

AEROGEN INC
Form 10-Q
May 13, 2002

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**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, 2002

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.)

2071 Stierlin Court, Mountain View, CA

(Address of principal executive offices)

94043

(zip code)

Registrant's telephone number, including area code: **(650) 864-7300**

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, 2002 there were 20,267,611 shares of the Registrant's Common Stock outstanding, par value \$0.001 per share.

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AEROGEN, INC.
(a development stage enterprise)
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Part I. Financial Information

Item 1. Condensed Consolidated Financial Statements

AEROGEN, INC.
(a development stage enterprise)
Condensed Consolidated Balance Sheets
(unaudited; in thousands)

**March 31,
2002**

**December 31,
2001**

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	March 31, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 22,594	\$ 15,714
Available-for-sale securities	4,494	20,363
Accounts receivable	52	193
Inventories	318	488
Prepaid expenses and other current assets	925	1,201
	<u>28,383</u>	<u>37,959</u>
Total current assets	28,383	37,959
Property and equipment, net	4,753	2,889
Goodwill and other intangible assets, net	1,338	1,362
Other assets	1,221	1,258
	<u>35,695</u>	<u>43,468</u>
Total assets	\$ 35,695	\$ 43,468
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 574	\$ 1,181
Accrued liabilities	2,540	3,321
	<u>3,114</u>	<u>4,502</u>
Total current liabilities	3,114	4,502
Deferred rent	493	223
Other long-term liabilities	206	212
	<u>3,813</u>	<u>4,937</u>
Total liabilities	3,813	4,937
Stockholders' equity:		
Common stock	20	20
Additional paid-in capital	110,067	110,428
Notes receivable from stockholders	(551)	(693)
Deferred stock-based compensation, net	(3,329)	(4,069)
Accumulated other comprehensive loss	(112)	(14)
Deficit accumulated during the development stage	(74,213)	(67,141)
	<u>31,882</u>	<u>38,531</u>
Total stockholders' equity	31,882	38,531
	<u>\$ 35,695</u>	<u>\$ 43,468</u>
Total liabilities and stockholders' equity	\$ 35,695	\$ 43,468

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

AEROGEN, INC.
(a development stage enterprise)
Condensed Consolidated Statements of Operations
(unaudited; in thousands, except per share data)

	Three Months Ended March 31,	
	2002	2001
Revenues:		
Research and development	\$ 26	\$ 609
Royalty, fee and other	63	66
	89	675
Costs and expenses:		
Cost of products sold and manufacturing start-up costs	231	
Research and development	5,023	5,012
Selling, general and administrative	2,127	1,520
	7,381	6,532
Total costs and expenses		
Loss from operations	(7,292)	(5,857)
Interest income, net	220	808
	\$ (7,072)	\$ (5,049)
Net loss		
Net loss per common share, basic and diluted	\$ (0.35)	\$ (0.26)
	20,043	19,466
Shares used in computing net loss per common share, basic and diluted		

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

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AEROGEN, INC.
(a development stage enterprise)
Condensed Consolidated Statements of Cash Flows
(unaudited; in thousands)

	Three Months Ended March 31,	
	2002	2001
Cash flows from operating activities:		
Net loss	\$ (7,072)	\$ (5,049)

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	Three Months Ended March 31,	
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	194	400
Amortization of deferred stock-based compensation	382	326
Accrued interest on notes receivable from stockholders	(8)	(7)
Loss on disposal of property and equipment	165	
Change in inventory reserves	234	
Changes in operating assets and liabilities:		
Accounts receivable	141	(90)
Inventories	25	
Prepaid expenses and other current assets	276	102
Other assets	37	
Accounts payable	(607)	(190)
Accrued liabilities	(870)	815
Deferred rent	270	
Other long-term liabilities	(4)	
	(6,837)	(3,693)
Cash flows from investing activities:		
Acquisition of property and equipment	(2,233)	(187)
Purchases of available-for-sale securities		(12,118)
Proceeds from maturities of available-for-sale securities	15,817	8,300
	13,584	(4,005)
Cash flows from financing activities:		
Proceeds from issuance of common stock	3	6
Repurchase of common stock	(6)	(8)
Repayment of note receivable from shareholder	150	
	147	(2)
Effect of exchange rate changes on cash	(14)	(142)
Net increase (decrease) in cash and cash equivalents	6,880	(7,842)
Cash and cash equivalents, beginning of period	15,714	48,810
Cash and cash equivalents, end of period	\$ 22,594	\$ 40,968

The accompanying notes are an integral part of these 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 products, including engaging in research and development activities with and without partners, raising capital, marketing of its initial product and recruiting personnel. The Company has incurred net losses since inception and expects 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 collaboration partners, interest income and debt. The process of developing products will continue to require significant research and development, clinical trials and regulatory approvals. These activities, together with selling, general and administrative expenses, are expected to result in substantial operating losses for the next several years.

These financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. Management believes its cash and cash equivalents and available-for-sale securities as of March 31, 2002 will be sufficient to meet the Company's capital and operating requirements through calendar year 2002. The Company will require additional financing in the future and may raise funds by selling shares of its common or preferred stock through private placements or public offerings, by collaborative relationships or other arrangements. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company. Additional equity or debt financing may involve substantial dilution to the Company's stockholders, restrictive covenants or high interest costs. Collaborative arrangements, if necessary to raise additional funds, may require the Company to relinquish rights to certain products, technologies or marketing territories. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the Company's business, operating results and financial condition.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America 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, 2001.

The results of operations for the three months ended March 31, 2002 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2002 or for any other future period.

Basis of consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Cash and cash equivalents

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

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 component of stockholders' equity. Realized gains and losses on sales of such investments are reported in earnings and computed using the specific identification cost method.

Inventories

Inventories are stated at the lower of cost (on a first-in, first-out basis) or market value. Inventories are summarized as follows (in thousands):

	<u>March 31, 2002</u>	<u>December 31, 2001</u>
	(unaudited)	
Raw materials	\$ 173	\$ 354
Work-in-process	112	99
Finished goods	33	35
	<u> </u>	<u> </u>
Total inventories	\$ 318	\$ 488
	<u> </u>	<u> </u>

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. Charges to these third parties are based upon negotiated rates for full time equivalent employees of the Company and actual out-of-pocket costs. Payments received that are related to future performance are recorded as deferred revenues and recognized as revenues as they are earned. None of the revenues recognized to date are refundable if the relevant research and development effort is not successful.

Revenues from product sales are recognized at the time of product shipment, provided an enforceable claim exists, any significant rights to return products have expired and that collection of the receivable is probable.

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 the Eurodollar 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 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.

Net loss per common share

Basic net loss per share is computed by dividing the net loss 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 and warrants. Options and warrants were not included in the diluted net loss per share calculations because the effect would be antidilutive.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per common share follows:

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	Three Months Ended March 31,	
	2002	2001
(unaudited, in thousands)		
Net loss per common share, basic and diluted:		
Net loss	\$ (7,072)	\$ (5,049)
Weighted average common shares outstanding	20,142	19,918
Less: Weighted average shares subject to repurchase	(99)	(452)
Weighted average shares used in computing basic and diluted net loss per common share	20,043	19,466

The following outstanding options, common stock subject to repurchase and warrants were excluded from the computation of diluted net loss per share as they had an antidilutive effect:

	Three Months Ended March 31,	
	2002	2001
(unaudited, in thousands)		
Options to purchase common stock	3,429	2,289
Common stock subject to repurchase	64	396
Warrants, based on common stock equivalents	32	32

Reclassification

Certain prior year balances have been reclassified to conform to the current year financial statement presentation.

Note 2 RECENT ACCOUNTING PRONOUNCEMENTS

The Company adopted Statement of Financial Accounting Standards ("SFAS") No. 142 "Goodwill and other Intangible Assets" on January 1, 2002. Under the new rules, goodwill is no longer amortized, but is subject to an annual impairment test. Amortization of goodwill for the three months ended March 31, 2001 was approximately \$92,000. As of March 31, 2002, the goodwill impairment test had been completed and it was determined that there was no impairment of goodwill at that time.

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, 2001 (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.

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are described in Item 7 of our Form 10-K and have not changed materially since that date.

Overview

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Aerogen was incorporated in November 1991. We specialize in the controlled delivery of drugs to the lungs for respiratory therapy or systemic drug delivery. We are using our 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 \$74.2 million as of March 31, 2002. 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 marketing and manufacturing of our initial products, and the general expansion of our business activities. 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, equipment lease financings and royalties.

Results of Operations

Revenues

Research and development revenues for the first quarter of 2002 were \$26,000, compared with \$0.6 million for the first quarter of 2001. The decrease resulted primarily from a lower level of product development activities performed for partner companies. We announced in December 2001 the termination of our development program with Chiron for pulmonary delivery of TOBI.

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 2002 to be lower than those for 2001.

There were no product revenues for the first quarter of 2002 or 2001. Our first product, the Aeroneb® Portable Nebulizer System, was launched in June 2001, and approximately \$185,000 of product revenues were recognized in 2001. Due to manufacturing issues which have been resolved and were not fundamental to our aerosol generator technology, no product was shipped, and therefore no product sales revenues were recorded in the first quarter of 2002.

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Royalty, fee and other revenues for the first quarter of 2002 were \$63,000, compared with \$66,000 for the first quarter of 2001.

Cost of products sold and manufacturing start-up costs

Cost of products sold and manufacturing start-up costs for the first quarter of 2002 were \$0.2 million, compared with none for the first quarter of 2001. Our first product, the Aeroneb® Portable Nebulizer System, was launched in June 2001. Effective April 2002, we implemented a price reduction on the Aeroneb® Portable Nebulizer System to enhance our competitive position in the home nebulizer market. We anticipate the new lower price will drive sales and, when coupled with future manufacturing cost reductions, will allow for reasonable margins on the product. The cost of products sold and manufacturing start-up costs primarily represent charges to reduce inventories to estimated market value and accrue future losses on current purchase commitments based on the reduced selling price.

Research and development expenses

Research and development expenses for both the first quarter of 2002 and 2001 were \$5.0 million. Incremental rent expenses primarily associated with our newly leased facility charged to research and development were approximately \$0.5 million in the first quarter of 2002. We maintained our approximately 38,000 square foot Sunnyvale facility through April 30, 2002, at which time we reduced our space there to approximately 10,000 square feet, which is primarily manufacturing and research and development space. We anticipate our move to the Mountain View facility will be completed by June 30, 2002 and we expect to vacate the Sunnyvale facility at that time. Certain capital equipment utilized in the Sunnyvale facility will not be utilized in the Mountain View facility; accordingly, we recorded a charge of \$0.1 million to reflect this asset impairment. In the first quarter of 2002, payroll and related expenses increased by approximately \$0.2 million, and materials and supplies increased by approximately \$0.2 million. These additional expenses incurred in the first quarter of 2002 were offset by approximately \$0.7 million of clinical trial and related expenses associated with our inhaled insulin product incurred in the first quarter of 2001 for which there were no corresponding expenses in the first quarter of 2002. Additionally, there were approximately \$0.4 million of expenses associated with outside professional services for our respiratory products for which there were no corresponding expenses in the first quarter of 2002.

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 expand our 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.

Selling, general and administrative expenses

Selling, general and administrative expenses for the first quarter of 2002 were \$2.1 million, compared with \$1.5 million for the first quarter of 2001. The increase was primarily due to increases in general and administrative costs of \$0.4 million and increases in selling costs of \$0.2 million. General and administrative expense increases were primarily due to additional personnel costs associated with

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general corporate infrastructure, including increased stock-based compensation of \$0.1 million, and incremental rent of approximately \$0.1 million associated with our newly leased facility. Selling expense increases were primarily associated with a full quarter of expenses related to our contract sales force. We expect that our selling, general and administrative expenses will continue to increase because the sales force was in place for only part of 2001, and as we commercialize new products in mid-2002 and thereafter.

Interest income, net

Interest income, net for the first quarter of 2002 was \$0.2 million, compared with \$0.8 million for the first quarter of 2001. The decrease in interest income, net was primarily due to lower average cash, cash equivalents and investment balances resulting from operations and capital expenditures and, to a lesser extent, lower interest rates.

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 \$98.0 million aggregate net proceeds from sales of our common and preferred stock through March 31, 2002, including approximately \$44.5 million of net proceeds from our initial public offering ("IPO").

As of March 31, 2002, we had cash, cash equivalents and available-for-sale securities of approximately \$27.1 million. Net cash used in operating activities of \$6.8 million during the three months ended March 31, 2002 resulted primarily from the net loss for the period and decreased accounts payable and accrued liabilities of \$1.5 million, partially reduced by non-cash related charges of approximately \$1.0 million and a decrease in current assets of \$0.4 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 reduced by non-cash charges of approximately \$0.7 million, and an increase in accrued liabilities of \$0.8 million.

Net cash provided by investing activities of \$13.6 million for the three months ended March 31, 2002 consisted primarily of proceeds from maturing available-for-sale securities of \$15.8 million, partially offset by acquisition of \$2.2 million of property and equipment primarily associated with leasehold improvements to our newly leased facility. Net cash used by investing activities of \$4.0 million for the three months ended March 31, 2001 consisted primarily of net purchases of available-for-sale securities over maturities of securities of \$3.8 million.

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 expand 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, marketing and manufacturing 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. We will need to raise additional funds through partner collaborations, sales of our securities or borrowing. There can be no assurance that we will be able to enter into such collaborations or raise additional funds through sales of securities or

borrowing. 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 pronouncements

We adopted Statement of Financial Accounting Standards ("SFAS") No. 142 "Goodwill and other Intangible Assets" on January 1, 2002. Under the new rules, goodwill is no longer amortized, but is subject to annual impairment test. Application of the non-amortization provisions of this statement are expected to result in a decrease to net loss of approximately 340,000 in fiscal year 2002, as compared with the previous accounting requirements. As of March 31, 2002 the goodwill impairment test had been completed and it was determined that there was no impairment of goodwill at that time.

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. As of March 31, 2002, we invest only in U.S. government and related agency securities and high quality money markets. These investments are generally of a short-term nature. As a result, other than changes in interest income due to changes in interest rates, we do not believe that near-term changes in interest rates will have a material effect on our future results of operations.

Exchange rate risk

Due to our Irish operations, we have market risk exposure to adverse changes in foreign currency exchange rates. The revenues and expenses of our subsidiary, Aerogen (Ireland) Limited, are denominated in Eurodollars. 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. Additionally, we occasionally have market risk exposure to adverse changes in foreign currency exchange rates associated with foreign vendors who require payment in their functional currencies. 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 may 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, 2001 and have not changed materially since such date. Please also see "Liquidity and Capital Resources" above.

Part II. Other Information

Item 1. Legal Proceedings

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

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