-twenty percent range from Kyowa Hakko Kirin on net sales of ARQ 197. 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 September 30, 2010, 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

	September 30, 2010	December 31, 2009	Increase (decrease) $	%
		(in millions)		
Cash, cash equivalents and marketable securities-short term	$ 86.3	$ 154.7	$ (68.4)	(44)%
Marketable securities-long term	2.2	8.8	(6.6)	(75)%
Notes payable	1.7	46.1	(44.4)	(96)%
Working capital	45.1	73.6	(28.5)	(39)%

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	Nine Months Ended		
	September 30, 2010	September 30, 2009	Increase (decrease)
	(in millions)		
Cash flow from:			
Operating activities	$ (29.3)	$ (28.7)	$ (0.6)
Investing activities	57.4	(45.4)	102.8
Financing activities	(43.9)	0.5	(44.4)

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 from our collaborators for services performed or upfront payments for future services. For the nine months ended September 30, 2010, 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 $29.3 million.

Cash flow from investing activities. Our net cash provided by investing activities of $57.4 million for the nine months ended September 30, 2010, was comprised of net sales of marketable securities. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of the Company s constant evaluation of conditions in financial markets, the maturity of specific investments, and our near term liquidity needs.

Our cash equivalents and marketable securities include U.S. Treasury bill funds, money market funds, commercial paper fully guaranteed by the FDIC under the Temporary Liquidity Guarantee Program, 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 included $59.5 million (at cost) at December 31, 2009 and $2.6 million (at cost) at September 30, 2010, invested in auction rate securities. Beginning in the first quarter of 2008 and through the third quarter of 2010, certain auction rate securities failed at auction due to sell orders exceeding buy orders. On November 3, 2008, the Company received a put option from UBS AG to repurchase auction rate securities owned by the Company at par value at any time during the period from June 30, 2010 through July 2, 2012 (the Put Option). The Company accounted for the Put Option as a freestanding financial instrument and elected to record the value under the fair value option for financial assets and financial liabilities.

During the three and nine months ended September 30, 2010 $22.9 million and $56.6 million, respectively, in auction rate securities were redeemed at par value by UBS AG. On June 30, 2010, the company exercised the Put Option, and in July 2010, UBS AG redeemed at par value all $22.9 million of the Company s remaining auction rate securities held by UBS AG. In July 2010, the Company used a portion of these proceeds to retire the remaining $14.5 million of notes payable that were outstanding at June 30, 2010 under its revolving credit line agreement with UBS AG. On July 2, 2010, the credit line at UBS AG was cancelled.

Cash used from financing activities. Our net cash used by financing activities of $43.9 million in the nine months ended September 30, 2010 was due to $44.4 million of payments on our notes payable, partially offset by proceeds from issuance of common stock of $0.5 million.

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.

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In light of our collaboration agreements and certain anticipated milestone and cost-sharing provisions, we expect that our available cash and cash equivalents will be sufficient to finance our working capital and capital requirements through at least the end of 2011.

Our contractual obligations were comprised of the following as of September 30, 2010:

	Payment due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Notes payable	$ 1,700	$ 1,700	$	$	$
Operating lease obligations	15,279	3,498	6,759	5,022	
Purchase obligations	9,013	9,013			
Total	$ 25,992	$ 14,211	$ 6,759	$ 5,022	$

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.

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 Consolidated Financial Statements included in our Annual Report for the fiscal year ended December 31, 2009 on Form 10-K filed with the SEC on March 2, 2010.

RESULTS OF OPERATIONS

The following are the results of operations for the three and nine months ended September 30, 2010 and 2009:

Revenue

			Increase (decrease)	
	2010	**2009**	**$**	**%**
	(in millions)			
For the three months ended September 30:				
Research and development revenue	$ 8.3	$ 6.4	$ 1.9	28%

For the nine months ended September 30:						
Research and development revenue	$	21.7	$	17.9	$	3.8	21%

Research and development revenue in the three and nine months ended September 30, 2010, is comprised of revenue from the Daiichi Sankyo development and research collaborations agreements and the Kyowa Hakko Kirin exclusive license agreement. The increase in the three month period is primarily due to $1.9 million of revenue recognized from the $5.0 million milestone received from Kyowa Hakko Kirin in September 2010. The increase in the nine month period is due to $1.9 million of revenue recognized from the $5.0 million milestone received from Kyowa Hakko Kirin in September 2010, and an increase of $1.9 million from Daiichi Sankyo.

Research and development

					Increase (decrease)	
	2010		**2009**		**$**	**%**
	(in millions)					
For the three months ended September 30:						
Research and development	$	11.5	$	11.3	$	0.2	1%
For the nine months ended September 30:						
Research and development	$	36.2	$	35.4	$	0.8	2%

Research and development expense in the third quarter of 2010 increased slightly from the comparable period of 2009. Research and development expense in the first nine months of 2010 increased by $0.8 million primarily due to an increase in clinical

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and preclinical costs. At September 30, 2010 we had 83 employees dedicated to our research and development program compared to 82 employees at September 30, 2009.

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	Nine Months Ended September 30, 2010	Program-to-date
c-Met program ARQ 197	Phase 2 completed, Pre-Phase 3	$ 9.7	$ 62.8

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, but 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 these types of products to each 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 are not substantially dependent on any one product. To the extent we are unable to build and maintain a broad pipeline of products, our dependence on the success of one or a few products increases.

Our strategy includes entering into alliance arrangements with third parties to participate in the development and commercialization of our products, such as our collaboration agreements with Daiichi and Kyowa Hakko Kirin. In the event that third parties have control over the clinical trial process for a product, the estimated completion date would be under control of that third

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party rather than under our control. We cannot forecast with any degree of certainty whether our products will be subject to future collaborative arrangements or how such arrangements would affect our development plans or capital requirements.

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

General and administrative

	2010	2009	Increase (decrease) $	Increase (decrease) %
	(in millions)			
For the three months ended September 30:				
General and administrative	$ 3.1	$ 3.1	$	
For the nine months ended September 30:				
General and administrative	$ 10.0	$ 10.0	$	

General and administrative expense for the third quarter and first nine months of 2010 was equivalent to the comparable 2009 periods. General and administrative headcount was 29 at September 30, 2010, compared to 30 at September 30, 2009.

Interest income, interest expense and other income (expense)

	2010	2009	Increase (decrease) $	Increase (decrease) %
	(in millions)			
For the three months ended September 30:				
Interest income	$	$ 0.2	$ (0.2)	(73)%
Interest expense		(0.2)	(0.2)	(93)%
Other income (expense)	(0.1)	0.4	(0.5)	(114)%
For the nine months ended September 30:				
Interest income	$ 0.6	$ 0.8	$ (0.2)	(32)%
Interest expense	(0.3)	(0.5)	(0.2)	(47)%
Other income (expense)	(0.7)	1.2	(1.9)	(154)%

Interest income is comprised primarily of interest income derived from our portfolio of cash, cash equivalents and investments. Interest expense was incurred on our notes payable and decreased in the third quarter of 2010 due to a lower outstanding loan balance. Other income (expense) in the three months ended September 30, 2010 includes a $0.1 million loss from the decrease in fair value of our auction rate securities. Other

income (expense) in the nine months ended September 30, 2010 includes a $0.7 million loss from the decrease in fair value of our auction rate securities and Put Option.

Income tax benefit

The Company recorded a $0.6 million income tax benefit in the nine months ended September 30, 2010 attributable to an election it made in the second quarter of 2010 under legislation that allowed net operating losses to offset 100% of alternative minimum tax (AMT). Prior to this legislation, only 90% of AMT could be offset by net operating losses. The Company received a refund in July 2010 of the $0.6 million AMT paid in 2009.

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.

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Recently Issued Accounting Standards

In October 2009, the FASB issued an accounting standards update (ASU) on, Multiple-Deliverable Revenue Arrangements. This standards update amends existing revenue recognition accounting pronouncements and provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately. Revenue from our existing multiple-deliverable arrangements is recognized over the estimated development period using the contingency adjusted performance model. Under the new approach, revenue for new contracts will be recognized based upon the estimated selling price of each element in the arrangement. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which for ArQule means no later than January 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011, will require us to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships.

In April 2010, the FASB issued ASU No. 2010-17, Revenue Recognition Milestone Method. This ASU provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. Under the milestone method of revenue recognition, consideration that is contingent upon achievement of a milestone in its entirety can be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. This standard provides the criteria to be met for a milestone to be considered substantive which includes that: a) performance consideration earned by achieving the milestone be commensurate with either performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from performance to achieve the milestone; and b) relate to past performance and be reasonable relative to all deliverables and payment terms in the arrangement. This standard is effective on a prospective basis for milestones in fiscal years beginning on or after June 15, 2010. We are still evaluating the impact of this standard. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships.

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 o similar meaning. You also can identify them by the fact that they do not relate strictly to historical or current facts. All statements which address operating performance, events or developments that the Company expects or anticipates will occur in the future, such as projections about its future results of operations, its financial condition, research, development and commercialization of its products and anticipated trends in its business are forward-looking statements.

In this report we make forward-looking statements regarding our drug development pipeline and our clinical trials involving ARQ 197. Additional forward-looking statements relate to our agreements with Kyowa Hakko Kirin and Daiichi Sankyo, including potential future milestones and royalty payments, and the timing and level of expenses that could result from the future development of ARQ 197.

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.

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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, 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, 2009 filed with the SEC on March 2, 2010, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The forward-looking statements contained herein represent the judgment of the Company as of the date of this report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Our cash and marketable securities include US Treasury bill funds, money market funds, and U.S. federal and state agency backed certificates, including auction rate securities that have strong credit ratings.

Our cash equivalents and our portfolio of marketable securities are subject to market risk due to changes in interest rates. Fixed rate interest securities may have their market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates.

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 September 30, 2010. 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 September 30, 2010, 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.

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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, 2009 filed with the SEC on March 2, 2010, 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. (REMOVED AND RESERVED) None.

ITEM 5. OTHER INFORMATION None.

ITEM 6. EXHIBITS.

EXHIBIT NO.	DESCRIPTION
10.1+	Amendment No. 1 to Collaborative Research, Development and License Agreement, dated October 8, 2010, by and between ArQule, Inc. and Daiichi Sankyo Co., Ltd., filed herewith.
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.

+ Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended or Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

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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: November 9, 2010

/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)