

ARQULE INC  
Form 10-Q  
November 06, 2007

## 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, 2007

Commission File No. 000-21429

**ArQule, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State of Incorporation)

**04-3221586**  
(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 ☒ No ☐

Indicate by check mark whether the registrant is large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check One)

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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

Number of shares outstanding of the registrant's Common Stock as of October 31, 2007:

Common Stock, par value \$.01

43,710,379 shares outstanding





**ARQULE, INC.**

**QUARTER ENDED SEPTEMBER 30, 2007**

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**ARQULE, INC.**



**CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)**

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	September 30, 2007	December 31, 2006
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)		
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,213	\$ 6,242
Marketable securities	134,279	89,590
Prepaid expenses and other current assets	1,684	2,162
Total current assets	145,176	97,994
Property and equipment, net	4,021	4,549
Other assets	1,845	2,277
Total assets	\$ 151,042	\$ 104,820
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,371	\$ 10,276
Current portion of deferred revenue	9,942	6,609
Current portion of deferred gain on sale leaseback	552	552
Total current liabilities	19,865	17,437
Restructuring accrual, net of current portion	895	1,366
Deferred revenue, net of current portion	26,011	1,967
Deferred gain on sale leaseback, net of current portion	3,682	4,096
Total liabilities	50,453	24,866
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; 43,693,211 and 35,811,709 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	437	358
Additional paid-in capital	367,374	307,965
Accumulated other comprehensive loss	(22)	(152)
Accumulated deficit	(267,200)	(228,217)
Total stockholders' equity	100,589	79,954
Total liabilities and stockholders' equity	\$ 151,042	\$ 104,820

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









**ARQULE, INC.**

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Research and development revenue	\$ 2,736	\$ 1,652	\$ 6,623	\$ 4,956
Costs and expenses:				
Research and development	12,529	14,944	39,310	35,007
General and administrative	3,356	3,355	10,662	8,336
Total costs and expenses	15,885	18,299	49,972	43,343
Loss from continuing operations	(13,149)	(16,647)	(43,349)	(38,387)
Net investment income	2,031	1,325	4,366	3,932
Net loss from continuing operations	(11,118)	(15,322)	(38,983)	(34,455)
Income from discontinued operations				15,845
Net loss	\$ (11,118)	\$ (15,322)	\$ (38,983)	\$ (18,610)
Basic and diluted income (loss) per share:				
Net loss from continuing operations	\$ (0.26)	\$ (0.43)	\$ (1.00)	\$ (0.97)
Income from discontinued operations				0.45
Net loss per share	\$ (0.26)	\$ (0.43)	\$ (1.00)	\$ (0.52)
Weighted average basic and diluted common shares outstanding	43,557	35,556	38,793	35,464

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



**ARQULE, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**

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	Nine Months Ended September 30,	
	2007	2006
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	\$ (38,983)	\$ (18,610)
Income from discontinued operations		(15,845)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,316	1,703
Amortization of premium/discount on marketable securities	(35)	130
Amortization of deferred gain on sale leaseback	(414)	(414)
Non-cash stock compensation	3,559	2,540
Loss on disposal of fixed assets	121	4
Changes in operating assets and liabilities:		
Accounts receivable		6
Prepaid expenses and other current assets	478	(532)
Other assets	432	(387)
Accounts payable and accrued expenses	(905)	6,474
Restructuring accrual, net of current portion	(471)	(495)
Deferred revenue	27,377	(1,208)
Net cash used in operating activities from discontinued operations		(6,747)
Net cash used in operating activities	(7,525)	(33,381)
Cash flows from investing activities:		
Purchases of marketable securities	(156,559)	(76,216)
Proceeds from sale or maturity of marketable securities	112,035	112,509
Additions to property and equipment	(909)	(400)
Net cash (used in) provided by investing activities	(45,433)	35,893
Cash flows from financing activities:		
Proceeds from stock offering, net	54,104	
Proceeds from issuance of common stock	1,825	1,520
Net cash provided by financing activities	55,929	1,520
Net increase in cash and cash equivalents	2,971	4,032
Cash and cash equivalents, beginning of period	6,242	4,805
Cash and cash equivalents, end of period	\$ 9,213	\$ 8,837

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

**ARQULE, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)**

**1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION**

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We are a clinical-stage biotechnology company organized as a Delaware Corporation in 1993 and are engaged in the research and development of innovative anti-cancer therapies. Our goal is to introduce novel products that act selectively against cancer cells, target multiple tumor types and are well tolerated by patients.

Our clinical-stage products consist of: ARQ 197, an orally administered inhibitor of the c-Met receptor tyrosine kinase; ARQ 501, an intravenously administered novel activator of the cell's DNA damage response mechanism mediated by the E2F-1 transcription factor; and ARQ 171, an intravenously administered second generation activator of E2F-1.

We retain full worldwide commercial rights to ARQ 197 outside of Japan and other select Asian countries, where we granted commercial rights to Kyowa Hakko Kogyo Co., Ltd. ( Kyowa ) on April 27, 2007. We are developing ARQ 501, ARQ 171 and ARQ 761, a new chemical entity based on ARQ 501, pursuant to our collaboration with Hoffmann-La Roche ( Roche ). Our agreements with Kyowa and Roche each provide for possible future milestone payments, royalties on product sales, and development funding, in addition to upfront payments that we have already received.

As part of our business since inception until 2006, we provided chemistry services to collaborators and customers for their discovery programs. In September 2005, we announced a strategic decision to exit our chemistry services operations in order to focus operationally on developing our oncology portfolio. On December 2, 2005, we received notice that our major collaborator and customer, Pfizer Inc ( Pfizer ), pursuant to the terms of the Collaborative Agreement ( Agreement ) with ArQule, was terminating the Agreement effective on May 22, 2006. We continued to provide chemistry services to Pfizer through this date.

We have prepared the accompanying condensed consolidated financial statements pursuant to the rules and regulations of the 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 consolidated financial statements should be read in conjunction with our audited financial statements and footnotes related thereto for the year ended December 31, 2006 that are included in our annual report on Form 10-K filed with the SEC on March 12, 2007.

The unaudited condensed consolidated financial statements include, in our opinion, all adjustments (consisting only of normal recurring adjustments) necessary to present fairly our financial position as of September 30, 2007, and the results of our operations and cash flows for the three and nine months ended September 30, 2007 and September 30, 2006. The results of operations for such interim periods are not necessarily indicative of the results to be achieved for the full year.

## 2. DISCONTINUED OPERATIONS

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On September 27, 2005, we announced our intention to exit our chemistry services operations. We received notice on December 2, 2005 that Pfizer had elected to terminate the Agreement, pursuant to the Agreement's terms, effective on May 22, 2006. The Agreement provided for six months prior written notice by either party to the other for termination without cause and, in the event of termination by Pfizer, certain payments to us. In accordance with these provisions, we received approximately \$19.8 million in December 2005 in connection with the termination. This amount was recorded as deferred revenue and was recognized as revenue when compounds were delivered through the termination date. We have fulfilled our compound production obligations under the Agreement, and recognized the remaining deferred revenue and ceased chemistry services operations in 2006.

The net book value of the assets associated with the chemistry services operations, which totaled \$1.4 million, approximated the fair market value of the underlying assets. In December 2006, management completed the sale of the chemistry services assets, which consisted of commercially available laboratory instrumentation, for approximately \$1.3 million, net of direct costs to sell such assets.

We considered the chemistry services asset group to be a component of an entity, as defined in Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), since it comprised operations and cash flows that were clearly distinguished, both operationally and for financial reporting purposes, from the remainder of our operations. Pursuant to SFAS 144, we reported the results of the chemistry services component as discontinued operations, since the related cash flows had been eliminated from our ongoing operations and we did not have any significant continuing involvement in the operations of the component or the assets that were disposed.

The following table presents operating results for the discontinued chemical services operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenue	\$	\$	\$	\$ 26,718
Costs and expenses:				
Cost of revenue				8,375
Restructuring charge				2,498
Total costs and expenses				10,873
Income from discontinued operations	\$	\$	\$	\$ 15,845

### 3. KYOWA LICENSING AGREEMENT



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On April 27, 2007, we entered into an exclusive license agreement with Kyowa 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 to ArQule, including the \$30 million cash upfront licensing payments. In addition, the agreement includes sales milestone payments. Upon commercialization, ArQule will receive double-digit royalties from Kyowa on net sales of ARQ 197. Kyowa 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.

Under the Kyowa agreement, the initial license fee and any subsequent milestone payments, once earned, will be recognized as research and development revenue using the contingency-adjusted performance model. Under this model, when payments are earned, revenue is immediately recognized on a pro-rata basis in the period we achieve the milestone based on the time elapsed from inception of the Kyowa agreement to the time the milestone is earned over the estimated duration of the development period under the agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated development period under the agreement. We currently estimate the development period to be through April 2016. This period may ultimately be shorter or longer depending upon the outcome of the development work, resulting in accelerated or deferred recognition of the development revenue. Royalty payments will be recognized as revenue when earned. The cost associated with satisfying the Kyowa contract is included in research and development expense in the Condensed Consolidated Statement of Operations.

For the three and nine months ended September 30, 2007, \$0.8 million and \$1.4 million were recognized as revenue. At September 30, 2007 \$28.6 million remains in deferred revenue.

#### **4. COMPREHENSIVE LOSS**

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Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (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, 2007 and September 30, 2006 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net loss	\$ (11,118)	\$ (15,322)	\$ (38,983)	\$ (18,610)
Unrealized gain on marketable securities	15	275	130	494
Comprehensive loss	\$ (11,103)	\$ (15,047)	\$ (38,853)	\$ (18,116)

**5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

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Accounts payable and accrued expenses include the following at September 30, 2007 and December 31, 2006:

	September 30, 2007		December 31, 2006
Accounts payable	\$ 535	\$	208
Accrued payroll	1,718		1,726
Accrued outsourced pre-clinical and clinical fees	4,773		6,197
Accrued professional fees	640		434
Accrued restructuring-current portion	636		678
Other accrued expenses	1,069		1,033
	\$ 9,371	\$	10,276

### 6. RESTRUCTURING CHARGES

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In 2002, we recorded a restructuring charge associated with abandoning our facility in Redwood City, California, which was comprised of the difference between the remaining lease obligation, which runs through 2010, and our estimate of potential future sublease income. The accrual balance was adjusted in 2003 to reflect a change in estimate due to continued deterioration in the local real estate market. The accrual balance was adjusted again in 2004 as a result of us entering into a sublease for the facility. The remaining facility-related restructuring accrual is primarily comprised of the difference between our lease obligation for this facility, which will be paid out through 2010, and the amount of sublease payments we will receive under our sublease agreement.

On January 19, 2006, our Board of Directors authorized termination benefits for employees in connection with a plan of termination for our chemistry services operations. The termination benefits, which affected 104 employees, consisted of cash payments and continuation of health care benefits. In 2006, a restructuring charge of \$2.5 million was recorded pursuant to this action and is included in the Condensed Consolidated Statement of Operations, for the nine months ended September 30, 2006, as part of Income from discontinued operations. As of December 31, 2006, all affected employees had been separated from the Company and the restructuring costs were fully paid.

Activities against the restructuring accrual in the nine months ended September 30, 2006 and September 30, 2007 were as follows:

	Balance as of December 31, 2005		2006 Provisions		2006 Payments		Balance as of September 30, 2006
Termination benefits-discontinued operations	\$		\$ 2,383	\$	(2,163)	\$	220
Other charges-discontinued operations			115		(107)		8
Facility-related		2,706			(495)		2,211
Total restructuring accrual	\$	2,706	\$ 2,498	\$	(2,765)	\$	2,439

	Balance as of December 31, 2006		2007 Provisions		2007 Payments		Balance as of September 30, 2007
Facility-related	\$	2,044	\$	\$	(513)	\$	1,531

### 7. NET INCOME (LOSS) PER SHARE

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Net loss per share is computed using the weighted average number of common shares outstanding. Basic and diluted net income (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 from continuing operations. In accordance with Statement of Financial Accounting Standards ( SFAS ) No. 128, Earnings Per Share, no potential common shares are included in the computation of any diluted per share amounts, including income (loss) per share from discontinued operations, as the Company reported a net loss from continuing operations for all periods presented. Potential common shares, the shares that would be issued upon the exercise of outstanding stock options, were 4,424,397 and 3,977,222 for the three and nine months ended September 30, 2007 and 2006, respectively.

**8. STOCK-BASED COMPENSATION AND STOCK PLANS**

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Effective January 1, 2006, we adopted the provisions of SFAS No.123(R), *Share-Based Payment* ( SFAS 123 (R) ), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123(R), 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, 2007 and September 30, 2006.

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,	
	2007	2006	2007	2006
Research and development	\$ 378	\$ 437	\$ 1,759	\$ 1,188
General and administrative	770	252	1,800	1,015
Discontinued operations				337
Total stock-based compensation expense	\$ 1,148	\$ 689	\$ 3,559	\$ 2,540

In the three and nine months ended September 30, 2007 and September 30, 2006, no stock-based compensation expense was capitalized and there were no recognized tax benefits associated with the stock-based compensation charge. In the nine months ended September 30, 2007, stock-based compensation expense of \$637, included in research and development, was related to Boston Biomedical, Inc. transition costs (see Note 11, Boston Biomedical, Inc. Collaboration in this Form 10-Q). In the three month and nine month periods ended September 30, 2007, \$438 of stock-based compensation expense was incurred in conjunction with the acceleration of vesting of 103,798 stock options and the extension of the post-employment exercise period of 395,942 stock options held by certain employees who will meet eligibility criteria for a retirement benefit within the next four years. On October 4, 2007 the exercise period associated with 1,115,000 stock options was extended and the vesting of 165,625 stock options was accelerated in conjunction with an amendment to the CEO's employment agreement. The amount of stock option expense associated with this amendment is expected to be \$703 in the quarter ending December 31, 2007 and \$1,406 in 2008.

Option activity under our stock plans for the nine months ended September 30, 2007 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2006	3,872,946	\$ 6.66
Granted	1,195,325	6.51
Exercised	(330,587)	5.13
Cancelled	(313,287)	6.40
Outstanding as of September 30, 2007	4,424,397	\$ 6.75
Exercisable as of September 30, 2007	2,321,585	\$ 7.33

The aggregate intrinsic value of options outstanding at September 30, 2007 was \$5.5 million, of which \$3.3 million related to exercisable options. The weighted average fair value of options granted in the nine months ended September 30, 2007 and 2006 was \$3.40 and \$4.05 per share, respectively. The intrinsic value of options exercised in the nine months ended September 30, 2007 and 2006 was \$1,131 and \$291.



The total compensation cost not yet recognized as of September 30, 2007 related to non-vested option awards was \$6.4 million, which will be recognized over a weighted-average period of 2.7 years. During the nine months ended September 30, 2007, there were 275,245 shares forfeited with a weighted average grant date fair value of \$4.01 per share. The weighted average remaining contractual life for options exercisable at September 30, 2007 was 4.9 years.

## **9. STOCK OFFERING**

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On June 13, 2007, we sold 7 million shares of common stock at \$7.75 per share for aggregate net proceeds of approximately \$50.5 million after commissions and other offering expenses. On July 18, 2007, we sold an additional 502,000 shares of common stock upon exercise of the underwriter's over allotment option at \$7.75 per share for aggregate additional net proceeds of approximately \$3.6 million after commissions and other offering expenses.

### **10. RECENT ACCOUNTING PRONOUNCEMENTS**

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In September 2006, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 157 *Fair Value Measurements* ( SFAS 157 ). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. This accounting standard is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 157 is not anticipated to have a material effect on our financial position or results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, ( SFAS 159 ), which is effective for financial statements issued for fiscal years beginning after November 15, 2007. Early adoption is permitted as of the beginning of a fiscal year that begins on or before November 15, 2007, provided the entity also elects to apply the provisions SFAS 157, *Fair Value Measurements*. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The Statement also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. The implementation of SFAS 159 is not expected to have a material impact on the Company's financial statements.

In June 2007, the Emerging Issues Task Force ( EITF ), reached a consensus on EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. This consensus is effective for fiscal years beginning after December 15, 2007. The initial adjustment to reflect the effect of applying the consensus as a change in accounting principle would be accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. We do not believe that our adoption of EITF 07-03 in the first quarter of 2008 will have a material impact on our financial statements.

### **11. BOSTON BIOMEDICAL, INC. COLLABORATION**

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In January 2007, we entered into a \$5.0 million, eight-month sponsored research agreement with the newly established Boston Biomedical, Inc. ( BBI ), an independent corporation led by our former chief scientific officer. Approximately 26 former employees of ArQule joined BBI.

BBI is conducting scientific research under the agreement that includes a number of *in vivo* and *in vitro* studies, reports and publications related to mechanisms of action and biomarkers for our clinical-stage products. These products include ARQ 197, ARQ 501 and ARQ 171. We retain all intellectual property and technology rights related to research conducted by BBI employees under the contract. ArQule has no equity position in BBI.

In connection with the foregoing events, on January 26, 2007, our former chief scientific officer entered into a separation agreement and general release with us and was paid a lump sum severance payment comprised of (i) one year's salary in the amount of \$321, (ii) the average of his cash bonuses over the last two years in the amount of \$110, and (iii) the amount of \$113 to which he was entitled under our Annual Incentive Program for fiscal year 2006.

In addition, he was granted an option to purchase 64,375 shares of our common stock, which is fully vested and exercisable on the date of grant and will expire on December 31, 2008. His previously vested option grants covering 216,250 shares were amended to extend the exercise period through December 31, 2007. In connection with his appointment as Chairman of our Scientific Advisory Board, he was granted an additional option to purchase 12,500 shares, which is fully vested and exercisable on the date of grant and will expire ten years after the date of grant. As a result of his separation from service, all his unvested options have lapsed.

Approximately 26 of our former employees joined BBI in January 2007 and each employee who transitioned to BBI executed and delivered a separation agreement and general release. In consideration for entering into such agreement, each employee received a fully-vested option to purchase shares of our common stock with an exercise period terminating on December 31, 2008, as well as an amendment to their previously vested stock options to extend the exercise period through December 31, 2007. The total number of fully vested stock options issued to these employees was 87,500, and the total number of stock options that were amended to extend the exercise period was 92,504. As a result of separation of service all unvested options of such employees have lapsed.

In the first quarter of 2007, we expensed approximately: \$431 related to lump sum cash payments under the separation and general release agreement with our former chief scientific officer, as well as certain non-cash charges for stock based compensation, including \$201 for stock options granted to him; and \$168 arising from the extension of the exercise period of his vested options. Additionally, in the first quarter of 2007, we expensed approximately \$197 for stock options granted to other employees related to their separation agreements and releases, and \$71 arising from the extension of the exercise period of their vested options.

Through September 30, 2007, in conjunction with the BBI sponsored research agreement, we incurred \$4,569 of research and development expense. We made payments of \$4,389 to BBI and the remaining \$180 is reported in other accrued expenses.

## **12. INCOME TAXES**

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We adopted the provisions of FASB Interpretation No. 48 ( FIN 48 ) *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* ( SFAS 109 ) on January 1, 2007. As a result of the implementation of FIN 48, we recorded no adjustment for unrecognized income tax benefits. At the adoption date of January 1, 2007 and also at September 30, 2007, 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 September 30, 2007, we had no accrued interest or penalties related to uncertain tax positions. The tax years 2003 through 2006 remain open to examination by the major taxing jurisdictions to which we are subject, which is primarily the U.S.

As of December 31, 2006, we had federal net operating loss ( NOL ), state NOL, and research and development ( R&D ) credit carryforwards of approximately \$126,104, \$75,723 and \$13,724 respectively, which can be used to offset future federal and state income tax liabilities and expire at various dates through 2026. Federal net capital loss carryforwards of approximately \$5,000 can be used to offset future federal capital gains and expire at various dates through 2008.

Utilization of NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future provided by Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing 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. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. The Company has not currently completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation due to the significant complexity and cost associated with such study and that there could be additional changes in control in the future. If we have experienced a change of control at any time since Company formation, utilization of our NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48.

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

**OVERVIEW**



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We are a clinical-stage biotechnology company organized as a Delaware Corporation in 1993 and are engaged in the research and development of innovative anti-cancer therapies. Our goal is to introduce novel products that act selectively against cancer cells, target multiple tumor types and are well tolerated by patients. We believe our clinical-stage products represent potential best-in class or first-in class small molecule candidates based on highly differentiated mechanisms of action.

Our clinical-stage products consist of: ARQ 197, an orally administered inhibitor of the c-Met receptor tyrosine kinase; ARQ 501, an intravenously administered novel activator of the cell's DNA damage response mechanism mediated by the E2F-1 transcription factor; and ARQ 171, an intravenously administered second generation activator of E2F-1. Results from Phase 1 clinical trials of ARQ 501 and ARQ 197 showed promising anti-cancer activity across multiple types of tumors. In these early-stage studies, there was no drug-related, serious adverse event (Grades 3/4) associated with ARQ 197; ARQ 501 showed clinical tolerability with hemolytic anemia identified as the dose-limiting toxicity.

We retain full worldwide commercial rights to ARQ 197 outside of Japan and other select Asian countries, where we granted commercial rights to Kyowa Hakko Kogyo Co., Ltd. ( Kyowa ) on April 27, 2007. We are developing ARQ 501, ARQ 171 and ARQ 761, a new chemical entity based on ARQ 501, pursuant to our collaboration with Hoffmann-La Roche ( Roche ). Our agreements with Kyowa and Roche each provide for possible future milestone payments, royalties on product sales, and development funding, in addition to upfront payments that we have already received.

Our pre-clinical programs are directed toward molecular targets that we believe play critical roles in the development of human cancers. The most advanced of these programs is focused on the development of inhibitors of the Eg5 Kinesin motor protein and the B-RAF kinase. Toxicology testing is planned to begin in late 2007 with a product candidate from one of these programs. Select additional molecular targets being explored in our research programs include Hsp90, HDAC and selected onco-kinases. We may elect to out-license certain product candidates discovered through our pre-clinical programs to corporate partners.

Our products and research programs 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 acting 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. We believe that our combined expertise in biology and chemistry differentiates us from other biotech companies.

In September 2005, we announced a strategic decision to exit our chemistry services operations in order to focus operationally on developing our oncology portfolio. We continued to provide chemistry services to Pfizer Inc ( Pfizer ) under a previous agreement until May 2006, at which time the collaboration with Pfizer was terminated, and we ceased chemistry services operations. We are retaining and continuing to use a broad spectrum of well-established chemistry capabilities in the discovery and development of our oncology portfolio.

We have an accumulated deficit of \$267 million at September 30, 2007. We expect research and development costs to increase throughout 2007 due to clinical testing of our lead product candidates. Although we have generated positive cash flow from operations for the six consecutive years from 2000-2005, these cash flows were attributable to our discontinued chemistry services operations. We recorded a net loss for all but one of those years. We recorded a net loss for 2006 and expect a net loss for 2007.

Our revenue consists of development funding from our alliance with Roche and license fee and development revenues from Kyowa. Under the Roche alliance, we are responsible for advancing drug candidates from early stage development to Phase 2 trials. Roche may opt to license worldwide rights for the development and commercialization of products resulting from this collaboration by paying an option fee. Assuming the successful development and commercialization of a compound under the program, we could receive up to \$276 million in pre-determined payments, plus royalties based on net sales. Additionally, we have the option to co-promote products in the U.S.

On April 27, 2007, we entered into an exclusive license agreement with Kyowa 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 to ArQule, including the \$30 million cash upfront licensing payments. In addition, the agreement includes sales milestone payments. Upon commercialization, ArQule will receive double-digit royalties from Kyowa on net sales of ARQ 197. Kyowa 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.

For the three and nine months ended September 30, 2007, \$0.8 million and \$1.4 million were recognized as revenue. At September 30, 2007, \$28.6 million remains in deferred revenue.

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 duration and outcomes of our clinical trials.

Revenue from our chemistry services operations ceased in the second quarter of 2006 as a result of our strategic decision to exit this business and the subsequent decision by Pfizer to terminate its Agreement with us effective on May 22, 2006. From December 2001 until that date, we produced for Pfizer annually an average of approximately 160,000 synthetic chemical compounds and received average annual cash payments of approximately \$50 million for those compounds and related services. The Agreement provided for six months prior written notice by either party to the other for termination without cause and, in the event of termination by Pfizer, certain payments to us. In accordance with these provisions, we received approximately \$19.8 million in December 2005 in connection with the termination.

## **LIQUIDITY AND CAPITAL RESOURCES**

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	September 30, 2007	December 31, 2006		Increase (decrease) \$	%
			(in millions)		
Cash, cash equivalents and marketable securities	\$ 143.5	\$ 95.8	\$	47.7	49.7%
Working capital	125.3	80.6		44.7	55.6%

	Q3 YTD 2007	Q3 YTD 2006		Increase (decrease) \$
			(in millions)	
Cash flow from:				
Operating activities	\$ (7.5)	\$ (33.4)	\$	25.9
Investing activities	(45.4)	35.9		(81.3)
Financing activities	55.9	1.5		54.4

*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 pre-clinical 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 license rights or future services. For the nine months ended September 30, 2007, our decrease in cash from operating activities was primarily driven by the difference between cash receipts from collaborators, and payments for operating expenses which resulted in a net cash outflow of \$7.5 million.

*Cash flow from investing activities.* Our net cash used by investing activities of \$45.4 million in the nine months ended September 30, 2007 was comprised of net sales of marketable securities of \$44.5 million and acquisitions of fixed assets of \$0.9 million. 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.

*Cash flow from financing activities.* Our net cash provided by financing activities of \$55.9 million in the nine months ended September 30, 2007 was comprised primarily of the proceeds from our June 13, 2007 stock offering, wherein we sold 7 million shares of common stock at \$7.75 per share for aggregate net proceeds of \$50.5 million after commissions and offering expenses. During July 2007, the Company received net proceeds of \$3.6 million when the underwriters of our June 13, 2007 offering exercised their over-allotment option to purchase an additional 502,000 shares of common stock. Stock option exercises provided additional cash inflow of \$1.8 million.

Although we were cash flow positive from operations from 1999 through 2005, we were not cash flow positive from operations in 2006, nor do we expect to be cash flow positive from operations for 2007, as a result of our decision to exit our chemistry services operations and the increased cost of developing our clinical candidates. We expect that our available cash and marketable securities, together with cash from operations and investment income, will be sufficient to finance our working capital and capital requirements into the second half of 2009, depending on decisions we may make regarding our clinical trials.

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 other factors, many of which are beyond our control. There can be no assurance that sufficient funds will be available to us when required, on satisfactory terms, or at all. 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 contractual obligations were comprised of the following as of September 30, 2007 (in thousands):

		Payment due by period				
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years	
Operating lease obligations	\$ 26,692	\$ 3,848	\$ 7,552	\$ 7,072	\$ 8,220	
Purchase obligations	6,055	6,055				
Total	\$ 32,747	\$ 9,903	\$ 7,552	\$ 7,072	\$ 8,220	

Included in the total minimum payments for operating leases is approximately \$1.5 million related to abandoned real estate in California, net of contractual sublease income. This net amount has been accrued as a liability as a part of the Company's restructuring charge in 2002 and subsequently adjusted in 2003 and 2004 (see Note 6 Restructuring Charges to the Condensed Consolidated Financial Statements in this Form 10-Q). Purchase obligations are comprised primarily of outsourced pre-clinical and clinical trial expenses and payments to license certain intellectual property to support the Company's research efforts.

#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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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 3 to the Consolidated Financial Statements included in our Annual Report on Form 10-K.

### **Research and Development Revenue Recognition**

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Under the terms of the Roche agreement, Roche obtained an option to license ArQule's E2F program in the field of cancer therapy. Roche provided immediate research funding of \$15 million, and financial support for ongoing research and development. ArQule is responsible for advancing drug candidates from early stage development into Phase 2 trials. Roche may opt to license worldwide rights for the development and commercialization of products resulting from this collaboration by paying an option fee. Assuming the successful development and commercialization of a compound under the program, ArQule could receive up to \$276 million in pre-determined milestone payments, plus royalties based on net sales. ArQule considers the development portion of the arrangement to be a single unit of accounting under EITF No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* for purposes of revenue recognition, and will recognize the initial and ongoing development payments as research and development revenue over the maximum estimated development period. We estimate the maximum development period could extend until December 2009. This period may ultimately be shorter depending upon the outcome of the development work, resulting in accelerated recognition of the development revenue. Milestone and royalty payments will be recognized as revenue when earned. The costs associated with satisfying the Roche contract are included in research and development expense in the Condensed Consolidated Statement of Operations.

On April 27, 2007, we entered into an exclusive license agreement with Kyowa 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 to ArQule, including the \$30 million cash upfront licensing payments. In addition, the agreement includes sales milestone payments. Upon commercialization, ArQule will receive double-digit royalties from Kyowa on net sales of ARQ 197. Kyowa 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.

Under the Kyowa agreement, the initial license fee and any subsequent milestone payments, once earned, will be recognized as research and development revenue using the contingency-adjusted performance model. Under this model, when payments are earned, revenue is immediately recognized on a pro-rata basis in the period we achieve the milestone based on the time elapsed from inception of the Kyowa agreement to the time the milestone is earned over the estimated duration of the development period under the agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated development period under the agreement. We currently estimate the development period to be through April 2016. This period may ultimately be shorter or longer depending upon the outcome of the development work, resulting in accelerated or deferred recognition of the development revenue. Royalty payments will be recognized as revenue when earned. The cost associated with satisfying the Kyowa contract is included in research and development expense in the Condensed Consolidated Statement of Operations.

For the three and nine months ended September 30, 2007, \$0.8 million and \$1.4 million were recognized as revenue. At September 30, 2007, \$28.6 million remains in deferred revenue.

## **RESULTS OF OPERATIONS**

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The following are the results of operations for the three and nine months ended September 30, 2007 and 2006:

### **Revenue**



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	2007	2006	Increase (decrease)	
	(in millions)		\$	%
For the three months ended September30:				
Research and development revenue	\$ 2.7	\$ 1.7	\$ 1.0	65.6%
For the nine months ended September 30:				
Research and development revenue	\$ 6.6	\$ 5.0	\$ 1.6	33.6%

Research and development revenue increased by \$1.0 million in the three month period and \$1.6 million in the nine month period primarily from revenue recognized in connection with the Kyowa licensing agreement.

**Research and development**

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	2007	(in millions)	2006	Increase (decrease)	%
	\$		\$	\$	
<i>For the three months ended September 30:</i>					
Research and development	\$	12.5	\$	14.9	\$ (2.4) (16.2)%
<i>For the nine months ended September 30:</i>					
Research and development	\$	39.3	\$	35.0	\$ 4.3 12.3%

Overview

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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, or the cost to support our alliance agreement with Roche. The expenses incurred by us to third-parties for pre-clinical and clinical trials in the third quarter of 2007 and since inception of each program were as follows (in thousands):

Oncology program	Current status	Three Months Ended September 30, 2007	Program-to-date
E2F modulation ARQ 501	Phase 2	\$ 1,415	\$ 25,415
E2F modulation ARQ 171	Phase 1	374	5,062
c-Met program ARQ 197	Phase 1	3,342	13,875

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 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 Roche and Kyowa. In the event that third parties have control over the clinical trial process for a product, the estimated completion date would largely be under control of that third party rather than under our control. We cannot forecast with any degree of certainty whether our products will be subject to future collaborative arrangements or how such arrangements would affect our development plans or capital requirements.

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As a result of the uncertainties discussed above, we are unable to determine 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.

The \$2.4 million decrease in research and development expense in the third quarter of 2007 compared with the prior year's quarter was primarily due to \$5.1 million lower costs for the Phase 2 trials with ARQ 501. This decrease was partially offset by a \$2.7 million increase in costs for Phase 1 trials and preparation for Phase 2 trials with ARQ 197.

The \$4.3 million increase in research and development expense in the first nine months of 2007 compared with the prior year's nine month period is primarily due to a \$6.0 million increase in costs for Phase 1 trials and preparation for Phase 2 trials with ARQ 197 and \$4.6 million of costs incurred in conjunction with our sponsored research agreement with BBI. These increases were offset in part by \$5.6 million lower costs for Phase 1 and 2 trials with ARQ 501 and lower lab expenses of \$0.7 million. At September 30, 2007, we had 72 employees dedicated to our research and development program, compared with 90 employees at September 30, 2006.

#### **General and administrative**

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	2007	2006	Increase (decrease)	
	(in millions)		\$	%
<i>For the three months ended September 30:</i>				
General and administrative	\$ 3.4	\$ 3.4	\$	%
<i>For the nine months ended September 30:</i>				
General and administrative	\$ 10.7	\$ 8.4	\$ 2.3	27.9%

General and administrative expense was unchanged in the three month period. The increase in the nine month period was due to increases of \$1.4 million in personnel related expenses, \$0.3 million in professional fees and \$0.6 million for facility costs, which are no longer absorbed by the chemical services operations. General and administrative headcount was 34 at September 30, 2007, compared to 40 at September 30, 2006.

## Investment income

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	2007		2006		Increase (decrease)	
	(in millions)				\$	%
For the three months ended September 30:						
Investment income	\$	2.0	\$	1.3	\$ 0.7	53.3%
For the nine months ended September 30:						
Investment income	\$	4.3	\$	3.9	\$ 0.4	11.0%

Investment income is derived from our portfolio of cash and short-term investments. Investment income increased in the three month and nine month periods due to an increase in the average portfolio balance from our June 2007 stock offering.



**Income from discontinued operations**

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	2007	2006	Increase (decrease)	
	(in millions)		\$	%
<i>For the nine months ended September 30:</i>				
Income from discontinued operations	\$	\$ 15.8	\$ (15.8)	(100)%

The decrease in income from the chemical services operations, discontinued operations, in first nine months of 2007 reflects the termination of the Pfizer collaboration during the second quarter of 2006.

**RECENT ACCOUNTING PRONOUNCEMENTS**

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In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* ( SFAS 157 ). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This accounting standard is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 157 is not anticipated to have a material effect on our financial position or results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, ( SFAS 159 ), which is effective for financial statements issued for fiscal years beginning after November 15, 2007. Early adoption is permitted as of the beginning of a fiscal year that begins on or before November 15, 2007, provided the entity also elects to apply the provisions of FASB Statement No. 157, *Fair Value Measurements*. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The Statement also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. The implementation of SFAS 159 is not expected to have a material impact on the Company's financial statements.

In June 2007, the EITF, reached a consensus on EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. This consensus is effective for fiscal years beginning after December 15, 2007. The initial adjustment to reflect the effect of applying the consensus as a change in accounting principle would be accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. We do not believe that our adoption of EITF 07-03 in the first quarter of 2008 will have a material impact on our financial statements.

### **FORWARD LOOKING STATEMENTS**

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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 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 Phase 1 and 2 monotherapy and combination therapy clinical trials involving ARQ 501 and ARQ 197, and the second generation ACT compound, ARQ 171. Additional forward-looking statements relate to our agreement with Kyowa, including potential future milestones and royalty payments 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.

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 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, 2006 as filed with the SEC on March 12, 2007, 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**

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As part of our investment portfolio we own financial instruments that are sensitive to market risk. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We invest our cash primarily in money market mutual funds and U.S. federal and state agency backed obligations and other investment grade debt securities. These investments are evaluated quarterly to determine the fair value of the portfolio. Our investment portfolio includes only marketable securities with active secondary or resale markets to help ensure liquidity. We have implemented policies regarding the amount and credit ratings of investments. Due to the conservative nature of these policies, we do not believe we have material exposure from market risk.

The carrying amounts reflected in the Condensed Consolidated Balance Sheet of cash and cash equivalents, trade receivables, and trade payables approximate fair value at September 30, 2007, due to the short-term maturities of these instruments.

### **ITEM 4. CONTROLS AND PROCEDURES**

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Our management, with the participation of our Chief Executive Officer and Chief Operating Officer (Principal Financial Officer), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2007. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the 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 principal financial officers, 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, 2007, our Chief Executive Officer 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.



**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, 2006, as filed with the SEC on March 12, 2007, 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. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.** None.

**ITEM 5. OTHER INFORMATION.** None.

**ITEM 6. EXHIBITS.**

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**EXHIBIT**

<b>NO.</b>	<b>DESCRIPTION</b>
31.1	Rule 13a-14(a) Certificate of Chief Executive Officer (1)
31.2	Rule 13a-14(a) Certificate of Principal Financial Officer (1)
32	Rule 13a-14(b) Certificate of Chief Executive Officer and Principal Financial Officer (1)

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(1) Filed herewith.

**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 6, 2007

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

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