AEROGEN INC Form 10-Q November 15, 2004

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 September 30, 2004

OR

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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, Suite 100, 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 (the Exchange Act) 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 filed (as defined in Rule 12b-2 of the Exchange Act): Yes o No \acute{y}

As of November 5, 2004, there were 4,884,829 shares of the Registrant s Common Stock, par value \$0.001, outstanding.

Aerogen, Inc.

Form 10-Q

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Part I. Financial Information

Item 1. Condensed Consolidated Financial Statements

Aerogen, Inc.

Condensed Consolidated Balance Sheets

(unaudited; in thousands, except per share data)

	Se	ptember 30, 2004	D	ecember 31, 2003
ASSETS				
Current assets:				
Cash and cash equivalents	\$	20,271	\$	762
Accounts receivable		935		445
Inventories, net		893		301
Prepaid expenses and other current assets		1,206		428
Total current assets		23,305		1,936
Property and equipment, net		3,157		3,901
Goodwill and other intangible assets, net		1,896		1,931
Restricted cash				1,200
Other assets		449		608
Total assets	\$	28,807	\$	9,576
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY				
Current liabilities:				
Accounts payable	\$	1,094	\$	937
Deferred revenue, current		529		500
Convertible debentures, net				1,486
Accrued liabilities		1,903		1,194
Total current liabilities		3,526		4,117
Deferred rent		204		1,658
Deferred revenue, non-current		1,903		1,875
Other long-term liabilities		241		246
Total liabilities		5,874		7,896
Convertible preferred stock Convertible preferred stock, par value \$0.001: Authorized: 5,000 shares; issued and outstanding: 1,142 shares at September 30, 2004 and no shares at December 31, 2003 (Liquidation				
preference: \$34,260 at September 30, 2004)		12,573		
Stockholders equity:				
Common stock, par value \$0.001: Authorized: 95,000 shares; issued and outstanding:				
4,870 shares at September 30, 2004 and 4,396 shares at December 31, 2003		5		4

Additional paid-in capital	131,442	110,991
Notes receivable from stockholders	(289)	(280)
Deferred stock-based compensation, net		(264)
Accumulated other comprehensive income	912	700
Accumulated deficit	(121,710)	(109,471)
Total stockholders equity	10,360	1,680
Total liabilities, convertible preferred stock and stockholders equity	\$ 28,807 \$	9,576

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

Aerogen, Inc.

Condensed Consolidated Statements of Operations

(unaudited; in thousands, except per share data)

		Three Mon Septem 2004		2003	Nine Mont Septem 2004		2003
Revenues:							
Product sales	\$	883	\$	394 \$	2,983	\$	2,660
Research and development							166
Royalty and other		330		125	1,024		375
Total revenues		1,213		519	4,007		3,201
Costs and expenses:							
Cost of products sold		809		249	2,803		1,694
Research and development		3,280		2,891	8,072		9,111
Selling, general and administrative		1,451		1,506	4,780		4,860
Total costs and expenses		5,540		4,646	15,655		15,665
Loss from operations		(4,327)		(4,127)	(11,648)		(12,464)
Interest income (expense), net		79		(127)	(456)		(75)
Other income (expense), net		158		(101)	(135)		265
Net loss		(4,090)		(4,355)	(12,239)		(12,274)
Dividends related to convertible preferred stock		(514)			(13,327)		
N	Φ.	(4.604)	Φ.	(4.255) A	(25.566)	Φ.	(10.054)
Net loss attributable to common stockholders	\$	(4,604)	\$	(4,355) \$	(25,566)	\$	(12,274)
N 1 . 1 . 1 . 1 . 1 . 1 . 1	Ф	(0.00)	Ф	(1.06) h	(5.45)	ф	(2.00)
Net loss per share, basic and diluted	\$	(0.96)	\$	(1.06) \$	(5.47)	\$	(3.00)
Weighted - average shares used in computing net		4.705		4.105	4.670		4.004
loss per share, basic and diluted		4,795		4,105	4,678		4,094

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

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Aerogen, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited; in thousands)

		Nine Mont Septem 2004	ed 2003		
Cash flows from operating activities:					
Net loss	\$	(12,239)	\$	(12,274)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization		926		966	
Changes in inventory reserves				8	
(Gain) / loss on disposal of property and equipment		755		(25)	
Accrued interest on notes receivable from stockholders		(10)		(7)	
Amortization of notes discount on convertible notes		522		131	
Amortization of premium on available for sales securities				6	
Amortization of deferred stock-based compensation		264		763	
Changes in operating assets and liabilities:					
Accounts receivable		(491)		(794)	
Inventories		(593)		73	
Prepaid expenses and other current assets		419		608	
Accounts payable		163		(55)	
Accrued liabilities		293		(63)	
Deferred rent		(1,454)		478	
Deferred revenue		57		1,292	
Other		24		2	
Net cash used in operating activities		(11,364)		(8,891)	
Cook flows from investing a stirition					
Cash flows from investing activities: Acquisition of property and equipment		(507)		(295)	
Proceeds from maturities of available-for-sale securities		(597)		(285)	
		(507)		5,615 5,330	
Net cash provided by (used in) investing activities		(597)		3,330	
Cash flows from financing activities:					
Proceeds from issuance of common stock		7		23	
Proceeds from issuance of preferred stock and warrants, net		30,928			
Proceeds from issuance of convertible debenture		505		950	
Repayment of note receivable from stockholder				165	
Net cash provided by financing activities		31,440		1,138	
Effect of exchange rate changes on cash		30		(317)	
Net increase (decrease) in cash and cash equivalents		19,509		(2,740)	
Cash and cash equivalents at beginning of period		762		3,266	
Cash and cash equivalents at end of period	\$	20,271	\$	526	
Supplemental disclosure of noncash investing and financing activities:					
Conversion of convertible debt and interest into common stock	\$	585	\$		
Issuance of warrants	\$	6,886	\$		
Beneficial conversion feature of preferred stock	\$	12,413	\$		
Conversion of convertible debt and interest into preferred stock	\$	1,567	\$		
Issuance of stock dividend	\$	913	\$		
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The accompanying notes are an integral part of these condensed consolidated financial statements.

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Aerogen, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited, tabular amounts in thousands, except per share data)

Note 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business of the Company

Aerogen, Inc. (Aerogen, the Company or we) was incorporated in November 1991. We are a specialty pharmaceutical company developing novel drug/device combination aerosol products for treatment of respiratory disorders in the critical care setting. Based on our proprietary OnQ Aerosol Generator (OnQ) for aerosolizing liquids, we are developing respiratory products for marketing by us, and products in collaboration with, and for marketing by, pharmaceutical and biotechnology companies for both respiratory therapy and for the delivery of drugs through the lungs to the bloodstream. Since inception, we have financed our operations primarily through equity and convertible debt financings, product revenues, research and development revenues, licensing fees, royalties, and the interest earned on related proceeds. The process of developing our products will continue to require significant research and development, clinical trials and regulatory approvals. These activities, together with manufacturing, selling, general and administrative expenses, are expected to result in substantial operating losses for the next several years.

These condensed consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The continued operation of the Company is dependent on our ability to obtain adequate funding and eventually establish profitable operations. On May 12, 2004, we completed a \$32.7 million financing providing net proceeds of \$30.9 million. As of September 30, 2004, Aerogen had cash, cash equivalents and short-term investments totaling \$20.3 million. Cash expenditures for the three months and nine months ended September 30, 2004 were higher than anticipated, primarily due to the absence of OnQ sales revenues during the third quarter from Evo Medical Solutions (Evo, formerly Medical Industries America) related to FDA action taken against Evo during that period. If our average rate of cash expenditures remains constant at the third quarter average rate, then our current cash resources will be insufficient to permit operations beyond November 2005.

As a result of our continued losses and current cash resources, we will need to raise additional funds through public or private financings, collaborative relationships or other arrangements within the next twelve months in order to continue as a going concern. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to either certain of our products or technologies or desirable marketing territories, or all of these.

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, 2003, filed with the Securities and Exchange Commission on April 14, 2004.

The results of operations for the three months ended September 30, 2004 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2004 or for any other future period.

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Inventories

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

	September :	September 30, 2004 (in thousands)			
Raw materials	\$	396	\$		228
Work-in-process		204			30
Finished goods		293			43
Net inventories	\$	893	\$		301

Warranty

The Company offers a warranty of certain products and records a liability for the estimated future costs associated with warranty claims, which is based on historical experience and the Company s estimated level of future costs. Warranty costs are reflected in the statements of operations as a cost of products sold. A reconciliation of the changes in the Company s warranty liability for the nine months ended September 30, 2004 and 2003 is as follows (in thousands):

		Nine Months Ended September 30,				
	20	04		2003		
Warranty accrual at January 1	\$	138	\$		101	
Accruals for warranties issued during the period		121			138	
Settlements made in kind during the period		(113)			(35)	
Warranty accrual at September 30	\$	146	\$		204	

Other Comprehensive Loss

Other comprehensive loss generally represents all changes in stockholders—equity except those resulting from investments or contributions by stockholders. Foreign currency translation gains and losses represent the only components of comprehensive income that are excluded from the Company—s net loss. Total comprehensive loss during the three and nine months ended September 30, 2004 and 2003 consisted of:

Three Months Ended September 30,			Nine Mon Septen	
2004	2003	3	2004	2003
\$ (4,604)	\$	(4,355)	\$ (25,566)	\$ (12,274)

Net loss attributable to common stockholders				
Foreign currency translation adjustments	26	152	212	(119)
Comprehensive loss	\$ (4,578) \$	(4,203) \$	(25,354) \$	(12,393)
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Net Loss Per Share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of vested shares outstanding for the period. Diluted net loss per share is computed giving effect to all potentially dilutive shares, including options, convertible debentures, convertible preferred stock and warrants. Options, convertible debentures, convertible preferred stock and warrants are not included in the diluted net loss per share calculations for periods in which the effect would be anti-dilutive.

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

	Three Months End 2004	ded S	September 30, 2003	Nine Months Ender 2004	d Sep	tember 30, 2003
Net loss attributable to common stockholders	\$ (4,604)	\$	(4,355)	\$ (25,566)	\$	(12,274)
Weighted-average common shares outstanding Less weighted-average shares subject to	4,795		4,105	4,678		4,095
repurchase Weighted-average shares used in computing basic and diluted net loss per common share	4,795		4,105	4,678		4,094
Net loss per share, basic and diluted	\$ (0.96)	\$	(1.06)	\$ (5.47)	\$	(3.00)

The following outstanding options, warrants, and convertible preferred stock were excluded from the computation of diluted net loss per share as they all had an antidilutive effect:

	September 30,			
	2004	2003		
Options to purchase common stock	4,084	492		
Warrants	11,772	276		
Convertible preferred stock	11,421			

Accounting for Stock-based Compensation

The Company accounts for stock-based compensation using the intrinsic value method under Accounting Principles Board Opinion No. 25 (APB No. 25), Accounting for Stock Issued to Employees, and related interpretations, and complies with the disclosure requirements of Statement of Financial Accounting Standards No. 148 (SFAS No. 148), Accounting for Stock-Based Compensation, Transition and Disclosure an amendment of FASB Statement No.123. The following provides a reconciliation of net loss and net loss per common share to pro forma net loss and pro forma net loss per common share as if the Company had applied the fair value recognition provisions of SFAS No. 123 Accounting for Stock-Based Compensation to all employee awards:

	Three Months Ended September 30,			Nine Months Ended September 30,			
		2004		2003	2004		2003
Net loss - as reported	\$	(4,604)	\$	(4,355) \$	(25,566)	\$	(12,274)
Add: stock-based compensation included in reported net loss		49		247	264		747