ARQULE INC
Form 10-Q
November 12, 2003

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, 2003 **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 ý NO o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

YES ý NO o

Number of shares outstanding of the registrant s Common Stock as of November 12, 2003:

Common Stock, par value $.01 28,080,838 shares outstanding

ArQule, Inc.

Quarter Ended September 30, 2003

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Consolidated Balance Sheet (Unaudited)

(In thousands, except share data)

	September 30, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,731	$ 40,283
Marketable securities	40,667	45,343
Accounts receivable	1,379	126
Prepaid expenses and other current assets	1,923	2,545
Total current assets	77,700	88,297
Property and equipment, net	47,690	51,516
Other assets	5,312	5,266
	$ 130,702	$ 145,079
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 12,981	$ 16,207
Current portion of long-term debt	6,452	7,350
Deferred revenue	4,092	10,564
Total current liabilities	23,525	34,121
Long-term debt, net of current portion	2,470	6,850
Deferred revenue	16,338	10,393
Total liabilities	42,333	51,364
Stockholders equity:		
Common stock, $0.01 par value; 50,000,000 shares Authorized; 28,014,163 and 21,373,848 shares Issued and outstanding at September 30, 2003 and December 31, 2002, respectively	280	214
Additional paid-in capital	267,456	243,285
Accumulated other comprehensive income	(160)	(199)
Accumulated deficit	(179,207)	(149,585)
Total stockholders equity	88,369	93,715
	$ 130,702	$ 145,079

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

ArQule, Inc.

Consolidated Statement of Operations (Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenue:				
Compound development revenue	$ 15,961	$ 15,959	$ 47,096	$ 45,192
Compound development revenue - related party		500		1,466
Total revenue	15,961	16,459	47,096	46,658
Costs and expenses:				
Cost of revenue	8,878	9,164	27,069	25,818
Cost of revenue - related party		200		620
Research and development	4,726	8,064	12,860	24,434
Marketing, general and administrative	2,349	3,444	7,165	10,268
Stock-based compensation		468		2,660
Amortization of intangibles		845		2,530
Restructuring credit	(290)		(290)	
In-process research and development	30,359		30,359	
Total costs and expenses	46,022	22,185	77,163	66,330
Loss from operations	(30,061)	(5,726)	(30,067)	(19,672)
Net investment income	152	258	445	902
Net loss	$ (29,909)	$ (5,468)	$ (29,622)	$ (18,770)
Basic and diluted net loss per share	$ (1.22)	$ (0.26)	$ (1.28)	$ (0.89)
Weighted average common shares outstanding:				
Basic and diluted	24,536	21,205	23,213	21,156

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

ArQule, Inc.

Consolidated Statement of Cash Flows (Unaudited)

(In thousands)

	Nine Months Ended September 30, 2003	2002
Increase (Decrease) in Cash and Cash Equivalents		
Cash flows from operating activities:		
Net loss	$ (29,622)	$ (18,770)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	7,070	7,295
Amortization of deferred compensation		2,787
Amortization of intangible assets		2,530
Purchase of in-process research and development	30,359	
Changes in operating assets and liabilities:		
Accounts receivable	(1,250)	(42)
Prepaid expenses and other current assets	675	(599)
Other assets		100
Accounts payable and accrued expenses	(5,994)	(920)
Deferred revenue	(527)	5,227
Net cash provided by (used in) operating activities	711	(2,392)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(53,535)	(17,968)
Proceeds from sale or maturity of marketable securities	58,161	54,036
Acquisition, net of cash acquired	(7,014)	
Additions to property and equipment	(1,968)	(7,340)
Net cash provided by (used in) investing activities	(4,356)	28,728
Cash flows from financing activities:		
Borrowing of long-term debt		1,622
Principal payments of long-term debt	(8,183)	(5,625)
Proceeds from issuance of common stock	5,307	879
Net cash used in financing activities	(2,876)	(3,124)
Effect of foreign exchange rates on cash and cash equivalents	(31)	32
Net increase (decrease) in cash and cash equivalents	(6,552)	23,244
Cash and cash equivalents, beginning of period	40,283	43,260
Cash and cash equivalents, end of period	$ 33,731	$ 66,504

Supplemental disclosure of non-cash activities:

Net assets and liabilities assumed in Cyclis Pharmaceuticals, Inc acquisition, See Note 7.

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

ArQule, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Nature of Operations

We are a biotechnology company engaged in the discovery and development of novel drugs for the treatment of cancer and inflammation. By combining our expertise in small-molecule chemistry, intelligent drug design and novel biology we aim to develop therapies that are more effective and less toxic than traditional cancer treatments. The acquisition of Cyclis Pharmaceuticals (Cyclis) in early September 2003 (see Note 7) enabled us to apply a unique approach to generating anti-cancer therapeutics through the Activated Checkpoint Therapy™ (ACT™) platform. ACT™ compounds are intended to selectively kill cancer cells by restoring and activating cellular checkpoints while sparing normal cells. Our oncology portfolio consists of our lead clinical candidate, ARQ 501 (formerly designated CO 501) and several discovery programs based on the ACT™ technology. We are also pursuing an internal drug discovery program to develop compounds that inhibit p38 MAP kinase, an enzyme involved with inflammatory disease.

Since inception, ArQule has provided collaborators and customers chemistry services for their discovery programs, and will continue to do so. Specifically, we apply our expertise in the design, production, and evaluation of chemical compounds that have the potential to become medicines. For example, we generate libraries, or large collections, of potential drug candidates, assess the drug likeness of candidates and select the most promising candidates, all using high throughput, automated chemistry. Our collaboration agreements involve several pharmaceutical companies, including Pfizer, Inc., Bayer AG, Solvay Pharmaceuticals B.V., Sankyo Company, Ltd and Novartis Biomedical Research Institute.

We are subject to risks common to companies in the biotechnology, medical services and diagnostics industries, including but not limited to, development by the company or our competitors of new technological innovations, 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 United States 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, 2002 included in our annual report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2003. The unaudited consolidated financial statements

include, in the opinion of management, all adjustments (consisting only of normal recurring adjustments) necessary to present fairly our financial position as of September 30, 2003, and the results of our operations for the three and nine months ended September 30, 2003 and 2002. The results of operations for such interim periods are not necessarily indicative of the results to be achieved for the full year. The results of the acquired Cyclis operations and the estimated fair value of the assets acquired and liabilities assumed are included in the financial statements from the date of acquisition.

3. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income. Other comprehensive income includes certain changes in stockholders equity that are excluded from net loss, including unrealized gains and losses on our available-for-sale securities and interest rate swaps and foreign currency translation amounts. Total comprehensive loss for three and nine months ended September 30, 2003 and 2002 consisted of the following (in thousands):

	Three Months Ended September 30		Nine months Ended September 30	
	2003	2002	2003	2002
Net loss	$ (29,909)	$ (5,468)	$ (29,622)	$ (18,770)
Unrealized gain (loss) on marketable securities and interest rate swaps	16	24	93	(7)
Foreign currency translation adjustments	(2)	32	(54)	82
Comprehensive loss	$ (29,895)	$ (5,412)	$ (29,583)	$ (18,695)

4. Restructuring Charge

In December 2002, we recorded restructuring charges of $12.7 million in connection with our decision to cease further development and commercialization of our *in silico* predictive models and realign our workforce to expedite the transition towards becoming a drug discovery and development company. The restructuring actions included closing our facilities in Redwood City, California (effective December 31, 2002) and Cambridge, United Kingdom (effective March 31, 2003), along with the termination of employees in these facilities and certain employees in our Massachusetts facilities. The components of the restructuring charges included: $2.1 million associated with the elimination of 128 managerial and staff positions worldwide; $5.8 million related to the remaining lease payment obligations associated with the closing of our facilities in Redwood City, California and Cambridge, United Kingdom, net of assumed sublease income; $3.8 million associated with the non-cash write-off of leasehold improvements and equipment no longer expected to provide future economic benefits at the closed facilities; and $900,000 of other charges primarily related to contractual obligations that no longer provide future value to the Company and other costs associated with closing the California and United Kingdom operations.

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, 2002	2003 Provisions/ Credits	2003 Payments	Balance as of September 30, 2003
Termination benefits	$ 2,029	$	$ (2,014)	$ 15
Facility related	6,285	(290)	(1,065)	4,930
Other charges	436		(365)	71
Total restructuring accrual	$ 8,750	$ (290)	$ (3,444)	$ 5,016

As of September 30, 2003, all employee terminations are complete and all remaining termination benefits will be paid out by December 31, 2003. California facility costs will be paid out through the remaining lease term of the facility, which extends through 2010, unless we are able to mitigate such costs by subleasing the facility or settling our leasehold position by paying a lump-sum payment to the landlord. During the quarter, ArQule reversed $290,000 of restructuring accrual to reflect a change in its original estimate of the remaining leasehold obligations and assumed sublease income in the United Kingdom.

In October 2003, ArQule completed an agreement with InPharmatica Ltd. to sell certain assets of its former operations in the United Kingdom and to assign its facility lease obligation.

5. Net Loss Per Share

The computations of basic and diluted net 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. Options to purchase 3,936,965 and 4,080,380 shares of common stock were not included in the September 30, 2003 and September 30, 2002 three and nine month computations of diluted net loss per share, respectively, because inclusion of such shares would have an anti-dilutive effect on net loss per share.

We apply Accounting Principles Board No. 25, *Accounting for Stock Issued to Employees*, 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 Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, our pro forma net loss and pro

forma basic and diluted net loss per share would have been as follows (in thousands, except per share data):

	Three months ended September 30		Nine months ended September 30	
	2003	2002	2003	2002
Net loss:				
Net loss reported	$ (29,909)	$ (5,468)	$ (29,622)	$ (18,770)
Add: Stock based employee compensation expense included in reported net loss		485		2,784
Less: Total stock-based employee compensation under the fair value method of SFAS 123	(649)	(1,271)	(5,125)	(9,154)
Pro forma net loss	$ (30,558)	$ (6,254)	$ (34,747)	$ (25,140)
Basic and diluted net loss per share:				
As reported	$ (1.22)	$ (0.26)	$ (1.28)	$ (0.89)
Pro forma	$ (1.25)	$ (0.29)	$ (1.50)	$ (1.19)

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 2002 and 2003; risk-free interest rates of 3.85% in 2002 and 2003; and expected lives of five years for 2002 and 2003 for options granted.

6. Contingencies

Medford Lease

ArQule leases approximately 56,000 square feet of laboratory and office space in Medford, Massachusetts, the majority of which is used for the Pfizer collaboration. The Company leases 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. The Company subleases portions of this facility pursuant to two sublease agreements.

On August 1, 2001, Cummings raised ArQule s rent significantly on the lease that expires July 30, 2006. The Company believes this increase to be in excess of that which is permissible under the lease agreement. Accordingly, on January 16, 2002, the Company 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, the Company is paying the rental rates proposed by Cummings. The Company seeks recovery of the funds that it has already paid, and is paying, under protest. If the Company is unsuccessful in its claim against Cummings and must pay all or a portion of the rental expense increase currently proposed by Cummings, it may be required to record an additional expense of up to approximately $800,000 to reflect the difference between its contractual rental payments and contractual subcontract rental income over the remaining period of the lease.

Investment

In July 2001, the Company purchased an 8% ownership share in a privately held proteomics company for $5 million (the Investment). ArQule s ownership interest contains anti-dilution rights designed to protect the Company s investment value in the event the proteomics company raises additional equity financing; however, there can be no assurance that such rights will not be renegotiated in the future. The Company is accounting for the Investment under the cost method since the Company does not exert significant influence in the Investment. ArQule assesses its investments for impairment each quarter, and if an investment is other than temporarily impaired, ArQule will write the investment down to its fair value and record a corresponding impairment charge. The Investment, which continues to be carried at cost, is included in other assets in the Consolidated Balance Sheet.

7. Acquisition of Cyclis Pharmaceuticals, Inc.

On September 8, 2003, ArQule acquired all of the outstanding securities of Cyclis Pharmaceuticals, Inc. (Cyclis), a privately held, development stage cancer-therapeutics company based in Norwood, Massachusetts, in a transaction accounted for as a purchase business combination. At that time, Cyclis was merged with and into ArQule and Cyclis ceased to exist as a separate entity. Pursuant to the terms of the acquisition agreement, ArQule issued approximately 4.6 million shares of common stock, paid cash of $5 million and forgave notes receivable of $500,000. ArQule incurred consulting, legal, accounting and other third-party costs of approximately $1.6 million in order to close the transaction. The shares issued were valued at $18.8 million based on the Company s share price on the measurement date of acquisition, resulting in a total purchase price of $25.9 million. The results of the acquired Cyclis operations

and the estimated fair value of the assets acquired and liabilities assumed are included in the financial statements from the date of acquisition.

The purchase price was allocated to the identifiable tangible and intangible assets acquired and liability assumed based on the Company s estimates of fair value at the acquisition date. The purchase price exceeded the amounts allocated to the identifiable tangible and intangible assets acquired and liabilities assumed by approximately $17.1 million. Since Cyclis was a development stage enterprise it is not considered a business under Emerging Issues Task Force No. 98-3, and therefore the excess purchase price cannot be allocated to goodwill. Consequently, the excess purchase price was allocated on a pro rata basis to the carrying value of the acquired long-lived assets, resulting in a step-up in basis of property and equipment and in-process research and development (IPR&D) of $700,000 and $16.4 million, respectively.

The following table shows the allocation of the purchase price to acquired assets and liabilities for the acquisition of Cyclis (in thousands):

Current assets	$	52
Property, plant and equipment		1,297
IPR&D		30,359
Other assets		46
Current liabilities		(3,081)
Long-term debt		(2,734)
	$	25,939

Approximately $14 million of the purchase price represents the estimated fair value of the purchased IPR&D (before the aforementioned step-up adjustment) that had not yet reached technical feasibility and had no alternative future use. Accordingly, the carrying value of the IPR&D, including the step-up adjustment, was immediately expensed in the consolidated statement of operations upon the acquisition date. The value assigned IPR&D was composed of the projected value of three Cyclis pre-clinical drug development projects based on the ACT™ technology. The valuation was determined using the income approach. Potential revenue and drug development expenses were projected through 2020 based on information obtained from management and from published third-party industry statistics for similar drug development businesses. The Company estimates that the development of these acquired projects through clinical trials to commercial viability will take approximately nine years and cost in excess of $500 million. The discounted cash flow method was applied to the projected cash flows, adjusted for the probability of success, using a discount rate of 30%. The discount rate takes into consideration the uncertainty surrounding successful development and commercialization of the IPR&D. Management is responsible for the assumptions used to determine the estimated fair value of IPR&D.

8. Recent Accounting Pronouncements

In November 2002, the Financial Accounting Standards Board (FASB) issued Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. FIN 45 does not prescribe a specific approach for subsequently measuring the guarantor s recognized liability over the term of the related guarantee. It also incorporates without change, the guidance in FASB Interpretation No. 34, *Disclosure of Indirect Guarantees of Indebtedness of Others*, which is being superseded. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor s fiscal year-end. The disclosure requirements in FIN 45 are effective for financial statements of interim or annual periods ending after December 15, 2002. The Company s adoption of FIN 45 did not have a material impact on its financial position, results of operations or cash flows.

In January 2003, the FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51* (FIN 46). The primary objective of FIN 46 is to provide guidance on the identification of, and financial reporting for, entities over which control is achieved through means other than voting rights; such entities are known as variable-interest entities (VIEs). FIN 46 applies immediately to new entities that are created or obtained after January 31, 2003. FIN 46 is effective to entities created before February 1, 2003 at the end of the first interim or annual period beginning after December 15, 2003. FIN 46 will be the guidance that determines (1) whether consolidation is required under the controlling financial interest model of Accounting Research Bulletin No. 51, Consolidated Financial Statements, or (b) other existing authoritative guidance, or, alternatively, (2) whether the variable-interest model under FIN 46 should be used to account for existing and new entities. The Company is evaluating the impact of FIN 46 on its financial statements.

In May 2003, the FASB issued SFAS 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS150). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after September 15, 2003. The adoption of SFAS 150 is not expected to have a material effect on the Company s financial statements.

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

OVERVIEW

Since our inception we have provided fee-based chemistry services to pharmaceutical and biotechnology companies to produce and develop novel chemical compounds with commercial potential. In 1999, we began moving the Company s business model toward drug discovery and development, where in addition to our chemistry services business we have been pursuing internal drug discovery programs with the purpose of generating drug-like compounds.

On September 8, 2003, ArQule acquired Cyclis Pharmaceuticals (Cyclis), an early-stage cancer therapeutics company. This acquisition enabled us to forward integrate into a therapeutic area, oncology, and focus our strategy on discovering and developing small-molecule anti-cancer drugs based on a unique proprietary technology platform called the Activated Checkpoint Therapy™ (ACT™) platform. ACT™ compounds are intended to kill cancer cells selectively and spare normal cells by restoring and activating cellular checkpoints that are defective in cancer cells. Preclinical results indicate that by using ACT™ compounds, cancer cells should be effectively and selectively targeted. In contrast to other approaches, ACT™ compounds are selective for cancer cells. We are hopeful that drugs based on ACT™ compounds will demonstrate the potential to be better tolerated by patients than traditional chemotherapies while retaining broad-spectrum activity against multiple types of cancer.

The Cyclis acquisition provided us with a near-term clinical candidate, for which an Investigational New Drug application (IND) has been filed with the U.S. Food and Drug Administration. On September 29, 2003, we commenced the first Phase 1 clinical trial on this compound, ARQ 501 (formerly designated CO-501). Our oncology discovery pipeline consists of several programs that target different ACT™ mechanisms and increased our biology expertise through the addition of 14 scientists including Dr. Chiang Li, the inventor and co-developer of the ACT™ platform. Dr. Li is now ArQule s Chief Scientific Officer and Vice President, Head of ArQule s Biomedical Institute.

In addition to the cancer programs we plan to pursue, we have an internal drug discovery program in inflammation. This program focuses on developing small-molecule compounds that inhibit p38 MAP kinase, an enzyme involved with inflammatory disease. We have used our expertise in high-throughput automated chemistry, intelligent design of molecules, and experimental and predictive ADME analysis in a parallel process to generate compounds that have an optimal balance of drug-like properties. These compounds, called Optimal Chemical Entity (OCE) compounds are based on target criteria for potency, selectivity, absorption, *in vivo* pharmacokinetics and functional activity. During the quarter, we advanced one compound, an OCE compound named ARQ 101, into pilot toxicity studies, where acute toxicity, dose-range finding toxicity, genotoxicity and pharmacokinetics characteristics were examined. Based on results from these studies, ARQ 101 has been nominated as ArQule s first wholly owned GLP toxicity candidate. We plan to commence GLP-tox studies by the end of this year.

In addition to building a portfolio of small molecule therapeutics for oncology and inflammation, we intend to continue our chemistry services business. In this area we will continue to provide a high level of service and commitment to our existing collaborators, Pfizer, Solvay, Sankyo and Novartis Biomedical Research Institute, while we use our chemistry expertise and unique technology platform to extend existing or enter new collaborations.

Historically we have generated revenues through such collaborative agreements for production and delivery of compound arrays and other research and development services. Under many of these collaborative agreements we also are entitled to receive milestone and royalty payments if our customer develops products resulting from the collaboration. To date, we have received three milestone payments and no royalty payments. We have not yet received any milestone or royalty revenue from our joint discovery programs with biotechnology companies or academic institutions, or from our internal drug discovery programs. We anticipate our revenues will continue to decrease in 2003 compared to 2002 as we intensify our transition to become a drug discovery and development company. We do not anticipate any revenue from our internal drug discovery programs, if ever, until at earliest the commencement of clinical trials. Our performance may vary from expectations, including quarterly variations in performance, because levels of revenue are dependent on our expanding or continuing existing collaborations, entering into additional corporate collaborations, or receiving future milestones and royalty payments, all of which are difficult to anticipate. See the discussion of our revenue recognition policy in the Critical Accounting Policies contained in the Company s annual report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2003.

As we further our transition to a drug discovery and development company, we may need to supplement our focus in the therapeutic areas of oncology and inflammation by acquisition, in-licensing and/or developing internal expertise. Such transactions could allow us to move more quickly toward developing additional candidates for clinical trials. We may also continue to invest in technology to enhance or expand our capabilities in drug discovery. Investments of this nature may result in near-term earnings fluctuations or impact the magnitude of profitability or loss.

We have incurred a cumulative net loss of $179 million from inception through September 30, 2003. Losses have resulted principally from costs incurred in research and development activities related to our efforts to develop our technologies, charges for in-process research and development, the associated administrative costs required to support those efforts, and from the cost of acquisitions. We were not profitable in 2001 or 2002, and we expect that we will not be profitable for the year ended December 31, 2003. Our ability to achieve sustained profitability is dependent on a number of factors, all of which are difficult to anticipate, including: our ability to perform under our collaborations at the expected cost; expansion or continuation of existing collaborations; timing of additional investments in technology; the cost and timing of clinical trials for our pipeline; our ability to make acquisitions and to integrate their operations with our own; and the realization of value from the development and commercialization of products in which we have an economic interest.

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 forward looking terminology such as believes , expects , intends , may , will , should , anticipates or similar 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 planned acquisitions or 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. See also the risks and uncertainties discussed in our Form 10-K for the year ended December 31, 2002 and subsequent filings with the Security and Exchange Commission, including the Form S-3 filed on October 24, 2003. As such, actual results could differ materially from those currently anticipated.

ACQUISITION OF CYCLIS PHARMACEUTICALS, INC.

On September 8, 2003, we acquired all of the outstanding securities of Cyclis, a privately held, development stage cancer-therapeutics company based in Norwood, Massachusetts, in a transaction accounted for as a purchase business combination. At that time, Cyclis was merged with and into ArQule and Cyclis ceased to exist as a separate entity. Pursuant to the terms of the acquisition agreement, we issued approximately 4.6 million shares of common stock, paid cash of $5 million and forgave notes receivable of $500,000. We incurred consulting, legal, accounting and other third-party costs of approximately $1.6 million in order to close the transaction. The shares issued were valued at $18.8 million based on our share price on the measurement date of acquisition, resulting in a total purchase price of $25.9 million. The results of the acquire Cyclis operations and the estimated fair value of the assets acquired and liabilities assumed are included in the financial statements from the date of acquisition.

Upon consummation of Cyclis acquisition, we immediately charged to income $30.4 million representing purchased in-process research and development (IPR&D) that had not yet reached technical feasibility and had no alternative future use. Approximately $14 million of the charge represents the fair value of the IPR&D. The remaining $16.4 million of the charge represents a step-up adjustment resulting from the excess of the purchase price over the identifiable tangible and intangible assets acquired and liabilities assumed which was allocated

on a pro rata basis to the carrying value of acquired long-lived assets. The value assigned IPR&D (before the aforementioned step-up adjustment) was composed of the projected value of three Cyclis pre-clinical drug development projects based on various mechanisms of actions associated with the ACT™ technology. The valuation was determined using the income approach. Potential revenue and drug development expenses were projected through 2020 based on information obtained from management and from published third-party industry statistics for similar drug development businesses. The expenditures that will be necessary to complete the clinical trials are subject to numerous uncertainties. Completion of clinical trials may take several years or more, and the estimate of time and cost to complete can be affected by factors such as the number of patients required to participate in the trials, the number of clinical sites involved in the trials, the length of time required to enroll a suitable number of patients and the type, complexity, novelty and intended use of a product. We estimate that the development of these acquired projects through clinical trials to commercial viability will take approximately nine years and cost in excess of $500 million. The discounted cash flow method was applied to the projected cash flows, adjusted for the probability of success, using a discount rate of 30%. The discount rate takes into consideration the uncertainty surrounding successful development and commercialization of the IPR&D.

If these projects are not successfully developed, the revenue and profitability of the Company may be adversely affected in future periods. We are continually monitoring our development projects. Management is responsible for the assumptions used to determine the estimated fair value of IPR&D, and we believe that these assumptions represent a reasonably reliable estimate of the future benefits attributed to purchased IPR&D. No assurance can be given that actual results will not deviate from those assumptions in the future.

RESTRUCTURING CHARGE

In December 2002, we recorded restructuring charges of $12.7 million in connection with our decision to cease further development and commercialization of our *in silico* predictive models and realign our workforce to expedite the transition towards becoming a drug discovery company. The restructuring actions included closing our facility in Redwood City, California (effective December 31, 2002) and Cambridge, United Kingdom (effective March 31, 2003), along with the termination of employees in these facilities and certain employees in our Massachusetts facilities. The components of the restructuring charges included: $2.1 million associated with the elimination of 128 managerial and staff positions worldwide; $5.8 million related to the remaining lease payment obligations associated with the abandonment of our facilities in Redwood City, California and Cambridge, United Kingdom, net of assumed sublease income; $3.8 million associated with the non-cash write-off of leasehold improvements and equipment no longer expected to provide future economic benefits at the abandoned facilities; and $0.9 million of other charges primarily related to contractual obligations that no longer provide future value to the Company and other costs associated with closing the California and United Kingdom operations.

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, 2002	2003 Provisions/ Credits	2003 Payments	Balance as of September 30, 2003
Termination benefits	$ 2,029	$	$ (2,014)	$ 15
Facility related	6,285	(290)	(1,065)	4,930
Other charges	436		(365)	71
Total restructuring accrual	$ 8,750	$ (290)	$ (3,444)	$ 5,016

As of September 30, 2003, all employee terminations are complete and all remaining termination benefits will be paid out by December 31, 2003. California facility costs will be paid out through the remaining lease term of the facility, which extends through 2010, unless we are able to mitigate such costs by subleasing the facility or settling our leasehold position by paying a lump-sum payment to the landlord. During the quarter, ArQule reversed $290,000 of restructuring accrual to reflect a change in its original estimate of the remaining leasehold obligations and assumed sublease income in the United Kingdom.

In October 2003, ArQule completed an agreement with InPharmatica Ltd. to sell certain assets of its former operations in the United Kingdom and to assign its facility lease obligation.

RESULTS OF OPERATIONS

Three months (Q3) and nine months ended September 30, 2003 and 2002:

Revenue

	2003	2002	Increase/(Decrease) $	%
	(in millions)			
For the three months ended September 30:				
Revenue	$ 16.0	$ 16.5	$ (0.5)	(3)%
For the nine months ended September 30:				
Revenue	$ 47.1	$ 46.7	$ 0.4	1%

The decrease in revenues in Q3 2003 from Q3 2002 is due to reductions in revenue from Bayer, Pharmacia and Solvay as these programs wind down, partially offset by an increase in revenue from Sankyo as ArQule made its final delivery of mapping array libraries under the terms of our contract with Sankyo. Revenues for the nine months ended September 30, 2003

increased slightly over the same period of 2002 due to increased revenues under the expanded Pfizer contract and from Bayer as a result of increased compound deliveries, partially offset by reductions in or no revenue from Solvay, GlaxoSmithKline and Wyeth as these contracts wind down and no revenue from Searle as this contract ended in Q2 2002. In Q3 2003, the Company completed its final contractual obligation to Bayer.

Cost of revenue

	2003	2002	Increase/(Decrease) $	Increase/(Decrease) %
	(in millions)			
For the three months ended September 30:				
Cost of revenue	$ 8.9	$ 9.4	$ (0.5)	(5)%
Gross margin % of revenue	44.4%	43.1%		
For the nine months ended September 30:				
Cost of revenue	$ 27.1	$ 26.4	$ 0.6	2%
Gross margin % of revenue	42.5%	43.3%		

Cost of revenue in Q3 2003 decreased in absolute dollars from Q3 2002 as a result of manufacturing yield efficiencies associated with the Pfizer collaboration which resulted in reduced material consumption and decreased spending to satisfy the Bayer collaboration due to the transition from development to production activities as the contract wound down. These reductions account for the improvement in gross margin percentage in Q3 2003 versus the prior year. For the nine months ended September 30, 2003 costs of revenue increased slightly, primarily due to increased labor, laboratory supplies, facility costs and depreciation to satisfy the Bayer and Pfizer collaborations. Gross margin percentage was lower in the nine month period ended September 30, 2003 versus the comparable 2002 period due to higher concentration of Pfizer revenue in 2003 which, due to the lower gross margin percentage associated with this contract, lowered the overall average gross margin percentage.

Research and development

	2003	2002	Increase/(Decrease) $	Increase/(Decrease) %
	(in millions)			
For the three months ended September 30:				
Research and development	$ 4.7	$ 8.1	$ (3.3)	(41)%
For the nine months ended September 30:				
Research and development	$ 12.9	$ 24.4	$ (11.6)	(47)%

The decreases in research and development in the three and nine month periods reflect the cost savings associated with the Company s decision in December 2002 to cease further development of its *in silico* predictive models and to close its facilities in Redwood City, California (effective December 31, 2002) and Cambridge, United Kingdom (effective March 31, 2003), and to realign its workforce in order to expedite its transition to a drug discovery and development company. The most significant components of the period-over-period reductions

were lower employee-related charges of $2.7 million in the three-month period and $8.3 million in the year to-date period due to the severance of 78 research and development employees. In addition, laboratory supplies and facility expenses were lower by $700,000 in Q3 2003 versus Q3 2002, and by $3.0 million for the nine-month period of 2003 versus 2002, due to the reduced research and development activities and the closure of the Redwood City and Cambridge facilities. The Company believes research and development expense will increase in 2004 as ARQ 501 continues clinical trials.

Marketing, general and administrative

	2003	2002	Increase/(Decrease) $	Increase/(Decrease) %
	(in millions)			
For the three months ended September 30:				
Marketing, general and administrative	$ 2.3	$ 3.4	$ (1.1)	(32)%
For the nine months ended September 30:				
Marketing, general and administrative	$ 7.2	$ 10.3	$ (3.1)	(30)%

The decreases in the three and nine month periods are primarily due to the severance of 31 marketing, general and administrative employees as part of the Company s restructuring actions in December 2002, and the closing of the Redwood City and Cambridge facilities. The decrease in Q3 2003 versus Q3 2002 was comprised of reductions in employee-related charges of $1.0 million and professional fees of $100,000. The decrease for the year-to-date period of 2003 versus 2002 was comprised of reductions in employee related charges of $2.1 million, professional fees of $360,000, and supply and facility related charges of $350,000.

Acquisition-related charges

	2003	2002	Increase/(Decrease) $
	(in millions)		
For the three months ended September 30:			
Acquisition-related charges	$ 30.4	$ 1.3	$ 29.0
For the nine months ended September 30:			
Acquisition-related charges	$ 30.4	$ 5.2	$ 25.2

Acquisition-related charges in 2002 pertain to the January 2001 acquisition of Camitro Corporation and are comprised of stock-based compensation and amortization of intangibles. In 2002, all remaining stock-based compensation related to the issuance of stock options below market value and restricted stock to former employees of Camitro had been either recognized, based on the vesting of the underlying security, or forfeited; therefore, there is no stock-based compensation expense in 2003. Amortization of intangibles in 2002 related to the amortization

of core technology acquired from Camitro. At December 31, 2002, the Company assessed the recoverability of its core technology balance and, based on the applicable accounting standards, recorded a full impairment charge; therefore there is no amortization of intangibles in 2003.

Acquisition-related charges in 2003 related solely to the charge for acquired in-process research and development purchased in connection with the acquisition of Cyclis in September 2003, which had not yet reached technological feasibility and had no alternative future use.

Net investment income

			Increase/(Decrease)	
	2003	2002	$	%
	(in millions)			
For the three months ended September 30:				
Net investment income	$ 0.2	$ 0.3	$ (0.1)	(41)%
For the nine months ended September 30:				
Net investment income	$ 0.4	$ 0.9	$ (0.5)	(51)%

The decrease in net investment income is due to lower interest rates and lower average principal balances of cash and marketable securities, partially offset by lower interest expense, also related to lower interest rates and reduced principal of debt outstanding.

Net loss

			Increase/(Decrease)	
	2003	2002	$	%
	(in millions)			
For the three months ended September 30;				
Net loss	$ 29.9	$ 5.5	$ 24.4	447%
For the nine months ended September 30;				
Net loss	$ 29.6	$ 18.8	$ 10.9	58%

The increase in the net losses in the 2003 periods versus the 2002 periods is due to the impact of the $30.4 million charge for purchased in-process research and development in connection with the Cyclis acquisition. This charge offset significant reductions in research and development and marketing, general and administrative expense, both of which benefited from savings that resulted from the Company s restructuring initiatives in December 2002, and the lack of acquisition-related charges related to the Camitro acquisition in 2003 compared to charges of $1.3 million and $5.2 million in the three and nine months ended September 30, 2002, respectively.

LIQUIDITY AND CAPITAL RESOURCES

	September 30, 2003	December 31, 2002	Increase/(Decrease) $	%
		(in millions)		
Cash, cash equivalents and marketable securities	$ 74.4	$ 85.6	$ (11.2)	(13.1)%
Working capital	54.2	54.2		

	Q3 YTD 2003	Q3 YTD 2002	Increase/(Decrease) $
		(in millions)	
Cash flow from:			
Operating activities	$ 0.7	$ (2.4)	$ 3.1
Investing activities	(4.4)	28.7	(33.1)
Financing activities	(2.9)	(3.1)	0.2

Cash and cash equivalents provided by operating activity for the nine months ended September 30, 2003 of $711,000 was comprised of $7.8 million of cash provided by operations excluding non-cash depreciation charges and purchased in-process research and development, partially offset by net changes in operating assets and liabilities of $7.1 million, primarily related to $6.0 million of payments of accounts payable and accrued liabilities, of which approximately $3.0 million related to liabilities assumed in the acquisition of Cyclis.

Cash used in investing activities for the nine months ended September 30, 2003 of $4.4 million was comprised of $7.0 million spent to acquire Cyclis and $2.0 million spent on capital additions, partially offset by net proceeds from the purchase, sale or maturity of marketable securities of $4.6 million. The cash cost to acquire Cyclis consisted of $5.0 million of cash purchase price, $1.5 million of consulting, legal and other professional costs to close the transaction and $500,000 of loans to Cyclis that were forgiven at closing.

Cash used in financing activities for the nine months ended September 30, 2003 of $2.9 million was comprised of principal repayments of long-term debt of $8.2 million offset by $5.3 million of proceeds from the issuance of common stock. Included in the principal repayments is $2.5 million related to long-term debt acquired from Cyclis which was repaid at closing.

We anticipate that our balances of cash, cash equivalents and marketable securities will change frequently as a result of the Company s constant evaluation of conditions in financial markets and the timing of specific investments.

The Company s future minimum lease commitments in all locations under non-cancelable operating leases for facilities and equipment as of September 30, 2003 are as follows (in thousands):

Remainder of 2003	$	668
2004		2,574
2005		2,613
2006		1,844
2007		1,100
2008		1,144
Thereafter		1,389
Total minimum lease payments	$	11,332

Included in the total minimum payments for operating leases is approximately $6.9 million related to unutilized real estate which was accrued as a liability, net of assumed sublease income, as part of the Company s restructuring charges in December 2002. The minimum lease payments will be due and payable as set forth above unless we are able to mitigate such costs by subleasing facilities or settling leasehold positions by paying our landlords lump-sum payments.

We expect that our available cash and marketable securities, together with operating revenues and investment income, will be sufficient to finance our working capital and capital requirements for the next several years. 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 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 costs associated therewith and other factors. We cannot guarantee that we will be able to obtain additional customers for our products and services, or that such products and services will produce revenues adequate to fund our operating expenses. If we experience increased losses, we may have to seek additional financing from public or 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.

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 insure 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.

Our use of derivative financial instruments is limited to the utilization of two 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. At September 30, 2003, the Company held one interest rate swap agreement which has a notional amount of $1,950,000 and expires on September 30, 2004. The fair market value of this swap at September 30, 2003 was an unrecognized loss of $55,000, and is included in accrued liabilities.

See Notes 2 and 11 to the consolidated financial statements in ArQule s 2002 Annual Report on Form 10-K filed March 31, 2003 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 approximates fair value at September 30, 2003 due to the short-term maturities of these instruments.

ITEM 4. DISCLOSURE CONTROLS AND PROCEDURES

Under the supervision and with the participation of the Company s President and Chief Executive Officer and Corporate Controller (its principal executive officer and acting principal accounting and financial officer), management has evaluated the effectiveness of the design and operation of the Company s disclosure controls and procedures. Based on the evaluation, the President and Chief Executive Officer and Corporate Controller have concluded that these disclosure controls and procedures are effective as of September 30, 2003. There were no changes in the Company s internal control over financial reporting 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(a) Exhibits.

2.2	Agreement and Plan of Reorganization by and between ArQule, Inc. and Cyclis Pharmaceuticals, Inc. dated as of July 16, 2003
2.3	Agreement and Plan of Merger by and between ArQule, Inc. and Cyclis Pharmaceuticals, Inc. dated as of July 16, 2003
10.24.10	Fourth Loan Modification Agreement between Fleet National Bank and the Company dated September 3, 2003.
10.44	Employment Agreement between the Company and Chiang J. Li, MD, dated September 5, 2003.
31.1	Certificate of Chief Executive Officer
31.2	Certificate of Acting Chief Financial Officer
32	Certificate of Chief Executive Officer and Acting Chief Financial Officer

Item 6(b) Reports on Form 8-K.

The Company filed a current report on Form 8-K on July 21, 2003 to file its press release announcing the signing of a definitive agreement to acquire Cyclis Pharmaceuticals, Inc.

The Company filed a current report on Form 8-K on August 19, 2003 to refile certain exhibits subject to a request for confidential treatment.

The Company filed a current report on Form 8-K on September 17, 2003 filing its press release announcing the completion of the acquisition of Cyclis.

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.

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 12, 2003 /s/ Thomas J. Phair, Jr.
Thomas J. Phair, Jr.
Corporate Controller (Acting Principal Accounting and Financial Officer)