ARQULE INC
Form 10-Q
November 09, 2004

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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, 2004

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 Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes þ No o

Number of shares outstanding of the registrant s Common Stock as of November 8, 2004:

Common Stock, par value $.01	28,894,906 shares outstanding

ARQULE, INC.

QUARTER ENDED SEPTEMBER 30, 2004

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PART I FINANCIAL INFORMATION

Item 1. ***Unaudited Consolidated Financial Statements***

ARQULE, INC.

CONSOLIDATED BALANCE SHEET (UNAUDITED)

	September 30, 2004	December 31, 2003
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,014	$ 32,139
Marketable securities	43,969	44,585
Accounts receivable	646	741
Prepaid expenses and other current assets	1,688	2,455
Total current assets	79,317	79,920
Property and equipment, net	43,451	47,942
Other assets	427	562
	$ 123,195	$ 128,424
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 9,132	$ 14,468
Current portion of long-term debt	1,992	5,980
Current portion of deferred revenue	11,313	4,774
Total current liabilities	22,437	25,222
Long-term debt, net of current portion	463	1,218
Deferred revenue, net of current portion	17,268	15,507
Total liabilities	40,168	41,947
Stockholders equity:		
Common stock, $0.01 par value; 50,000,000 shares authorized; 28,830,309 and 28,724,771 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively	288	287
Additional paid-in capital	271,210	270,663
Accumulated other comprehensive income	(223)	(137)
Accumulated deficit	(188,248)	(184,336)
Total stockholders equity	83,027	86,477
	$ 123,195	$ 128,424

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

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ARQULE, INC.

CONSOLIDATED STATEMENT OF OPERATIONS (UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(In thousands, except per share data)			
Revenue:				
Compound development revenue	$12,692	$ 15,961	$36,313	$ 47,096
Compound development revenue related party	250		750	
Research and development revenue	1,652		3,304	
Total revenue	14,594	15,961	40,367	47,096
Costs and expenses:				
Cost of revenue compound development	7,695	8,878	23,449	27,069
Cost of revenue compound development related party	125		375	
Research and development	5,001	4,726	14,680	12,860
Marketing, general and administrative	2,117	2,349	6,934	7,165
Restructuring credit	(1,496)	(290)	(424)	(290)
In-process research and development		30,359		30,359
Total costs and expenses	13,442	46,022	45,014	77,163
Income (loss) from operations	1,152	(30,061)	(4,647)	(30,067)
Net investment income	320	152	735	445
Net income (loss)	$ 1,472	$(29,909)	$ (3,912)	$(29,622)
Basic net income (loss) per share	$ 0.05	$ (1.22)	$ (0.14)	$ (1.28)
Diluted net income (loss) per share	$ 0.05	$ (1.22)	$ (0.14)	$ (1.28)
Weighted average common shares outstanding:				
Basic	28,830	24,536	28,789	23,213
Diluted	28,986	24,536	28,789	23,213

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

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ARQULE, INC.

CONSOLIDATED STATEMENT OF CASH FLOWS (UNAUDITED)

	Nine Months Ended September 30,	
	2004	**2003**
	(In thousands)	
Increase (Decrease) in Cash and Cash Equivalents		
Cash flows from operating activities:		
Net loss	$ (3,912)	$(29,622)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	5,708	7,070
Non-cash restructuring charge	76	
Non-cash stock compensation	55	
Purchase of in-process research and development		30,359
Changes in operating assets and liabilities:		
Accounts receivable	95	(1,250)
Prepaid expenses and other current assets	767	675
Other assets	135	
Accounts payable and accrued expenses	(5,242)	(5,994)
Deferred revenue	8,300	(527)
Net cash provided by operating activities	5,982	711
Cash flows from investing activities:		
Purchases of marketable securities	(22,501)	(53,535)
Proceeds from sale or maturity of marketable securities	22,926	58,161
Acquisition, net of cash acquired		(7,014)
Additions to property and equipment	(1,220)	(1,968)
Net cash used in investing activities	(795)	(4,356)
Cash flows from financing activities:		
Principal payments of long-term debt	(4,743)	(8,183)
Proceeds from issuance of common stock	417	5,307
Net cash used in financing activities	(4,326)	(2,876)
Effect of foreign exchange rates on cash and cash equivalents	14	(31)
Net increase (decrease) in cash and cash equivalents	875	(6,552)
Cash and cash equivalents, beginning of period	32,139	40,283
Cash and cash equivalents, end of period	$ 33,014	$ 33,731

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

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ARQULE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Nature of Operations

We are a biotechnology company engaged in the research and development of small molecule cancer therapeutics based on a novel biological approach to cancer, our Activated Checkpoint Therapy^{SM} (ACT^{SM}) platform, and our expertise in small molecule chemistry and intelligent drug design. We also provide fee-based services to pharmaceutical companies and biotechnology companies, using our chemistry-based technology and expertise to attract collaborators. We have an experienced and highly qualified scientific and management team that can apply our chemistry technology platform to produce compounds that have medicinal attributes.

We are subject to risks common to companies in the biotechnology, pharmaceutical, medical services, and diagnostics industries, including but not limited to, development by the Company or our competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with governmental regulation.

2. Basis of Presentation

We have prepared the accompanying consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission. 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 consolidated financial statements should be read in conjunction with our audited financial statements and footnotes related thereto for the year ended December 31, 2003 included in our annual report on Form 10-K filed with the Securities and Exchange Commission on March 12, 2004. These unaudited 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, 2004, and the results of our operations for the three months and nine months ended September 30, 2004 and September 30, 2003 and cash flows for the nine months ended September 30, 2004 and September 30, 2003. The results of operations for such interim periods are not necessarily indicative of the results to be achieved for the full year.

3. Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income. Other comprehensive income includes certain changes in stockholders equity that are excluded from net income (loss), including unrealized gains and losses on our available-for-sale securities and interest rate swaps and foreign currency translation amounts. Comprehensive income (loss) for the three and nine months ending September 30, 2004 and September 30, 2003 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income (loss)	$1,472	$(29,909)	$(3,912)	$(29,622)
Unrealized gain (loss) on securities and interest rate swaps	233	16	(171)	93
Foreign currency translation adjustments		(2)	86	(54)
Comprehensive income (loss)	$1,705	$(29,895)	$(3,997)	$(29,583)

4. Restructuring Actions

In the first quarter of 2004, we implemented a restructuring to shift resources from our chemical technologies business to our internal cancer therapy research. The restructuring included the termination of

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53 staff and managerial employees, or approximately 18% of the workforce, in the following areas: 30 in chemistry production positions, 7 in chemistry-based research and development positions and 16 in administrative positions. In connection with these actions we recorded a restructuring charge of $1.1 million in the first quarter of 2004 for termination benefits.

In connection with a restructuring in December 2002, we recorded a restructuring charge related to the closure of our facility in Redwood City, California. As of December 31, 2003 we had a remaining accrual of $6.2 million that primarily represented the remaining lease payments on our primary lease obligation less an estimate of sublease income. In the third quarter of 2004, we entered into a sublease for the California facility with Threshold Pharmaceuticals, Inc. The term of the sublease extends through 2010, the remaining term of the Company s primary lease obligation. As a result of signing the sublease, we reassessed the remaining restructuring accrual and, since the sublease was on terms more favorable than previously estimated, we recorded a $1.5 million restructuring credit in the third quarter of 2004.

Year-to-date activity against the restructuring accrual (which is included in accrued liabilities in the Consolidated Balance Sheet) was as follows (in thousands):

	Balance as of December 31, 2003	2004 Provisions/ (Credits)	2004 Payments	Balance as of September 30, 2004
Termination benefits	$ 10	$ 1,072	$(1,082)	$
Facility-related	6,160	(1,496)	(1,024)	3,640
Other charges	69		(69)	
Total restructuring accrual	$6,239	$ (424)	$(2,175)	$3,640

As of September 30, 2004, all employee termination benefits had been paid. The facility-related accrual, which is primarily comprised of the difference between the Company s lease obligation for its California facility and the amount of sublease payments it will receive under its sublease agreement with Threshold Pharmaceuticals, Inc., will be paid out through 2010.

5. Net Income (Loss) Per Share

The computations of basic and diluted net income (loss) per common share are based upon the weighted average number of common shares outstanding and potentially dilutive securities. Potentially dilutive securities include stock options. The computations of net loss per share for the nine months ended September 30, 2004 and the three and nine months ended September 30, 2003 excluded options to purchase 4,541,000 and 4,080,380 shares common of stock, respectively, since inclusion of such shares would have an anti-dilutive effect on net loss per share.

We apply APB No. 25 and related interpretations in accounting for option grants under the Company s stock option plans. Had compensation cost been determined based on the estimated fair value of options at the grant date consistent with the provisions of SFAS No. 123, as amended by SFAS 148, our pro forma net

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income (loss) and pro forma basic and diluted net income (loss) per share would have been as follows for the three and nine months ended September 30, 2004 and 2003 (in thousands, except per share data):

	Three months ended September 30		Nine months ended September 30	
	2004	2003	2004	2003
Net income (loss):				
Net income (loss) reported	$1,472	$(29,909)	$(3,912)	$(29,622)
Add: Stock based employee compensation expense included in reported net income (loss)	6		54	
Less: Stock-based employee compensation under fair value method of SFAS 123	(897)	(649)	(5,038)	(5,125)
Pro-forma net income (loss)	$ 581	$(30,558)	$(8,896)	$(34,747)
Basic net income (loss) per share:				
As reported	$ 0.05	$ (1.22)	$ (0.14)	$ (1.28)
Pro forma	$ 0.02	$ (1.25)	$ (0.31)	$ (1.50)
Diluted net income (loss) per share:				
As reported	$ 0.05	$ (1.22)	$ (0.14)	$ (1.28)
Pro forma	$ 0.02	$ (1.25)	$ (0.31)	$ (1.50)

For the purposes of pro forma disclosure, the estimated value of each employee and non-employee option grant was calculated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option-pricing models require the use of highly subjective assumptions, including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective assumptions can materially affect the fair value estimates, in management s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock-based compensation. The model was calculated using the following weighted-average assumptions: no dividend yield for all years; volatility of 95% for 2003 and 2004; risk-free interest rates of 3.85% in 2003 and 3.5% in 2004; and expected lives of five years for 2003 and 2004 for options granted.

6. Contingencies Medford Lease

We lease approximately 56,000 square feet of laboratory and office space in Medford, Massachusetts. We lease this facility from Cummings Properties, LLC (Cummings) under two lease agreements, one of which expires on July 30, 2005 and one of which expires on July 30, 2006. We sublease a portion of these facilities pursuant to a sublease agreement.

On August 1, 2001, Cummings significantly raised our rent on the lease that expires July 30, 2006. We believe this increase to be in excess of that which is permissible under the lease agreement. Accordingly, on January 16, 2002, we brought a complaint for declaratory relief and damages against Cummings arising, in part, out of Cummings attempts to increase the lease rates. Nevertheless, during the pendency of this dispute, we are paying the rental rates proposed by Cummings. We seek recovery of the excess funds that we have already paid, and continue to pay, under protest. Management has made an estimate of the most likely outcome of this contingency and has concluded that no provision is required at September 30, 2004. However, if we are unsuccessful in our claim against Cummings and must pay all or a portion of the rental expense increase currently proposed by Cummings, we may be required to record an additional expense of up to approximately $450,000 to record the difference between our contractual rental payments and contractual sublease rental income over the remaining period of the lease. Conversely, if the contingency is resolved in our favor and we are entitled to a refund of amounts previously paid, we may record a gain in a future period.

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7. Pfizer Inc.

Since the inception of our relationship with Pfizer Inc. in 1999, we have produced collections of chemical compounds exclusively for Pfizer using our automated high-speed compound production system. Pfizer also received a non-exclusive license to use this system in its internal production program. We expanded this contract in December 2001 to a seven-year agreement. We renegotiated this contract again in early February 2004. Under the amended terms of the contract ArQule will continue to work with Pfizer s scientists to more closely match its compound deliveries to those libraries which Pfizer believes have the greatest developmental opportunity. Under this new agreement, ArQule will maintain compound deliveries at approximately the same level to be supplied in 2004 instead of increasing compound deliveries as specified in the previous agreement. If our amended relationship with Pfizer is successful, we could earn up to $291 million over the term of the contract (2001 2008). This amendment will result in a decrease in the total potential contract value of $54 million compared to the terms agreed to in 2001.

In May 2003, the Financial Accounting Standards Board issued Emerging Issues Task Force 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, (EITF 00-21). EITF 00-21 became effective for contracts entered into after July 1, 2003 and addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting for purposes of revenue recognition. In applying the guidance, revenue arrangements with multiple deliverables can only be considered as separate units of accounting if: a) the delivered item has value to the customer on a standalone basis, b) there is objective and reliable evidence of the fair value of the undelivered items and c) if the right of return exists, delivery of the undelivered items is considered probable, and substantially in the control of the vendor. If these criteria are not met, the revenue elements must be considered a single unit of accounting for purposes of revenue recognition. We concluded that the modification was substantial enough to require evaluation of the contract to determine if EITF 00-21 applied. We concluded that because the contract does contain multiple deliverables (license to technology, research services and compound deliveries) EITF 00-21 did apply. We further determined that there was insufficient evidence of fair value of the undelivered elements (compound delivery), and therefore the amended contract represented a single unit of accounting for revenue recognition purposes. As a result, in the first quarter of 2004 ArQule began treating the amended Pfizer agreement as a single unit of accounting and recognizing revenue based on the delivery and acceptance of compounds against the contractual compound delivery schedule.

8. Hoffmann-La Roche

On April 2, 2004, ArQule announced an alliance with Hoffmann-La Roche (Roche) to discover and develop drug candidates targeting the E2F biological pathway. The alliance includes a compound which is currently in phase 1 clinical development. Under the terms of the 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 payments, plus royalties based on net sales. Additionally, ArQule has the option to co-promote products in the U.S.

ArQule considers the development portion of the arrangement to be a single unit of accounting under EITF 00-21 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, although this period may ultimately be shorter depending upon the outcome of the development work, which would result in accelerated recognition of the development revenue. Milestone and royalty payments will be recognized as revenue when earned. The cost associated with satisfying the Roche contract is included in research and development expense in the Consolidated Statement of Operations.

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Item 2. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

Overview

We are a biotechnology company engaged in the research and development of small molecule cancer therapeutics. We also provide fee-based chemistry services to pharmaceutical and biotechnology companies to produce novel chemical compounds with drug-like characteristics.

We have incurred a cumulative net loss of $188 million from inception through September 30, 2004. Our losses prior to the acquisition of Cyclis Pharmaceuticals, Inc. (Cyclis) in September 2003 related to development activities associated with our chemistry services, the associated administrative costs required to support those efforts, and the cost of acquisitions. We expect research and development costs to increase in 2004 as we pursue development of our cancer programs. We do not expect to make additional investments to expand chemistry services capacity during 2004. Although we have generated positive cash flow from operations for the last five years, we have recorded a net loss in all but one of those years, and expect to record a loss for 2004. Based on our cash position at the end of 2003, we believe we will be able to dedicate approximately $25 million per year over the next three years to our oncology research and development program. This estimate is based upon the assumption that we will continue to operate our chemistry services on a cash flow positive basis, and that we will invest in cancer related research and development.

Our revenue is primarily derived from compound development chemistry services performed for our customers and, beginning in 2004, oncology research and development funding from collaborators. Revenue, expenses and gross margin fluctuate from quarter to quarter based upon contract deliverables and the timing of the recognition of revenue under our revenue recognition policy (see the discussion of this under Critical Accounting Policies below). As we increase our activities in cancer related research and development, the timing and extent of these efforts, together with the length and outcome of our clinical trials, will further impact the fluctuation of results from operations.

In February 2004, we amended our contract with Pfizer. Under the amended terms of the contract ArQule will continue to work with Pfizer s scientists to match more closely its compound deliveries to those libraries which Pfizer believes represent the greatest developmental opportunities. Under this new agreement, ArQule will maintain compound deliveries at approximately the same level to be supplied in 2004 instead of increasing compound deliveries as specified in the previous agreement. If our amended relationship with Pfizer is successful, we could earn up to $291 million over the term of the contract (2001 2008). This amendment will result in a decrease in the total potential contract value of $54 million compared to the terms agreed to in 2001.

On April 2, 2004 we announced an alliance with Roche to discover and develop drug candidates targeting the E2F biological pathway. The alliance includes a compound that is currently in phase 1 clinical development. Under the terms of the agreement, Roche obtained an option to license our E2F program in the field of cancer therapy. Roche provided immediate research funding of $15 million, and will provide financial support for ongoing research and development. We are responsible for advancing drug candidates ranging 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.

This report, including the Management s Discussion and Analysis of Financial Condition and Results of Operation (MD&A), contains statements reflecting management s current expectations regarding our future performance. These statements are forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements also may be included in other statements that we make. All statements that are not descriptions of historical fact are forward-looking statements, based on estimates, assumptions and projections that are subject to risks and uncertainties. These statements can generally be identified by use of terminology such as believes , expects , intends , may , will , should , anticipates or similar

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terminology. Although we believe that the expectations reflected in such forward looking statements are reasonable as of the date thereof, such expectations are based on certain assumptions regarding the progress of product development efforts under collaborative agreements, the execution of new collaborative agreements, and other factors relating to our growth. Such expectations may not materialize if product development efforts, including any necessary trials of our potential drug candidates, are delayed or suspended, if positive early results are not repeated in later studies or in humans, if negotiations with potential collaborators are delayed or unsuccessful, if we are unsuccessful at integrating acquired assets or technologies, if our planned transition to a drug discovery and development company takes longer or is more expensive than we anticipated, or if other assumptions prove incorrect. As a result, actual results could differ materially from those currently anticipated. See also the risks and uncertainties discussed in our Annual Report on Form 10-K for the year ended December 31, 2003 filed on March 12, 2004.

Liquidity and Capital Resources

	September 30, 2004	December 31, 2003	Increase/(Decrease) $	Increase/(Decrease) %
		(In millions)		
Cash, cash equivalents and marketable securities	$77.0	$76.7	$0.3	
Working capital	56.9	54.7	2.2	4%

	Q3 YTD 2004	Q3 YTD 2003		
Cash flow from:				
Operating activities	$ 6.0	$ 0.7	$ 5.3	741%
Investing activities	(0.8)	(4.4)	3.6	82%
Financing activities	(4.3)	(2.9)	(1.5)	(50)%

Cash flow from operating activities. The uses of our cash flow from 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 of payments from our collaborators for services performed or upfront payments for future services. For the nine months ended September 30, 2004, the net source of funds of $6.0 million was primarily due to the receipts of upfront research funding from Roche of $15 million, an operating profit (excluding non-cash charges) of $1.9 million and $0.8 million related to reductions in prepaid assets due to the timing of prepayments for service contracts, offset by $2.2 million related to payments of severance and facility related restructuring costs, $2.7 million related to decreases in accounts payable and other accruals resulting from the payment in 2004 of annual bonuses and other accruals at December 31, 2003, and $6.7 million related to recognition of deferred revenues.

Cash flow from investing activities. For the nine months ended September 30, 2004, the net use of $0.8 million was comprised of acquisitions of fixed assets of $1.2 million, partially offset by proceeds from maturity or sale of marketable securities, net of investments, of $0.4 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 the Company s near term need for liquidity.

Cash flow from financing activities. For the nine months ended September 30, 2004, the net use of $4.3 million was comprised of principal repayments on long-term debt of $4.7 million, partially offset by the cash proceeds from the issuance of common stock.

We have reported positive cash flow from operations for five consecutive years. We expect that our available cash and marketable securities of $77 million at September 30, 2004, together with operating revenues and investment income, will be sufficient to finance our working capital and capital requirements for the next three years. In April 2004, we entered into a strategic alliance agreement with Roche, under which we received $15 million in immediate research funding and could receive up to $276 million in payments, plus

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royalties. In addition, we are currently considering raising additional capital through a public offering of our securities. On December 15, 2003 we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission covering securities having an aggregate maximum value at the time of sale of $50 million.

Our cash requirements may vary materially from those now planned for development activities and facility enhancements depending upon the results of our drug discovery and development strategies, our ability to enter into any 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. We cannot guarantee that we will be able to obtain additional customers for our chemistry services, or that such services will produce revenues adequate to fund our operating expenses. We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product. If we experience increased losses, we may have to seek additional financing from public and private sale of our securities, including equity securities. There can be no assurance that additional funding will be available when needed or on acceptable terms.

Our principal contractual obligations were comprised of the following as of September 30, 2004 (in thousands):

	Total	Under 1 year	Between 1-4 years	Between 4-7 years	After 7 years
Long-term debt obligations	$ 2,285	$1,865	$ 420	$	$
Capital lease obligations	170	127	43		
Operating lease obligations	8,936	2,852	4,407	1,677	
Purchase obligations	2,313	1,933	380		
Total	$13,704	$6,777	$5,250	$1,677	$

Included in the total minimum payments for operating leases is approximately $5.9 million related to unoccupied real estate in California which was accrued as a liability, net of contractual sublease income, as a part of the Company s restructuring actions in 2002, and as subsequently adjusted (see Restructuring actions below). 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.

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. See the discussion in our significant accounting policies in Note 2 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2003 filed with the Security and Exchange Commission on March 12, 2004 for additional information.

Revenue recognition

Historically, ArQule has entered into various collaborative agreements with pharmaceutical and biotechnology companies under which ArQule produces and delivers compound arrays and provides research and development services. In each instance, the Company analyzes each distinct revenue element of the contract to determine the basis for revenue recognition. Revenue for each element is generally recognized over the period compounds are delivered and/ or services are performed, provided there is a contractual obligation on behalf of the customer to pay ArQule and payment is reasonably assured. The nature of each distinct revenue element, the facts surrounding the services provided, and ArQule s ongoing obligations to provide those services dictate how revenue is recognized for each revenue element. This accounting conforms to Generally Accepted Accounting Principles in the United States, in particular Staff Accounting Bulletin No. 104,

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Revenue Recognition in Financial Statements, and is disclosed more fully in Note 2 to the Consolidated Financial Statements included in our latest Annual Report on Form 10-K.

In May 2003, the Financial Accounting Standards Board reached a consensus on Emerging Issues Task Force No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21). EITF 00-21 addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting. In applying the guidance, revenue arrangements with multiple deliverables can only be considered as separate units of accounting if: a) the delivered item has value to the customer on a standalone basis, b) there is objective and reliable evidence of the fair value of the undelivered items and c) if the right of return exists, delivery of the undelivered items is considered probable and substantially in the control of the vendor. If these criteria are not met, the revenue elements must be considered a single unit of accounting for purposes of revenue recognition. EITF 00-21 became effective for new revenue arrangements entered into after July 30, 2003.

In February 2004, the Company entered into an amended contract with Pfizer. The amendment modified the quantity and composition of compounds to be produced and delivered by ArQule, with a corresponding adjustment to the remaining contractual billings for undelivered elements under the contract. We concluded that the modification was substantial enough to require evaluation of the contract to determine if EITF 00-21 applied. We concluded that because the contract does contain multiple deliverables (license to technology, research services and compound deliveries) EITF 00-21 did apply. We determined that there was not sufficient evidence of fair value of the undelivered elements (compounds), and therefore the amended contract represented a single unit of accounting for revenue recognition purposes. As a result, in Q1 2004 ArQule began treating the amended Pfizer agreement as a single unit of accounting and recognizing revenue based on the delivery and acceptance of compounds against the contractual compound delivery schedule.

On April 2, 2004, ArQule announced an alliance with Hoffmann-La Roche (Roche) to discover and develop drug candidates targeting the E2F biological pathway. The alliance includes a compound which is currently in phase 1 clinical development. Under the terms of the 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 payments, plus royalties based on net sales. Additionally, ArQule has the option to co-promote products in the U.S. ArQule considers the development portion of the arrangement to be a single unit of accounting under EITF 00-21 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, although this period may ultimately be shorter depending upon the outcome of the development work, which would result in accelerated recognition of the development revenue. Milestone and royalty payments will be recognized as revenue when earned. The cost associated with satisfying the Roche contract is included in research and development expense in the Consolidated Statement of Operations.

Results of Operations

Three months (Q3) and nine months ended September 30, 2004 and 2003:

Revenue

			Increase/(Decrease)	
	2004	2003	$	%
	(In millions)			
For the three months ended September 30:				
Revenue	$14.6	$16.0	$(1.4)	(9)%
For the nine months ended September 30:				
Revenue	$40.4	$47.1	$(6.7)	(14)%

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The decrease in total revenue in the third quarter of 2004 compared to the third quarter of 2003 primarily reflects (a) no compound development revenue in 2004 from Bayer under a contract which ended in the third quarter 2003, compared to $2.2 million in Q3 2003, and (b) no compound delivery revenue from Sankyo under a contract which ended June 30, 2004, compared to $0.9 million in Q3 2003. These decreases were partially offset by the Q3 2004 recognition of $1.7 million of research and development revenue related to the strategic alliance agreement with Roche. The decrease in revenue for the nine months ended September 30, 2004 compared to the same period of 2003 is due to reductions in compound development revenue from Bayer of $6.8 million, Sankyo of $1.0 million and Pharmacia of $0.8 million as the result of contracts which ended at various times in 2003 and 2004, and a reduction of revenue from Pfizer of $2.6 million resulting from the February 2004 amendment to the collaborative agreement. These decreases were partially offset by the receipt of a milestone payment from Wyeth resulting from the filing of an investigative new drug application with the U.S. Food and Drug Administration for a compound whose discovery was facilitated by a collaborative program with ArQule, and the inclusion of $3.3 million of research and development revenue from Roche. We expect compound development revenue to decrease in 2004 as a result of the amended Pfizer agreement and the completion of the Bayer, Sankyo and Pharmacia contracts, but to be partially offset by the inclusion of research and development revenue from Roche.

Cost of revenue compound development

			Increase/(Decrease)	
	2004	**2003**	**$**	**%**
			(In millions)	
For the three months ended September 30:				
Cost of revenue compound development	$ 7.8	$ 8.9	$(1.1)	(12)%
Compound development gross margin %	39.6%	44.4%	n/a	(4.8)% pts
For the nine months ended September 30:				
Cost of revenue compound development	$23.8	$27.1	$(3.2)	(12)%
Compound development gross margin %	35.7%	42.5%	n/a	(6.8)% pts

Cost of revenue decreased in the three and nine months ended September 30, 2004 compared to the same periods of 2003 due to reduced material and supply costs necessary to satisfy the Bayer, Sankyo and Pharmacia programs, which ended at various times in 2003 and 2004, lower depreciation charges resulting from reduced capital spending in new equipment and a lower depreciable basis in existing capital equipment, and a reduction in personnel dedicated to compound development as a result of the amended Pfizer collaborative agreement and the corporate restructuring in the first quarter of 2004 (See Restructuring actions below). Compound development gross margin percentages were lower in the three and nine months ending September 30, 2004 compared to the same periods last year due partially to higher gross margins in the 2003 periods as a result of the recognition of deferred revenue from Bayer at the end of that contract for which the associated costs were incurred in prior years and partially to the lower overall level of revenue in 2004 available to offset fixed overhead and facility-related expenses. We anticipate cost of revenue in 2004 will continue to be lower than 2003 based on the lower revenue levels.

Research and development

			Increase/(Decrease)	
	2004	**2003**	**$**	**%**
			(In millions)	
For the three months ended September 30:				
Research and development	$ 5.0	$ 4.7	$0.3	6%
For the nine months ended September 30:				
Research and development	$14.7	$12.9	$1.8	14%

The increase in research and development expense in the three and nine months ended September 30, 2004 compared to the comparable periods of 2003 reflects the hiring of additional scientists, increased laboratory and facility expenses, and the cost of preclinical and clinical studies to further develop the

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Company s E2F program and other cancer programs. At September 30, 2004, we had approximately 66 employees dedicated to our research and development program, up from 47 at December 31, 2003 and 44 at September 30, 2003. We expect research and development expenses to continue to increase throughout 2004 as we expand our oncology discovery pipeline and begin preclinical and clinical trials as part of the development process.

Marketing, general and administrative

			Increase/(Decrease)	
	2004	2003	$	%
			(In millions)	
For the three months ended September 30:				
Marketing, general and administrative	$2.1	$2.3	(0.2)	(10)%
For the six months ended September 30:				
Marketing, general and administrative	$6.9	$7.2	(0.2)	(3)%

Marketing, general and administrative expenses decreased slightly in the three and nine months ended September 30, 2004 compared to the comparable periods of 2003. In February 2004, we eliminated 16 administrative positions as part of our restructuring actions to reallocate resources to our oncology and drug discovery efforts. The cost savings associated with these personnel reductions were partially offset by increased legal expenses related to the negotiation of the alliance agreement with Roche in the first quarter of 2004 and increased costs associated with protecting our intellectual property.

Restructuring actions

In the first quarter of 2004, we implemented a restructuring to shift resources from our chemical technologies business to our internal cancer therapy research. The restructuring included the termination of 53 staff and managerial employees, or approximately 18% of the workforce, in the following areas: 30 in chemistry production positions, 7 in chemistry-based research and development positions and 16 in administrative positions. The Company anticipates annualized saving of approximately $4.4 million associated with the terminations. In connection with these actions we recorded a restructuring charge of $1.1 million in the first quarter of 2004 for termination benefits.

In connection with a restructuring in December 2002, we recorded a restructuring charge related to the closure of our facility in Redwood City, California. As of December 31, 2003 we had a remaining accrual of $6.2 million that primarily represented the remaining lease payments on our primary lease obligation less an estimate of sublease income. In the third quarter of 2004, we entered into a sublease for the California facility with Threshold Pharmaceuticals, Inc. The term of the sublease extends through 2010, the remaining term of the Company s primary lease obligation. As a result of signing the sublease, we reassessed the remaining restructuring accrual and, since the sublease was on terms more favorable than previously estimated, we recorded a $1.5 million restructuring credit in the third quarter of 2004.

Year-to-date activity against the restructuring accrual (which is included in accrued liabilities in the Consolidated Balance Sheet) was as follows (in thousands):

	Balance as of December 31, 2003	2004 Provisions/ (Credits)	2004 Payments	Balance as of September 30, 2004
Termination benefits	$ 10	$ 1,072	$(1,082)	$
Facility-related	6,160	(1,496)	(1,024)	3,640
Other charges	69		(69)	
Total restructuring accrual	$6,239	$ (424)	$(2,175)	$3,640

As of September 30, 2004, all employee termination benefits have been paid. The facility-related accrual, which is primarily comprised of the difference between the Company s lease obligation for its California

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facility and the amount of sublease payments it will receive under its sublease agreement with Threshold Pharmaceuticals, Inc., will be paid out through 2010.

Net investment income

			Increase/(Decrease)	
	2004	2003	$	%
	(In millions)			
For the three months ended September 30:				
Net investment income	$0.3	$0.2	$0.2	111%
For the nine months ended September 30:				
Net investment income	$0.7	$0.4	$0.3	65%

The increase in net investment income reflects reduced interest expense due to lower outstanding debt principal and higher investment yields on marketable securities.

Net income (loss)

			Increase/(Decrease)	
	2004	2003	$	%
	(In millions)			
For the three months ended September 30:				
Net income (loss)	$ 1.5	$(29.9)	$31.4	na
For the nine months ended September 30:				
Net income (loss)	(3.9)	$(29.6)	$25.7	87%

The improvements in net income (loss) in the three and nine months ended September 30, 2004 compared to the same periods of 2003 are due to the $30.4 million write-off of in-process research and development in Q3 2003 associated with the Company s acquisition of Cyclis, and the $1.5 million restructuring credit in Q3 2004 associated with subleasing the Company s California facility on more favorable terms than previously estimated. Excluding these factors, results in the 2004 periods were less profitable than the comparable 2003 periods due to the lower compound development revenue in 2004, increased research and development spending and the restructuring charge in the first quarter of 2004, partially offset by 2004 research and development revenue.

Item 3. ***Quantitative and Qualitative Disclosures About Market Risk***

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 is held for trading purposes. We invest our cash primarily in money market mutual funds and U.S. Government 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 creditworthiness of investments. Due to the conservative nature of these policies, we do not believe we have material exposure from market risk.

Our use of derivative financial instruments is limited to the utilization of interest rate swap agreements. Any differences paid or received on interest rate swap agreements are recognized as adjustments to interest expense over the life of each swap, thereby adjusting the effective interest rate of the underlying obligations. There were no such agreements outstanding on September 30, 2004.

See Notes 2 and 12 to the consolidated financial statements in ArQule s 2003 Annual Report on Form 10-K filed March 12, 2004 for a description of our use of derivatives and other financial instruments. The carrying amounts reflected in the consolidated balance sheet of cash and cash equivalents, trade receivables, and trade payables approximate fair value at September 30, 2004 due to the short-term maturities of these instruments.

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Item 4. ***Controls and Procedures***

Under the supervision and with the participation of the Company s President and Chief Executive Officer and Chief Financial Officer (its principal executive officer and principal accounting and financial officer), the Company has evaluated the effectiveness of the design and operation of its disclosure controls and procedures. Based on that evaluation, the President and Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures are effective as of September 30, 2004. There were no changes in the Company s internal controls and procedures over financial reporting during the quarter ended September 30, 2004 that have materially affected, or are reasonably likely to materially affect, the internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. ***Legal Proceeding.***

This information as set forth in Note 6 of Notes to Consolidated Financial Statements, appearing in Item 1 of Part 1 of this report is incorporated herein by reference.

Item 2. ***Changes in 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.***

31.1	Rule 13a-14 (a) Certificate of Chief Executive Officer
31.2	Rule 13a-14 (a) Certificate of Chief Financial Officer
32	Rule 13a-14 (b) Certificate of Chief Executive Officer and Chief Financial Officer

Through its website at www.arqule.com, the Company makes available, free of charge, its annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and all amendments thereto, as soon as reasonably practicable after such reports are filed with or furnished to the Securities and Exchange Commission.

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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.

/s/ LOUISE A. MAWHINNEY

Louise A. Mawhinney
Vice President, Chief Financial Officer and Treasurer

Date: November 8, 2004