

AEROGEN INC
Form 10-Q
May 11, 2001

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2001

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 0-31913

Aerogen, Inc.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

33-0488580

(I.R.S. Employer Identification No.)

1310 Orleans Drive, Sunnyvale, CA

(Address of principal executive offices)

94089

(zip code)

Registrant's telephone number, including area code: (408) 543-2400

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 ☒ No ☐

As of April 30, 2001 there were 19,989,908 shares of the Registrant's Common Stock outstanding, par value \$0.001 per share.

Aerogen, Inc.
(a company in the development stage)
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Part I. Financial Information

Item 1. Financial Statements

Aerogen, Inc.
(a development stage company)
Condensed Consolidated Balance Sheets
(unaudited; in thousands)

	March 31, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	\$40,968	\$48,810
Available-for-sale securities	15,992	12,166
Accounts receivable	851	762
Prepaid expenses and other current assets	1,099	1,201
Total current assets	58,910	62,939
Property and equipment, net	1,902	1,905
Goodwill and other intangible assets, net	1,614	1,823
Other assets	45	45
Total assets	\$62,471	\$66,712

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$725	\$915
Accrued liabilities	1,952	1,135
Deferred revenues	248	250
Total current liabilities	2,925	2,300
Other long-term liabilities		
	172	184
Total liabilities	3,097	2,484
Stockholders' equity:		
Common stock	20	20
Additional paid-in capital	110,349	110,692
Notes receivable from stockholders	(672)	(665)
Deferred stock-based compensation, net	(5,428)	(6,095)
Accumulated other comprehensive income (loss)	(107)	15
Deficit accumulated during development stage	(44,788)	(39,739)
Total stockholders' equity	59,374	64,228
Total liabilities and stockholders' equity	\$62,471	\$66,712

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

Aerogen, Inc.
(a development stage company)
Condensed Consolidated Statements of Operations
(unaudited; in thousands, except per share data)

	Three Months Ended March 31,	
	2001	2000
Revenues:		
Research and development revenues	\$609	\$1,139
Royalty, fee and other revenues	66	
Total revenues	675	1,139
Operating expenses:		
Research and development	5,012	2,937
General and administrative	1,520	928
Total operating expenses	6,532	3,865
Loss from operations	(5,857)	(2,726)
Interest income, net	808	88

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Net loss	\$(5,049)	\$(2,638)
Net loss per common share, basic and diluted	\$(0.26)	\$(1.28)
Shares used in computing net loss per common share, basic and diluted	19,466	2,054

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

Aerogen, Inc.
(a development stage company)
Condensed Consolidated Statements of Cash Flows
(unaudited; in thousands)

	Three Months Ended March 31,	
	2001	2000
Cash Flows From Operating Activities:		
Net loss	\$(5,049)	\$(2,638)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	398	147
Amortization of deferred stock-based compensation	326	63
Accrued interest on notes receivable from stockholders	(7)	(5)
Changes in assets and liabilities:		
Accounts receivable	(90)	19
Prepaid expenses and other current assets	103	(56)
Accounts payable	(189)	172
Accrued liabilities	817	489
Deferred revenue	(2)	99
Net cash used in operating activities	(3,693)	(1,710)
Cash Flows From Investing Activities:		
Acquisition of property and equipment	(187)	(340)
Purchases of available-for-sale securities	(12,118)	-
Proceeds from maturities of marketable investments	8,300	18
Net cash used in investing activities	(4,005)	(322)
Cash Flows From Financing Activities:		
Proceeds from issuance of convertible preferred stock, net	-	2,465
Proceeds from issuance of common stock	6	27
Repurchase of common stock	(8)	-
Repayment of notes payable	-	(77)
Net cash provided by (used in) financing activities	(2)	2,415
Effect of exchange rates on cash	(142)	-
Net increase (decrease) in cash and cash equivalents	(7,842)	383
Cash and cash equivalents, at beginning of the period	48,810	1,822

Cash and cash equivalents, at end of the period	\$40,968	\$2,205
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The accompanying notes are an integral part of these condensed consolidated financial statements.

AEROGEN, INC.
(a development stage company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business of the Company

Aerogen, Inc., formerly Fluid Propulsion Technologies, Inc. (the Company or Aerogen), was incorporated in November 1991 to develop products using a proprietary aerosol generator.

The Company is in the development stage and since inception has devoted substantially all of its efforts to developing its products, including engaging in research and development activities with and without partners, raising capital, and recruiting personnel. The Company has incurred net losses since inception and is expected to incur substantial losses for the next several years. To date, the Company has funded its operations primarily through the sale of equity securities, payments from partners, and interest income.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements of Aerogen have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10-01 of Securities and Exchange Commission Regulation S-X. Accordingly, they do not contain all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying unaudited, condensed consolidated financial statements reflect all adjustments (consisting of normal, recurring adjustments) considered necessary for a fair presentation of the Company's interim financial information. These financial statements and notes should be read in conjunction with the audited financial statements and notes thereto of the Company included in the Company's Annual Report on Form 10-K for the year ended December, 31, 2000.

The results of operations for the three months ended March 31, 2001 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2001 or for any other future period.

Basis of consolidation

In May 2000, the Company acquired Cerus, Ltd. which is now Aerogen (Ireland) Limited, a wholly owned subsidiary of the Company. The consolidated financial statements include the accounts of the Company and its subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents include money market and deposit accounts.

Available-for-sale securities

All investments are classified as available-for-sale and therefore are carried at fair market value. Unrealized gains and losses on such investments are reported as a separate component of stockholders' equity. Realized gains and losses on sales of all such investments are reported in earnings and computed using the specific identification cost method.

Revenue recognition

Research and development revenues are earned under agreements with third parties for contract research and development activities and are recorded as the related expenses are incurred, up to contractual limits. Charges to these third parties are based upon negotiated rates for full time equivalent employees of the Company, and such rates are intended to approximate the Company's anticipated costs. Payments received that are related to future performance are recorded as deferred revenue and recognized as revenues as they are earned. None of the revenues

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recognized to date are refundable if the relevant research effort is not successful.

Royalty revenues are recorded as earned. Fee and other revenues are recorded in accordance with Staff Accounting Bulletin No. 101 (SAB No. 101), Revenue Recognition in Financial Statements .

Research and development expenses

Research and development costs are charged to operations as incurred. Certain research and development projects are funded under agreements with third parties, and the costs related to these activities are included in research and development expenses.

Foreign currency translation

The Company's Irish subsidiary uses its local currency as its functional currency. Assets and liabilities are translated at exchange rates in effect at the balance sheet date and income and expense amounts at the average exchange rates during the period. Resulting translation adjustments are recorded directly to a separate component of stockholders' equity.

Comprehensive income (loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. The Company's unrealized gains and losses on available-for-sale securities and foreign currency translation gains and losses represent the only components of comprehensive income (loss) that are excluded from the Company's net loss.

Note 2 NET LOSS PER COMMON SHARE

Basic net loss per share is computed by dividing net loss available to common stockholders by the weighted average number of vested common shares outstanding for the period. Diluted net loss per share is computed giving effect to all potential dilutive common shares, including options, warrants and convertible preferred stock. Options, warrants, unvested outstanding stock, and convertible preferred stock were not included in the diluted net loss per share calculations because the effect would be antidilutive.

Note 3 EQUITY

The Company issued 4,140,000 shares of common stock at \$12.00 per share for net proceeds of approximately \$44.5 million in its initial public offering (IPO) in November and December 2000.

During 2000, the Company issued 1,923,078 shares of Series E convertible preferred stock at \$2.60 per share for gross proceeds of approximately \$5 million, in conjunction with research and development agreements. The Company also issued 1,725,000 shares of Series E convertible preferred stock in conjunction with the acquisition of Cerus Limited, now Aerogen (Ireland) Limited. Additionally, in July 2000, the Company issued 7,498,223 shares of Series F convertible preferred stock at \$2.25 per share for gross proceeds of \$16,871,002. Concurrent with the closing of the Company's IPO, all outstanding shares of preferred stock (39,010,653 shares) were converted into 13,003,514 shares of common stock of the Company.

Note 4 RECENT ACCOUNTING PRONOUNCEMENT

Effective January 1, 2001 the Company adopted No. 133 (SFAS No. 133), Accounting for Derivative Instruments and Hedging Activities. SFAS No. 133 requires that all derivatives be recognized at fair value in the statement of financial position, and that the corresponding gains or losses be reported either in the statement of operations or as a component of comprehensive income, depending on the type of relationship that exists. The Company does not currently hold derivative instruments or engage in hedging activities and does not believe that the adoption of SFAS No. 133 will have any significant impact on its financial position or results of operations.

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

In addition to historical information, this report contains predictions, estimates and other 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. Actual results could differ materially from any future performance suggested in this report as a result of many factors, including those referred to in Factors That May Affect Future Operating Results, elsewhere in this report and in the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (the Form 10-K). The following discussion should be read in conjunction with the unaudited condensed consolidated financial statements and notes included elsewhere in this report and the information included in the Form 10-K.

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Overview

Aerogen was incorporated in November 1991. We specialize in the controlled delivery of drugs to the lungs. Our core technology consists of a proprietary aerosol generator. We are using the technology to develop respiratory products for marketing by us, and we are developing products in collaboration with pharmaceutical and biotechnology companies for both respiratory therapy and for the delivery of drugs via the lungs to the bloodstream.

We are in the development stage and since inception have devoted substantially all of our efforts to the development of products. We have an accumulated deficit of approximately \$44.8 million as of March 31, 2001. We expect to incur significant additional operating losses over the next several years and expect cumulative losses to increase primarily due to the expansion of our research and development activities, an increase in the number and size of clinical trials, the costs associated with the manufacturing and marketing of our products, and the general expansion of our business activities. To date, we have not had product sales. We anticipate that our quarterly financial results will fluctuate for the foreseeable future. Therefore, period to period comparisons should not be relied upon as predictive of the results in future periods. Our sources of working capital have been equity financings, research and development revenues, interest earned on investments and, to a lesser extent, equipment lease financings and royalties.

Results of Operations

Revenues

Research and development revenues for the first quarter of 2001 were \$0.6 million, compared with \$1.1 million for the first quarter of 2000. The decrease resulted primarily from a lower level of product development activities performed for partner companies other than PathoGenesis Corporation (now a wholly-owned subsidiary of Chiron Corporation).

Research and development revenues can be expected to vary from period to period based on the activities requested by partner companies in any particular period, and therefore are not predictable. Based on agreements we currently have in place, we expect research and development revenues for 2001 to be lower than those for 2000.

Royalty, fee and other revenues for the first quarter of 2001 were \$0.1 million, compared with none for the first quarter of 2000. The increase resulted primarily from minimum royalties from a consumer products company.

Research and development expenses

Research and development expenses for the first quarter of 2001 were \$5.0 million, compared with \$2.9 million for the first quarter of 2000. The increase reflects increased expenses associated with the development of the Company's products, and is largely attributable to increases in salary and benefit costs (\$0.8 million), clinical trial costs (\$0.6 million), costs incurred by our Irish subsidiary (\$0.3 million including Irish payroll-related costs), and amortization of deferred stock-based compensation (\$0.2 million).

Research and development expenses represent expenses related to our own research and development projects, as well as the costs related to research and development activities for our partners. Research and development expenses for partner activities approximate our revenues from those partners. Research and development expenses include salaries and benefits for scientific and development personnel, laboratory supplies, consulting services, clinical expenses, and the expenses associated with the development of manufacturing processes, including related overhead. We expect research and development spending to increase significantly over the next several years as we increase clinical trials, expand our research and development activities to support our products and those which we develop in our collaborations, and initiate commercial manufacturing. Future research and development and clinical expenditures cannot be predicted reliably, as they depend in part upon our success in continuing existing development collaborations, entering into new partnering agreements, and the level of internally funded research and development efforts.

General and administrative expenses.

General and administrative expenses for the first quarter of 2001 were \$1.5 million, compared with \$0.9 million for the first quarter of 2000. The increase was primarily due to increased personnel costs associated with product launch preparations (\$0.3 million), other marketing costs (\$0.2 million), amortization of goodwill associated with the Irish acquisition (\$0.1 million), and additional costs associated with operating as a public company (\$0.1 million), offset by decreases in certain other general and administrative expenses. Aerogen expects that its general and administrative expenses will increase as its business expands and as the Company launches and sells its products.

Interest income, net

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Interest income, net for the first quarter of 2001 was \$0.8 million, compared with \$ 0.1 million for the first quarter of 2000. The increase in interest income, net was primarily due to higher average cash, cash equivalents and investment balances resulting from the completion of equity placements of our common and convertible preferred stock. We sold convertible preferred stock in July, May and March of 2000 for total net proceeds of approximately \$21.3 million. Sales of common stock in our initial public offering resulted in approximately \$44.5 million of net proceeds, including \$6.0 million from exercise of the underwriters' over-allotment option.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through equity financings, research and development revenues and the interest earned on these funds. We have received approximately \$97.5 million aggregate net proceeds from sales of our common and preferred stock through March 31, 2001, including approximately \$44.5 million of net proceeds from our initial public offering.

As of March 31, 2001, we had cash, cash equivalents and available-for-sale securities of approximately \$57.0 million. Net cash used in operating activities of \$3.7 million during the three months ended March 31, 2001 resulted primarily from the net loss for the period, partially offset by non-cash related charges of approximately \$0.7 million and an increase in accrued liabilities of \$0.8 million. Net cash used in operating activities of \$1.7 million during the three months ended March 31, 2000 resulted primarily from the net loss for the period, partially offset by increases in liabilities of approximately \$0.8 million and non-cash charges of approximately \$0.2 million.

Net cash used in investing activities of \$4.0 million for the three months ended March 31, 2001 consisted primarily of purchases of investments, net of maturities of investments. Net cash used in investing activities of \$0.3 million for the three months ended March 31, 2000 consisted primarily of acquisitions of property and equipment.

Net cash provided by financing activities of \$2.4 million for the three months ended March 31, 2000 primarily consisted of proceeds from the sale of convertible preferred stock.

The development of our technology and products will require a commitment of substantial funds to conduct the costly and time-consuming product development and clinical trials required to develop and refine our technology and products and to bring any such products to market. Our future capital requirements and operating expenses will depend on many factors including, but not limited to, research and development activities, the timing, cost, extent and results of clinical trials, our success in licensing drugs for use in our products, regulatory approvals, the status of competitive products, manufacturing and marketing costs associated with commercialization of products, costs involved in obtaining and maintaining patents, and our ability to enter into collaborative agreements.

Based upon our current plans, we believe that our cash, cash equivalents and available-for-sale securities will be sufficient to meet our capital requirements through calendar year 2002. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. The factors described above, as well as the risk factors discussed in the Form 10-K, will impact our future capital requirements and the adequacy of our available funds.

Recent Accounting Pronouncement

Effective January 1, 2001 the Company adopted No. 133 (SFAS No. 133), Accounting for Derivative Instruments and Hedging Activities. SFAS No. 133 requires that all derivatives be recognized at fair value in the statement of financial position, and that the corresponding gains or losses be reported either in the statement of operations or as a component of comprehensive income, depending on the type of relationship that exists. We do not currently hold derivative instruments or engage in hedging activities and do not believe that the adoption of SFAS No. 133 will have any significant impact on our financial position or results of operations.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Interest rate risk

Interest rate risk represents the risk of loss that may impact our financial position, operating results, or cash flows due to changes in interest rates. This exposure is directly related to our normal operating activities. Our cash, cash equivalents, and short-term investments are invested with high quality issuers and are generally of a short-term nature. As a result, we do not believe that near-term changes in interest rates will have a material effect on our future results of operations. As of March 31, 2001 there had been no material change in the Company's interest rate exposure from that described in the Company's Annual Report on Form 10-K for the year ended December 31, 2000.

Exchange rate risk

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Due to our Irish operations, we have market risk exposure to adverse changes in foreign exchange rates. The revenues and expenses of our subsidiary, Aerogen (Ireland) Limited, are denominated in Irish currency. At the end of each quarter, the revenues and expenses of our subsidiary are translated into U.S. dollars using the average currency exchange rate in effect for that quarter, and assets and liabilities are translated into U.S. dollars using the exchange rate in effect at the end of that quarter. Fluctuations in exchange rates therefore impact our financial condition and results of operations, as reported in U.S. dollars. To date, we have not experienced any significant negative impact as a result of fluctuations in foreign currency markets. As a policy, we do not engage in speculative or leveraged transactions, nor do we hold financial instruments for trading purposes.

We plan to expand our overseas operations. As a result, our operating results may become subject to more significant fluctuations based on changes in exchange rates of foreign currencies in relation to the U.S. dollar. We will periodically analyze our exposure to currency fluctuations and we may adjust our policies to allow for financial hedging techniques to minimize exchange rate risk.

Factors That May Affect Future Operating Results

Risk factors that may affect future operating results are described in Part I of our Form 10-K for the year ended December 31, 2000 and have not changed materially since such date. Please also see [Liquidity and Capital Resources](#) above.

Part II. Other Information

Item 1. Legal Proceedings
None

Item 2. Changes in Securities and Use of Proceeds
No change in securities

In November 2000, the Securities Exchange Commission declared our Registration Statement on Form S-1 effective. We completed our initial public offering, including exercise of the underwriters' over-allotment option, of 4,140,000 shares at an initial public offering price of \$12.00 per share, for aggregate cash proceeds of approximately \$49.7 million. The managing underwriters of the offering were Chase Securities Inc., CIBC World Markets Corp., and SG Cowen Securities Corporation.

In connection with the offering, we paid a total of approximately \$3.5 million in underwriting discounts and commissions and \$1.7 million in other offering costs and expenses. After deducting the underwriting discounts and commissions and the offering costs and expenses, our net proceeds from the offering, including the over-allotment option were approximately \$44.5 million.

From January 1, 2001 through March 31, 2001 the proceeds from the offering were used for research and development and clinical activities, manufacturing and marketing expenditures for existing and future products, capital expenditures, and general corporate purposes. In the future we intend to use the net proceeds in a similar manner.

As of March 31, 2001 \$40.5 million of the proceeds remained available and were primarily invested in cash equivalents and short-term available-for-sale securities.

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 and Reports on Form 8-K

a. Exhibits
None

b. Reports on Form 8-K
None

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Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, (the Exchange Act) the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Aerogen, Inc.

(Registrant)

Dated: May _____, 2001

By:

/s/ JANE E. SHAW

Jane E. Shaw, Phd.
Chairman and Chief Executive Officer

Dated: May _____, 2001

By:

/s/ DEBORAH K. KARLSON

Deborah K. Karlson
*Vice President, Finance and Chief
Financial Officer*