

AEROGEN INC
Form 10-Q
November 13, 2001

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 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, 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
(IRS Employer Identification No.)

1310 Orleans Drive, Sunnyvale, CA
(Address of principal executive offices)

94089
(Zip Code)

(408) 543-2400

(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 No

As of October 31, 2001 there were 20,140,319 shares of the Registrant's Common Stock, par value \$0.001 per share, outstanding.

AeroGen, Inc.
(a development stage company)
Form 10-Q

Table of Contents

		<u>Page Number</u>
Part I.	<u>Financial Information</u>	
Item 1.	Condensed Financial Statements (unaudited)	
	Condensed Consolidated Balance Sheets at September 30, 2001 and December 31, 2000	3
	Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2001 and 2000	4
	Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2001 and 2000	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	9
Item 3.	Quantitative and Qualitative Disclosures About Market Risk and Factors that May Affect Future Operating Results	13
Part II.	<u>Other Information</u>	
Item 1.	Legal Proceedings	14
Item 2.	Changes in Securities and Use of Proceeds	14
Item 3.	Defaults Upon Senior Securities	14
Item 4.	Submission of Matters to a Vote of Securities	14
Item 5.	Other Information	14
Item 6.	Exhibits and Reports on Form 8-K	14
Signatures		15

Part I. Financial Information

Item 1. Consolidated Financial Statements

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

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	September 30, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 30,261	\$ 48,810
Available-for-sale securities	15,952	12,166
Accounts receivable	502	762
Inventories	388	
Prepaid expenses and other current assets	881	1,201
	<u>47,984</u>	<u>62,939</u>
Total current assets	47,984	62,939
Property and equipment, net	2,097	1,905
Goodwill and other intangible assets, net	1,489	1,823
Other assets	39	45
	<u>51,609</u>	<u>66,712</u>
Total assets	\$ 51,609	\$ 66,712
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,095	\$ 915
Accrued liabilities	4,610	1,135
Deferred revenues	292	250
	<u>5,997</u>	<u>2,300</u>
Total current liabilities	5,997	2,300
Other long-term liabilities	221	184
	<u>6,218</u>	<u>2,484</u>
Total liabilities	6,218	2,484
Stockholders' equity:		
Common stock	20	20
Additional paid-in capital	110,343	110,692
Notes receivable from stockholders	(686)	(665)
Deferred stock-based compensation, net	(4,545)	(6,095)
Accumulated other comprehensive income	98	15
Deficit accumulated during the development stage	(59,839)	(39,739)
	<u>45,391</u>	<u>64,228</u>
Total stockholders' equity	45,391	64,228
	<u>\$ 51,609</u>	<u>\$ 66,712</u>
Total liabilities and stockholders' equity	\$ 51,609	\$ 66,712

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

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Condensed Consolidated Statements of Operations

(unaudited; in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Revenues:				
Research and development	\$ 432	\$ 1,571	\$ 1,934	\$ 5,140
Product sales	99		99	
Royalty, fee and other	63		187	
Total revenues	594	1,571	2,220	5,140
Costs and expenses:				
Cost of products sold	134		134	
Research and development	5,521	4,531	16,232	12,035
Selling, general and administrative	2,148	1,023	5,878	2,821
Purchased in-process research and development				3,500
Litigation settlement	2,000		2,000	
Total costs and expenses	9,803	5,554	24,244	18,356
Loss from operations	(9,209)	(3,983)	(22,024)	(13,216)
Interest income, net	473	330	1,924	508
Net loss	(8,736)	(3,653)	(20,100)	(12,708)
Dividends related to beneficial conversion features of preferred stock		(16,307)		(16,516)
Net loss available to common stockholders	\$ (8,736)	\$ (19,960)	\$ (20,100)	\$ (29,224)
Net loss per common share, basic and diluted	\$ (0.44)	\$ (8.77)	\$ (1.03)	\$ (13.26)
Shares used in computing net loss per common share, basic and diluted	19,749	2,277	19,606	2,204

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)

**Nine Months Ended
September 30,**

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	Nine Months Ended September 30,	
	2001	2000
Cash flows from operating activities:		
Net loss	\$ (20,100)	\$ (12,708)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	968	630
Purchased in-process research and development		3,500
Amortization of deferred stock-based compensation	982	487
Accrued interest on notes receivable from stockholders	(21)	(17)
Amortization of investment premium	(77)	
Loss on disposal of property and equipment	1	
Changes in operating assets and liabilities:		
Accounts receivable	260	(1,570)
Inventories	(388)	
Prepaid expenses and other current assets	320	(664)
Other assets	6	(9)
Accounts payable	180	697
Accrued liabilities	3,475	1,095
Deferred revenues	42	
Other long-term liabilities	43	
	<u> </u>	<u> </u>
Net cash used in operating activities	(14,309)	(8,559)
	<u> </u>	<u> </u>
Cash flows from investing activities:		
Acquisition of property and equipment	(828)	(1,290)
Purchases of available-for-sale securities	(15,928)	(6,091)
Proceeds from maturities of available-for-sale investments	12,358	6,843
Cash acquired, net		392
	<u> </u>	<u> </u>
Net cash used in investing activities	(4,398)	(146)
	<u> </u>	<u> </u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	224	219
Proceeds from issuance of convertible preferred stock, net		21,252
Repayment of note payable		(211)
Repurchase of common stock	(5)	(3)
Issuance of note receivable from stockholder		(50)
	<u> </u>	<u> </u>
Net cash provided by financing activities	219	21,207
	<u> </u>	<u> </u>
Effect of exchange rate changes on cash	(61)	(12)
Net increase (decrease) in cash and cash equivalents	(18,549)	12,490
Cash and cash equivalents, beginning of period	48,810	1,822
	<u> </u>	<u> </u>
Cash and cash equivalents, end of period	\$ 30,261	\$ 14,312
	<u> </u>	<u> </u>

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 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 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 partners, interest income and debt.

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, 2000.

The results of operations for the three and nine months ended September 30, 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 Limited, 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

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 all such investments are reported in earnings and computed using the specific identification cost method.

Inventories

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Inventories are stated at the lower of cost (on a first-in, first-out basis) or market value. At September 30, 2001, inventory is comprised of \$183,000 of raw materials, \$160,000 of work in process and \$45,000 of finished goods. There were no inventories as of December 31, 2000.

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 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 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 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 net loss available to common stockholders by the weighted average number of vested common shares outstanding for the period. Weighted average shares subject to repurchase excluded from the basic loss per share calculation were 258,177 and 361,430 for the three and nine months, respectively, ended September 30, 2001 and 462,806 and 374,034, respectively, for the three and nine months ended September 30, 2000. Diluted net loss per share is computed giving effect to all potential dilutive common shares, including options, warrants and convertible preferred stock. Options, warrants, common stock subject to repurchase and convertible preferred stock were not included in the diluted net loss per share calculations because the effect would be antidilutive. Options, warrants, and common stock subject to repurchase were 2,954,000 and 1,924,000 shares as of September 30, 2001 and 2000, respectively. Convertible preferred stock was none and 13,003,514 shares as of September 30, 2001 and 2000, respectively.

Reclassification

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

Note 2 SUBSEQUENT EVENTS

Litigation settlement

In October 2001, the Company settled a lawsuit brought by the Company against Becton, Dickinson and Company ("BD"). As a result of the settlement, the Company owns all of the intellectual property developed by either party under the now terminated agreement and BD has a

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nonexclusive license to certain technology developed by BD under the agreement for use outside the field of inhaled insulin. Under the settlement agreement, the Company will pay BD a total of \$2.0 million, to be paid in equal installments in October 2001 and February 2002. The charge associated with the settlement is included in operations for the quarter and nine months ended September 30, 2001.

Commitments

In October 2001, the Company entered into an operating lease for new California facilities. The lease term is approximately ten years, with a five-year renewal option. Total future minimum rent payments are \$26.7 million and are expected to begin in February 2002. Under the terms of the lease, the Company is required to provide the landlord with a \$1.2 million letter of credit. The letter of credit will be secured with \$1.2 million of investments.

Note 3 RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 141 "Business Combinations" which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, "Business Combinations", and FASB Statement No. 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises". SFAS No. 141 requires that all business combinations be accounted for using one method, the purchase method. The provisions apply to all business combinations initiated after June 30, 2001. The adoption of SFAS No. 141 is expected to have no material impact on financial reporting and related disclosures of the Company.

In July 2001, the FASB issued SFAS No. 142 "Goodwill and Other Intangible Assets," ("SFAS No. 142") which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, "Intangible Assets". SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of SFAS No. 142 are effective for fiscal years beginning after December 15, 2001. The Company will adopt SFAS No. 142 during the first quarter of fiscal 2002, and is in the process of evaluating the impact of implementation on the financial position of the Company and results of operations.

In October 2001, the FASB issued SFAS No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS 144 supersedes FASB Statement No. 121 and APB 30, however, SFAS 144 retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. SFAS 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. The Company is in the process of evaluating the impact of implementation on the Company's financial position and results of operations.

8

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

In addition to historical information, this report contains 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.

Overview

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 \$59.8 million as of September 30, 2001. We expect to incur significant additional operating losses over the next several years, and we 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

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equity financings, research and development revenues, interest earned on investments and, to a small extent, equipment lease financings and royalties.

Results of operations

Revenues

Research and development revenues for the three and nine months ended September 30, 2001 were \$0.4 million, and \$1.9 million, respectively, compared with \$1.6 million and \$5.1 million for the same periods of 2000. The decreases in revenues resulted primarily from a lower level of product development activities performed for partner companies. Research and development revenues can be expected to vary from period to period based on the number of agreements in place at any given time with partners, as well as 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.

Product revenues for both the three and nine months ended September 30, 2001 were \$0.1 million compared with none for the same periods of 2000. These revenues represent sales of our Aeroneb[®] Portable Nebulizer System and spare parts to our distributor since the launch of the product in June 2001, less amounts which have been deferred until special return rights on the initial units shipped have expired.

Royalty, fee and other revenues for the three and nine months ended September 30, 2001 were \$0.1 million and \$0.2 million, respectively, compared with none for the same periods of 2000. The increases resulted primarily from minimum royalties earned from a consumer products company in

9

connection with licensing of our technology to that company for application in certain non-medically related fields.

Cost of products sold

Cost of products sold for both the three and nine months ended September 30, 2001 were \$0.1 million compared with none for the same periods of 2000. The costs represent initial production of our first commercial product at very low volumes in our current facility. We anticipate that per unit costs will decrease over time following the move to our new manufacturing facility, planned for mid 2002, and as volumes increase and manufacturing processes are streamlined and automated.

Research and development expenses

Research and development expenses for the three and nine months ended September 30, 2001 were \$5.5 million and \$16.2 million, respectively, compared with \$4.5 million and \$12.0 million, respectively, for the same periods of 2000. The increase in research and development expenses resulted primarily from the expansion of development activities for the respiratory products we plan to market ourselves and our Aerodose[®] insulin inhaler. The increases are primarily attributable to increased salary and benefit costs (\$0.4 million and \$2.1 million, respectively), increased machining, tooling, and supplies (\$0.5 million and \$0.9 million, respectively), increased costs incurred by our Irish subsidiary (\$0.2 million and \$0.8 million, respectively, including payroll related costs), increased amortization of deferred stock-based compensation (none and \$0.5 million, respectively), and increased clinical costs (none and \$0.3 million, respectively), partially offset by decreased clinical costs (\$2.0 million and none, respectively) and professional services (\$0.1 million and \$0.6 million, respectively), as well as fluctuations in other categories of research and development spending.

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. We expect research and development spending to increase significantly over the next several years as we increase clinical trials and expand our research and development activities to support products for marketing by Aerogen and those, which we develop in our collaborations. 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

Selling, general and administrative expenses for the three and nine months ended September 30, 2001 were \$2.1 million and \$5.9 million, respectively, compared with \$1.0 million and \$2.8 million for the same periods of 2000. The increases for both periods were primarily due to increased personnel and other costs associated with sales and marketing (\$0.5 million and \$1.5 million), other costs associated with operating as

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a public company (\$0.6 million and \$0.7 million), and payroll other than sales and marketing related (\$0.1 million and \$0.6 million). We expect that selling, general and administrative expenses will increase as our business expands and as we increase our sales efforts and launch additional products.

Purchased in-process research and development

Purchased in-process research and development expenses of \$3.5 million were recorded for the nine months ended September 30, 2000 in conjunction with our acquisition of Aerogen (Ireland) Limited in May 2000. There were no corresponding expenses in 2001.

10

Litigation settlement

The litigation settlement charge for the three and nine months ended September 30, 2001 was \$2.0 million resulting from the settlement of a lawsuit brought by the Company against BD. The settlement amount will be paid in two equal installments in October 2001 and in February 2002. There were no corresponding expenses in 2000. As a result of the settlement, we own all of the intellectual property developed by either party under the now terminated agreement and BD has a nonexclusive license to certain technology developed by BD under the agreement for use outside the field of inhaled insulin.

Interest income, net

Interest income, net for the three and nine months ended September 30, 2001 was \$0.5 million and \$1.9 million, respectively, compared with \$0.3 million and \$0.5 million for the same periods 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 stock in our initial public offering ("IPO") and convertible preferred stock, partially offset by lower interest rates. We sold convertible preferred stock in July, May and March of 2000 for total net proceeds of approximately \$21.3 million. The sale of common stock in our IPO in November of 2000 resulted in approximately \$44.5 million of net proceeds, including \$6.0 million from exercise of the underwriters' over-allotment option.

Dividends related to beneficial conversion features of preferred stock

The three and nine month periods ended September 30, 2000 include a one time charge of \$16.3 million and \$16.5 million, respectively, for dividends relating to beneficial conversion features of preferred stock. The dividends related to issuance of preferred stock in May and July of 2000 in private placements at prices lower than the IPO price. There were no corresponding expenses in 2001.

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 \$97.8 million aggregate net proceeds from sales of our common and preferred stock through September 30, 2001, including approximately \$44.5 million of net proceeds from our IPO.

As of September 30, 2001, we had cash, cash equivalents and available-for-sale securities of approximately \$46.2 million. Net cash used in operating activities of \$14.3 million during the nine months ended September 30, 2001 resulted primarily from the net loss for the period, partially reduced by non-cash related charges of approximately \$1.9 million and an increase in accrued liabilities of \$3.5 million. Net cash used in operating activities of \$8.6 million during the nine months ended September 30, 2000 resulted primarily from the net loss for the period, partially reduced by non-cash charges of approximately \$4.6 million, \$3.5 million of which were recorded in conjunction with the acquisition of Aerogen (Ireland) Limited.

Net cash used in investing activities of \$4.4 million for the nine months ended September 30, 2001 consisted primarily of \$3.6 million of net purchases over proceeds of available-for-sale securities and acquisition of \$0.8 million of property and equipment. Net cash used by investing activities of \$0.1 million for the nine months ended September 30, 2000 consisted primarily of acquisitions of property and equipment of \$1.3 million offset by net proceeds from maturities of securities in excess of purchases of securities of \$0.8 million.

Net cash provided by financing activities of \$21.2 million for the nine months ended September 30, 2000 primarily consisted of proceeds from the sale of convertible preferred stock.

11

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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.

We have entered into a lease for new California facilities. We will make certain improvements to the new facility before locating there. The facility improvements are estimated to cost \$3.0-\$3.5 million. Depending upon the timing of completion of these improvements, the Company anticipates moving its administrative functions to the new facility in the first quarter of 2002 and its manufacturing in the third of quarter 2002. The Company intends to extend the lease for its current facility, as required.

Aerogen (Ireland) Limited intends to purchase land from the Irish Development Agency and build a facility of approximately 10,000 square feet in Galway Ireland. The total cost of the land and building is estimated to be approximately \$1.4 million. It is currently anticipated that an Irish bank will provide a building mortgage of approximately \$1.0 million to the subsidiary; Aerogen, Inc. intends to guarantee payments under the subsidiary's mortgage.

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 to meet our subsequent operating needs. 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 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

In July 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 141 "Business Combinations" which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, "Business Combinations," and FASB Statement No. 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises". SFAS No. 141 requires that all business combinations be accounted for using one method, the purchase method. The provisions apply to all business combinations initiated after June 30, 2001. We expect the adoption of SFAS No. 141 will have no material impact on our financial reporting and related disclosures.

In July 2001, the FASB issued SFAS No. 142 "Goodwill and Other Intangible Assets," ("SFAS No. 142") which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, "Intangible Assets". SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of SFAS No. 142 are effective starting with fiscal years beginning after December 15, 2001. We will adopt SFAS No. 142 during the first quarter of fiscal 2002, and are in the process of evaluating the impact of implementation on our financial position and results of operations.

In October 2001, the FASB issued SFAS No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS 144 supersedes FASB Statement No. 121 and

APB 30, however, SFAS 144 retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. SFAS 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. We are in the process of evaluating the impact of the implementation on our financial position and results of operations.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Interest rate risk

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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 September 30, 2001, the Company invests only in U.S. government and related agency securities and qualified 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 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. 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 and have not changed materially since such date. Please also see "Liquidity and Capital Resources" above.

13

Part II. Other Information

Item 1. Legal Proceedings

On August 21, 2001, we filed a lawsuit in the Federal District Court for the Northern District of California, San Jose Division, against Becton, Dickinson and Company ("BD") alleging breach of contract and other matters. The complaint requested damages, rescission of the agreement between the parties, restitution and an adjudication of the intellectual property rights that arose under the agreement. On October 1, 2001, the lawsuit was settled, and the complaint has been dismissed. As a result of the settlement, we own all of the intellectual property developed under the agreement, BD has a nonexclusive license to certain technology developed by BD under the agreement for use outside the field of inhaled insulin. No future payments, which would have been owed under the agreement, will be made and Aerogen will pay BD \$2.0 million in two equal installments, in October 2001 and February 2002.

Item 2. Changes in Securities and Use of Proceeds

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 September 30, 2001 the proceeds from the offering were used for research and development and clinical activities, marketing and manufacturing 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 September 30, 2001, \$29.4 million of the proceeds from our IPO remained available and were primarily invested in cash equivalents and short-term available-for-sale securities.

