

AEROGEN INC
Form S-3/A
August 06, 2004

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As filed with the Securities and Exchange Commission on August 6, 2004

Registration No. 333-115813

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Amendment No. 3

to

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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 94043
(650) 864-7300**

(Address, including Zip Code, and Telephone Number,
including Area Code, of Registrant's Principal Executive Offices)

**JANE E. SHAW
CHIEF EXECUTIVE OFFICER
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2071 STIERLIN COURT, SUITE 100
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(650) 864-7300**

(Name, Address, including Zip Code, and Telephone Number,
including Area Code, of Agent For Service)

Copies to:

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Approximate date of commencement of proposed sale to the public:
As soon as practicable after this registration statement becomes effective.

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If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the Prospectus is expected to be made pursuant to Rule 434, please check the following box.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SECTION 8(a), MAY DETERMINE.

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THE SELLING STOCKHOLDERS MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

DATED AUGUST 6, 2004

24,302,459 Shares

AEROGEN, INC.

Common Stock

The selling stockholders listed beginning on page 13 are offering up to 24,302,459 shares of Aerogen, Inc. common stock, which includes 11,420,940 shares of common stock issuable to the selling stockholders upon conversion of Series A-1 Preferred Stock, 11,331,519 shares of common stock issuable to the selling stockholders upon the exercise of warrants to purchase common stock and 1,500,000 shares of common stock as a good faith estimate of dividends payable to the holders of Series A-1 Preferred Stock. We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders.

Our common stock trades on the Nasdaq SmallCap Market under the trading symbol AEGN. On August 5, 2004, the last reported sale price of our common stock was \$2.54 per share.

The selling stockholders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See "Plan of Distribution" beginning on page 20 for more information about how the selling stockholders may sell their shares of common stock. We will not be paying any underwriting discounts or commissions in this offering.

**INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK.
SEE "RISK FACTORS" BEGINNING ON PAGE 1.**

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

August 6, 2004.

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This prospectus is part of a registration statement we filed with the Securities and Exchange Commission. You should rely only on the information we have provided or incorporated by reference in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of our common stock.

AEROGEN

Aerogen, Inc. ("Aerogen" the "Company" or "we") was incorporated in Delaware in November 1991, and we are based in Mountain View, California. We are a specialty pharmaceutical company focusing on respiratory therapy in the acute care setting. Our core technology is our proprietary OnQ(tm) Aerosol Generator. Using our technology, 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.

RISK FACTORS

This offering involves a high degree of risk. You should carefully consider the following risk factors, in addition to other information included or incorporated by reference in this prospectus, before making an investment decision. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and you may lose all or part of your investment.

In order for any of our drug products to complete Phase 3 clinical trials, we will most likely need capital in excess of our current cash resources.

Our cash resources will most likely be insufficient to complete Phase 3 clinical trials for any of our products, and may be insufficient to complete all of our anticipated Phase 2 clinical trials. Sufficient cash to complete our Phase 2 and 3 clinical trials may be provided from strategic partnerships, such as from out-licensing and partnering of our insulin product, and product sales in excess of our expectations. There can be no guarantee, however, that these capital resources will materialize in sufficient magnitude or at all, or that product sales will meet our expectations. In the alternative, the Company will have to raise significant capital through the sale of convertible debt, convertible securities, and/or common stock, and there can be no guarantee that such capital will be available on favorable terms, if at all, and could result in significant dilution to our current shareholders.

Our recent equity financing has resulted in a concentration of ownership.

Twelve Series A-1 investors own equity securities that, if all such securities were converted into common stock, would represent ownership of approximately 86% of the outstanding common shares of the Company. While each of these investors is contractually prohibited from owning more than 4.99% of the Company's common stock at any one time, any investor can waive this limitation as to the shares it holds upon 61 days' written notice to the Company. Additionally as few as eleven of these investors, or investors to whom the A-1 securities are resold, could acquire in excess of 50% of the voting securities of the Company without exceeding this limitation. To our knowledge, the Series A-1 investors have not acted as a group in seeking, negotiating, or making their investment in the Company, have not acted as a group since making their investment, and consider themselves to be independent investors. Due to the termination of our rights plan, there can be no assurance that further concentration of ownership will not occur, or that these securities will not be resold to different investors who may or may not act as a group.

The conversion of our Series A-1 preferred stock into common stock and the exercise of warrants issued to the Series A-1 investors may depress the price of our common stock and will substantially dilute the ownership interests of existing common stockholders.

If the Series A-1 preferred stockholders were to exercise all of the warrants they hold and convert all of the shares of preferred stock they own as of July 23, 2004, they would own approximately

22,670,330 shares of our common stock, in addition to any other shares such stockholders may now or in the future own. If the Series A-1 preferred stockholders exercise the warrants or convert our preferred stock into shares of common stock and sell the shares into the market, such sales could have a negative effect on the market price of our common stock and will dilute the holdings of our existing common stockholders. The Company may choose to pay the cumulative quarterly dividend on the Series A-1 Preferred Stock in shares of Common Stock instead of cash, in which case more dilution will result. Dilution or the potential for dilution also could materially impair our ability to raise capital through the future sale of equity securities. As a result of the issuance of the Series A-1 preferred stock and warrants, the Company recorded a charge in the first and second quarters of 2004 related to the beneficial conversion feature of the preferred stock in the amount of \$7.9 million and \$4.5 million respectively. If the Company were to issue additional equity securities in a future financing transaction at a per share price lower than the current conversion price of the Series A-1 Preferred Stock, then the conversion price of the Series A-1 Preferred Stock would automatically adjust downward to be equal to the common stock equivalent price of the newly-issued securities, and an additional deemed dividend charge would be recorded. Any such charge would reduce stockholder's equity and the amount of net income available to common stockholders. While the Company currently has no plans to issue securities in a manner that would trigger these anti-dilution provisions, it may elect to do so in the future. The full details of these anti-dilution provisions are contained in the Series A-1 Preferred Stock Certificate of Designation, which was filed on the Company's Form 8-K on March 23, 2004, and incorporated by reference herein.

We have a history of losses, anticipate future losses and may never achieve or maintain profitability.

We have never been profitable. Through March 31, 2004, we have incurred an accumulated deficit of approximately \$113.8 million. We expect to continue to incur substantial losses over at least the next several years as we:

expand our research and development efforts;

expand our preclinical and clinical testing activities;

expand our manufacturing efforts, including our commercial production capability; and

build our sales and marketing capabilities and launch our products currently being developed.

To achieve and sustain profitability, we must, alone or with others, develop, obtain regulatory approval for, manufacture, market and sell products. We cannot be sure that we will generate sufficient product revenues, royalties or research and development revenues to become profitable or to sustain profitability.

Our operating results may fluctuate significantly and may fail to meet the expectations of investors.

We expect that our operating results may fluctuate in the future, and may vary from investors' expectations, depending on a number of factors described in this "Risk Factors" section including:

demand for our existing products and any we may introduce in the future;

timing of the introduction of new products and enhancements of existing products;

changes in domestic and international economic, business, regulatory, industry and political conditions;

allocation of our resources, particularly when they are limited;

the costs and expenses relating to any litigation;

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the ability to successfully identify and consummate appropriate collaborations with corporate partners; and

our manufacturing, development and marketing partners' changing priorities and resources.

We have a significant backlog of unfilled orders for our products that may adversely impact our distributors' ability or willingness to sell our products.

Due to our extremely limited cash resources at the end of 2003 and during the first quarter of 2004, we were at times unable to procure critical components and/or manufacturing services necessary to satisfy customer demand for our products, most of whom were unable to provide cash payments in a timeframe that resolved our procurement issues. Compounding this limitation, orders in the same time period exceeded our expectations. As a result, we currently have a backlog of orders that we believe will not be completely filled until late in the second quarter of 2004, assuming that new orders in the second quarter of 2004 do not materially exceed our revised expectations. As of April 13, 2004, the current value of this backlog was approximately \$524 thousand.

Our stock price may continue to be volatile.

The market prices for securities of many companies in the life sciences industry have historically been highly volatile, and the market from time-to-time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. Prices for our common stock may be influenced by many factors, including:

market conditions relating to the life sciences industry;

investor perception of us as a company;

securities analysts' recommendations;

delays in the development, regulatory approval or commercialization of our products;

announcements of technological innovations or new commercial products by us, our partners or competitors;

failure to establish new collaborative relationships or termination of existing collaborative relationships;

developments or disputes concerning patent or intellectual property rights;

regulatory and pricing developments in both the United States and foreign countries;

public concern as to the safety of drugs and drug delivery technologies, including those of our competitors;

period-to-period fluctuations in financial results; and

economic and other external factors.

Our common stock is currently trading at a market price significantly below the initial public offering price. There can be no assurance that the price will increase in the future or will recover to the initial public offering price.

Many of our products are in research and development stages, which makes it difficult to evaluate our business and prospects.

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Many of our products are in the research or development stages. Before we can begin to commercialize our new products, we will need to invest in substantial additional activities, generally including the conduct of clinical trials. To further develop our products, we will need to obtain

additional funds and address engineering and design issues, including ensuring that our products deliver a consistent and reproducible amount of drug to the lung and that they can be manufactured successfully. We cannot assure that:

our research and development efforts will be successful;

any of our inhaler, nebulizer or drug products will prove safe and effective;

we will obtain regulatory clearance or approval to sell any additional products; or

any of our existing or future products can be manufactured in commercial quantities or at an acceptable cost or marketed successfully.

Our technologies are relatively unproven, so they may not work effectively or safely enough to commercialize inhalers, nebulizers or drug-containing products.

Since our pulmonary drug delivery technologies are new and relatively unproven, many of our products are currently in the research, development or clinical stages. Extensive additional testing will need to be performed to demonstrate that:

drugs may be safely and effectively delivered using our technologies;

our inhalers and nebulizers are safe across a range of drugs and formulations;

our products consistently deliver accurate and reproducible amounts of drug over time; and

drug formulations are stable in our products.

If our products do not prove to be safe and effective, we may be required to abandon some or all of them. If we cannot develop new products, our business will suffer.

If clinical trials of our drug products are not successful, drug products using our inhalers or nebulizers may not be commercialized.

Before either we or our partners can file for regulatory approval for the commercial sale of combination products using our inhalers or our nebulizers, the FDA, and other governmental agencies in other countries, will require extensive clinical trials to demonstrate product safety and efficacy. We are developing drug/inhaler and drug/nebulizer combinations, each of which will require clinical testing. To date, we have completed limited clinical trials using prototype inhalers and nebulizers. If we do not successfully complete appropriate clinical trials, we will not be able to commercialize our products. The results of initial clinical trials do not necessarily predict the results of more extensive clinical trials. Furthermore, we cannot be certain that clinical trials of our products will demonstrate that they are safe and effective to the extent necessary to obtain regulatory approvals. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials.

We have limited experience manufacturing our technology. We depend on key suppliers and contract manufacturers, and their failure to supply us may delay or prevent commercialization of our products.

We have built our own manufacturing capabilities to produce key components of our products. We have manufactured only limited quantities of our first three products, and limited clinical supplies of other products. We currently produce all of our aerosol generators for our products, partnered or not, in a single facility. We plan to continue using contract manufacturers to produce certain other key components and subassemblies of our products, many of which are produced in unique facilities and/or with unique tooling. We may assemble some of our products ourselves, or we may use contract manufacturers for the final assembly of all of our products. We do not have long-term supply contracts with most of our key suppliers or contract manufacturers. In addition, most of them are currently our

sole source of supply. We may not be able to enter into, or maintain, satisfactory contracts or arrangements. In addition, manufacturing of our products could be delayed by supply problems at our suppliers or contract manufacturers. If we need to qualify a new supplier or redesign the product, there could be significant delay, and a regulatory filing could be required before we could use the new supplier to provide material for our products. There can be no assurance that we, or our contract manufacturers, can successfully manufacture in high volumes in a timely manner, at an acceptable cost, or at all. We cannot assure that:

the design of our products will permit their manufacture on a commercially sustainable scale;

manufacturing and quality control problems will not arise as we attempt to scale-up production; or

any scale-up of production can be achieved in a timely manner or at a commercially reasonable cost.

Failure to address these issues adequately could delay or prevent clinical testing and commercialization of our products.

Our Aerodose inhaled insulin product is our most mature product in development for systemic drug delivery; however, we have suspended development of that product.

We have completed four small clinical trials (two Phase 1 and two Phase 2a) of our Aerodose insulin inhaler product. Early studies generally focus on the safety of a product rather than its effectiveness in treating the disease. We cannot be sure that the results of these and/or other additional clinical trials will prove the safety and effectiveness of our product. We have not secured an agreement with a marketing partner to fund the additional development and clinical trials necessary to obtain regulatory approval and to commercialize the product; therefore we have not yet resumed our work on that product, and do not expect to re-start the program until we have an acceptable partner to pay for additional clinical trials. We cannot assure that we will ever be able to enter into a satisfactory agreement with a marketing partner, and we currently do not have sufficient funds to conduct the necessary development and clinical programs ourselves.

Of our drug/device combination products currently under active development, our amikacin product is the most advanced, and is the only one to have completed a human clinical trial.

Our ability to become a successful specialty pharmaceutical company depends upon our ability to commercialize our own combination drug/device products, the majority of which will incorporate our Pulmonary Drug Delivery System ("PDDS"). Although our PDDS leverages the basic technology platform of the Aeroneb Pro, and has been CE marked for clinical use in Europe, the PDDS has not been approved as a commercial product. Our lead product in development, a PDDS drug combination product incorporating the aminoglycoside amikacin, has only completed one small Phase 2 clinical trial. The development of this product will require, at a minimum, a second Phase 2 clinical trial and a Phase 3 clinical trial program in order to support a New Drug Application ("NDA"), which must be filed with the United States Food and Drug Administration ("FDA") to obtain approval prior to marketing the product in the United States. If these clinical trials fail to meet their objectives, or are halted for safety reasons, we may be required to suspend further development of this product, conduct additional clinical trials, or return to an earlier stage of research and development. Any or all of these possible outcomes could materially impair our ability to raise additional capital on attractive economic terms, if at all.

Our ability to market and sell our products depends upon receiving regulatory approvals, which we may not obtain.

Our products are subject to extensive regulation by the FDA, state and local government agencies, and by international regulatory authorities. These agencies regulate the development, testing, manufacture, labeling, storage, approval, advertising, promotion, sale and distribution of medical devices, drugs and biologics. If we, or our partners, fail to obtain regulatory clearances or approval to develop or to market our products, our business will be harmed and we, or our collaborative partners, will not be able to market and sell our products. Even if granted, regulatory approvals may include significant limitations on the uses for which products may be tested or marketed. Once obtained, required approvals may be withdrawn, or we may not remain in compliance with regulatory requirements. The process for obtaining necessary regulatory approvals for drugs and biologics is generally lengthy, expensive and uncertain. Obtaining and maintaining foreign regulatory approvals in multiple countries is expensive, and we cannot be certain that we will receive approvals in any foreign country in which we or our partners plan to market our products. If we or our partners fail to obtain regulatory approval in the United States or in any foreign country in which we plan to market our products, our revenues will be lower. A longer than expected regulatory process, additional or significant changes in regulatory requirements, or more expensive clinical studies than we anticipate, may cause us to stop development of particular products.

We may not be able to develop certain products if we do not enter into additional collaborative relationships or gain access to compounds from third parties.

Our strategy depends partially on our ability to enter into collaborative relationships with partners to conduct and fund the clinical trials, manufacturing, marketing and sales activities necessary to commercialize certain products. To develop products to be marketed by us, we will need to purchase or license, and possibly reformulate and package, drugs for use with our Aerodose inhalers and Aeroneb® nebulizers. We cannot assure that we will be able to establish these kinds of arrangements on favorable terms, or at all, or that our existing or future collaborative arrangements will be successful.

If our products do not gain commercial acceptance, we will not generate significant revenue.

Our success in commercializing our products depends on many factors, including acceptance by healthcare professionals and patients. Their acceptance of our products will depend largely on our ability to demonstrate that our products can compete with alternative delivery systems with respect to:

safety;

efficacy;

the benefits associated with pulmonary delivery;

ease of use; and

price.

We cannot be sure that our products will compete effectively, or that we, or our partners, will be able to successfully market any products in a timely manner.

If we are unable to develop a successful sales and marketing effort, we will not be able to sustainably commercialize our products.

We currently have a small sales and marketing staff and modest marketing budget, and many of our competitors have substantial sales and marketing infrastructures and significant marketing budgets. We rely on third party distributors to sell our products, some of which have limited experience in the markets that we are trying to access. Our success in commercializing our respiratory products in the

United States and worldwide will depend on our and our partners' ability to develop and execute a successful sales and marketing effort. There can be no assurance that our current products, which include the Aeroneb Pro System and the Aeroneb Go Nebulizer will be successful. In any event, these products are not expected to generate revenues sufficient enough to solely support the Company's operations in the foreseeable future. We will initially have financial losses resulting from the marketing and sales expenditures necessary to launch and grow the products. Our distribution and marketing partners have significant discretion in allocating and applying their selling and marketing efforts, so we have limited ability to predict or manage the end-user acceptance of our products, and there can be no guarantee that we can meet demand that rises sharply as a result of our partners' selling and/or marketing efforts.

Our corporate partners may not commercialize our products or may develop products that compete against our products.

Our business model includes collaborations with pharmaceutical and biotechnology companies. There can be no assurance that we will be able to enter into arrangements that result in successful commercial products. Even if we do enter into such arrangements, we will depend on corporate partners to commercialize the products developed in collaboration with us. If any of our existing or future corporate partners do not complete the development and commercialization of products to which they have obtained rights from us, our business could be impaired. In the drug delivery industry, it is common for corporate partners to conduct feasibility studies with multiple partners. There can be no assurance that our existing or future corporate partners will continue to choose our technology over their own technology or that of our competitors. Collaboration agreements generally provide that the partner can terminate the agreement at any time.

If we are unable to attract and retain the highly skilled personnel necessary for our business, we may not be able to develop our products successfully.

Because of the specialized nature of our business, we depend upon qualified scientific, engineering, technical and managerial personnel. In particular, our business and prospects depend in large part upon the continued employment of Dr. Jane E. Shaw, our Chairman and Chief Executive Officer. We do not have an employment agreement with Dr. Shaw. Even with the recent downturn in the global economy, there is intense competition for qualified personnel in our business. In addition, our location in northern California makes recruiting qualified personnel from outside the San Francisco Bay area more difficult due to the very high cost of housing. Therefore, we may not be able to attract and retain the qualified personnel necessary to grow our business. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical, engineering and managerial personnel in a timely manner, would harm our research and development programs and our business.

If our manufacturing facilities, or those of our subcontractors and/or licensees, do not meet federal, state and international manufacturing standards, we may not be able to sell our products in the United States or internationally.

Our manufacturing facilities, and those of our subcontractors and manufacturing licensee MIA, are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated by the FDA for compliance with QSR. We moved into a new facility in Mountain View, California during the second quarter of 2002. Prior to transferring product manufacturing to this facility, we underwent a successful inspection by the FDA, which was completed in May 2002. We received our registration in August 2002. We registered with the FDA an additional manufacturing site in Galway, Ireland, in April 2003. In September 2003, the site in Galway underwent an inspection by the FDA. Two observations were noted. One addressed the manner in which Aerogen records documented in-process acceptance test results and the other addressed the calibration standard operating procedure

("SOP") and equipment that was no longer in use, but had exceeded its calibration period. We submitted a timely response to the FDA, which was accepted and the 483 was closed.

All medical devices marketed in the European Union are required to bear the CE Mark. Aerogen, MIA and certain Aerogen subcontractors are required to comply with the MDD and comply with ISO, the International Organization for Standards, to meet the quality standards. ISO is a worldwide network of national standards institutes. ISO has developed ISO 13485 in order to assist companies in implementing and operating quality management systems to meet the MDD.

In May of 2003, the Mountain View facility successfully obtained certification to ISO 13485:1996. If Aerogen, MIA or Aerogen's subcontractors fail to maintain compliance with QSRs, ISO 13485 or other international regulatory requirements, we may be required to among other things recall product or cease all or part of our operations until we comply with the regulations. We cannot be certain that our facilities, or those of MIA and/or our subcontractors, will be found to comply on an ongoing basis with the QSRs, ISO or other international regulatory requirements.

The State of California requires that we maintain a license to manufacture medical devices at our Mountain View facility, and our facilities and manufacturing processes may be inspected from time to time to monitor compliance with the applicable regulations. We are subject to licensing requirements and periodic inspections by the California Department of Health Services, the County of Santa Clara and various environmental agencies. If we are unable to maintain a license following any future inspections, we will be unable to manufacture or ship any products. Similar requirements exist in other jurisdictions where our products are manufactured.

We rely on several, sole-source outside manufacturing service providers and raw material suppliers. If one or more of these outside vendors becomes unable to supply us, we may be unable to locate an alternate supplier, which may adversely impact our ability to sell our products.

We outsource production of many components of our products to manufacturers in the United States and elsewhere. Generally, there is more than one potential supplier for these components, but some are manufactured to our specifications and an interruption in supply could adversely affect our ability to manufacture and supply our products. The brazing process used in assembly of our OnQ Aerosol Generators is conducted at a third party's facilities. Loss of the use of those facilities would result in several months' delay in our supply of components while we establish an alternative brazing site. Palladium, which we use in our OnQ aperture plate, is expensive and is subject to price volatility. The palladium plating bath chemicals we use to manufacture our OnQ Aerosol Generators are formulated by a single supplier.

Our products may not be commercially viable if government health administration authorities, private health insurers or other third-party payors do not provide adequate reimbursement for the cost of our products.

In both domestic and foreign markets, sales of our potential products will depend, in part, on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. There is significant uncertainty about the reimbursement status of newly approved healthcare products. We cannot assure that any of our products will be reimbursed by third-party payors. In addition, we cannot assure that our products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of health care products may change before our products are approved for marketing, and any such changes could further limit reimbursement. One of our first commercial products, the Aeroneb Pro, is not currently reimbursed by insurance or government entities, which may limit its market penetration.

Our competitors may be more successful in developing competing technologies and gaining market acceptance.

We currently compete with device and medical equipment companies for sales of our nebulizer products; as we introduce our drug products, we will compete with pharmaceutical and biotechnology companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in developing non-invasive drug delivery dosage forms. In the area of systemic drug delivery, competing non-invasive alternatives to injectable drug delivery include oral, buccal, intranasal, transdermal and colonic absorption dosage forms. We also compete with entities producing and developing injectable dosage forms. Several of these entities are working on sustained-release injectable systems. While these systems still require injections, the lower number of injections could allow these products to compete effectively with non-invasive therapies.

Many of these companies and entities have greater research and development, manufacturing, marketing, financial and managerial resources and experience than we do. Accordingly, our competitors may succeed in developing competing technologies and products, obtaining regulatory approval for products or gaining market acceptance more rapidly than we can. If competitors bring effective products to market before we do, there is a risk that we may not be able to gain significant market share because our competitors may have firmly established their products in the market. It is also possible that a competitor may develop a technology or product that renders our technology or products obsolete.

We may be unable to effectively protect our intellectual property, which could enable third parties to use our technology and impair our ability to compete effectively.

Our ability to compete effectively depends in part on developing and maintaining the proprietary aspects of our aerosolization technology. We cannot be sure that the patents we have obtained, or any patents we may obtain as a result of our pending United States or international patent applications and, in particular, our vibratory aerosolization technology, which is technology that aerosolizes liquids by vibrating a metal plate that contains holes, will provide any competitive advantages for our products. We also cannot assure that those patents will not be successfully challenged, invalidated or circumvented in the future. In addition, we cannot assure that competitors, many of which have substantial resources and have made substantial investments in competing technologies, have not already applied for, or obtained, or will not seek to apply for and obtain, patents that will prevent, limit or interfere with our ability to make, use and sell our products either in the United States or in international markets. Patent applications are maintained in secrecy for a period after filing. We may not be aware of all of the patents and patent applications potentially adverse to our interests.

A number of pharmaceutical, medical device and other companies, as well as universities and research institutions, have filed patent applications or have issued patents relating to methods and apparatuses for aerosolization and pulmonary drug delivery. We have become aware of, and may become aware of in the future, patent applications and issued patents that relate to certain aspects of the technology employed in our products, including certain aspects of vibratory aerosolization technology. Our pending patent applications, and those that we may file in the future, may not result in patents being issued. We do not believe that our products currently infringe any valid and enforceable claims of the issued patents that we have reviewed. However, if third-party patents or patent applications contain claims infringed by our products and such claims are ultimately determined to be valid, we may not be able to obtain licenses to those patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. Our inability to do either would have a material adverse effect on our business, financial condition, results of operations and prospects. We cannot assure that we will not have to defend ourselves in court against allegations of infringement of third-party patents, or that such defense would be successful.

In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements. We require our employees and key consultants to execute confidentiality agreements upon the commencement of employment or a consulting relationship with us. We cannot assure that employees or consultants will not breach these agreements, that we would have adequate remedies for any breach or that our trade secrets will not otherwise become known to or be independently developed by competitors.

We have in the past and may become in the future subject to patent litigation, which has been and may be costly to defend and could invalidate our patents.

The pharmaceutical and medical device industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in these industries have used intellectual property litigation to gain a competitive advantage. We cannot assure that we will not become subject to, whether within or outside of the United States, patent infringement claims or litigation or interference proceedings declared by the United States Patent and Trademark Office, ("USPTO"), to determine the priority of inventions. Although we prevailed in a 1999 interference proceeding before the USPTO, that granted to Aerogen all but one of the independent claims of Bepak's 5,261,601 patent, we entered into a cross-license agreement with Bepak, as a result of which Bepak has a license to certain of our technology, including the right to sublicense. The scope of the granted license was limited to products employing technology which was disclosed by Bepak in United States Patent No. 5,261,601. Additionally, in April 2003, we received notice that a German patent infringement suit had been filed by PARI GmbH in the regional court in Munich, Germany alleging that Aerogen's Aeroneb Pro product infringes a patent licensed to PARI GmbH. While the suit has not yet been formally initiated by the German regional court, we believe that it is without merit and intend to vigorously defend against all allegations in the suit. In May 2003, we filed an action in the German patent office requesting that the patent in question be rendered null and void.

Our patent position involves complex legal and factual questions and is generally uncertain. Legal standards relating to the validity and scope of patent claims in the biotechnology and pharmaceutical field are evolving. Defending and prosecuting intellectual property suits, USPTO interference proceedings and related legal and administrative proceedings are costly and time-consuming. Further litigation may be necessary to enforce our patents, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings will be costly and will result in significant diversion of effort by technical and management personnel. An adverse determination in any of the litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties, require us to license disputed rights from third parties or require us to cease using such technology, which would have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, which could include ongoing royalties. We cannot assure that we can obtain the necessary licenses on satisfactory terms, if at all.

If we were successfully sued for product liability, we could face substantial liabilities that may exceed our resources.

Researching, developing and commercializing medical devices and pharmaceutical products entail significant product liability risks. The use of our products in clinical trials and the commercial sale of our products may expose us to liability claims. These claims might be made directly by consumers, by our partner companies or by others selling such products. Companies often address the exposure of this risk by obtaining product liability insurance. Although we currently have product liability insurance, we cannot assure that we can maintain such insurance or obtain additional insurance on acceptable terms

in amounts sufficient to protect our business or at all. A successful claim brought against us in excess of our insurance coverage would have a material adverse effect on our business.

We use hazardous and toxic materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our operations involve the use of hazardous and toxic materials and generate hazardous, toxic and other wastes. In particular, we use a special metal alloy to build our aerosol generators, a component of which is regulated as a hazardous material. The risk of accidental contamination or injury from hazardous and toxic materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and this liability could exceed our resources. Our operations could be shut down by government officials if we were not in compliance with environmental laws.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus and the documents incorporated by reference are forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our industry's results, levels of activity, performance or achievement to be materially different from any future results, performance or achievements expressed or implied in or contemplated by the forward-looking statements. Words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may," "should," "estimate," "predict," "potential," "continue," or the negative of such terms or other similar expressions, identify forward-looking statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Our actual results could differ materially from those anticipated in such forward-looking statements as a result of several factors more fully described under the caption "Risk Factors" above and in the documents incorporated by reference. The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We do not undertake any obligation to update forward-looking statements. The risks contained in this prospectus, among other things, should be considered in evaluating our prospects and future financial performance.

USE OF PROCEEDS

The proceeds from the sale of the common stock offered pursuant to this prospectus are solely for the accounts of the selling stockholders. We will not receive any proceeds from the sale of these shares of common stock.

SELLING STOCKHOLDERS

On January 23, 2004, we issued a secured convertible debenture and warrant to the Carpenter 1983 Family Trust UA (the "Carpenter Trust"). The warrant (the "Carpenter Warrant") is exercisable on or after July 26, 2004 for up to 82,129 shares of our common stock at an exercise price of \$3.044 per share, and expires on January 23, 2008.

On March 11, 2004, we entered into a Purchase Agreement (the "Purchase Agreement") with Xmark Fund, L.P., Xmark Fund, Ltd., and the other investors set forth on Schedule I, Schedule II and Schedule III to the Purchase Agreement (collectively, the "Investors"). Pursuant to the Purchase Agreement, we issued 1,142,094 shares of Series A-1 Convertible Preferred Stock (the "Preferred Stock") to the Investors (the "Financing"). The Preferred Stock is convertible for up to 11,420,940 shares of common stock at a conversion price of \$3.00 per share. In addition to the Preferred Stock, the Company issued the Investors warrants to purchase up to 11,249,390 shares of common stock at an exercise price of \$3.25 per share (the "Warrants"). Each holder of Preferred Stock is entitled to cumulative dividends at a rate of \$1.80 per share per annum, payable quarterly out of legally available funds or in common stock.

As part of the Financing, SF Capital Partners, Ltd. ("SF Capital") and the Carpenter Trust agreed to exchange the outstanding debentures previously issued to them for an aggregate of 52,232 shares of Series A-1 Preferred Stock. SF Capital also received a warrant to purchase up to 350,770 shares of our common stock at an exercise price of \$3.25 per share in connection with its debt exchange.

The terms of the Preferred Stock and Warrants preclude each Investor from converting Preferred Stock or exercising Warrants if the conversion or exercise would result in the Investor and/or its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following the conversion or exercise. Each Investor can waive this provision with respect to the Preferred Stock or Warrants it holds by providing 61 days' advance written notice to the Company. In addition, no warrant issued to SF Capital can be exercised if it would result in SF Capital and/or its affiliates beneficially owning more than 9.999% of our outstanding common stock. This provision cannot be waived.

We intend to issue a total of 127,906 shares of common stock as dividends on the Preferred Stock payable on April 1, 2004 and July 1, 2004. If we continue to elect to pay the quarterly dividend due on the Preferred Stock with shares of common stock, the actual number of common shares issuable in satisfaction of such quarterly dividends will vary with the fair market value of the Company's common stock at the end of each calendar quarter. As it is impossible to predict the fair market value of the Company's common stock in the future, it is impossible to accurately predict how many shares of common stock will be issued to satisfy any one quarterly dividend obligation in the future. Furthermore, it is impossible to predict when or if some or all of the Preferred Stock will convert into common stock, which would terminate the dividend obligation as to such converted shares. Based on our current cash resources, we expect to continue to pay the Preferred Stock dividend in common stock, and our good faith estimate of the number of shares that we will issue to satisfy the dividend is 1,500,000 shares.

An additional 50,000 shares of common stock are also being offered hereunder, consisting of shares of common stock issued to CA-Shoreline Technology Park Limited Partnership ("CA-Shoreline") pursuant to that certain Second Amendment to the Lease Agreement by and between the Company and CA-Shoreline (the "Second Amendment"), dated as of March 9, 2004. The Company agreed to register such additional shares pursuant to registration rights we had granted to CA-Shoreline in connection with the Second Amendment.

The shares being offered hereunder include: (i) the 11,420,940 shares of common stock issuable upon conversion of the Series A-1 Preferred Stock, (ii) the 11,249,390 shares of common stock issuable upon exercise of the Warrants, (iii) the 1,500,000 shares of common stock estimated to be payable as

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dividends on the Preferred Stock, (iv) the 82,129 shares of common stock issuable upon exercise of the Carpenter Warrant and (v) the 50,000 shares of common stock issued to CA-Shoreline.

We are registering the above-referenced shares to permit each of the selling stockholders and their pledgees, donees, transferees or other successors-in-interest that receive their shares from each selling stockholder as a gift, partnership distribution or other non-sale related transfer after the date of this prospectus to resell the shares.

The following table sets forth the name of each selling stockholder, the number of shares owned by each of the respective selling stockholders, the number of shares that may be offered under this prospectus and the number of shares of our common stock owned by the selling stockholders after this offering is completed. Except as otherwise disclosed below, none of the selling stockholders has, or within the past three years has had, any position, office or other material relationship with us. The number of shares in the column "Number of Shares Being Offered" represents all of the shares that a selling stockholder may offer under this prospectus, and assumes the exercise of all the warrants for common stock. The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares. The shares offered by this prospectus may be offered from time to time by the selling stockholders.

Our Chief Executive Officer and Chairman of our Board of Directors, Jane E. Shaw, and her husband, Peter Carpenter, are co-trustees of the Carpenter Trust.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934. Unless otherwise noted, none of the share amounts set forth below represents more than 1% of our outstanding stock as of August 2, 2004, adjusted as required by rules promulgated by the SEC. The percentages of shares beneficially owned prior to the offering are based on 4,784,506 shares of our common stock outstanding as of August 2, 2004, plus the shares of common stock beneficially owned by the respective selling stockholder, as set forth in the following table and more fully described in footnote 2, below. The percentages of shares beneficially owned after the offering are based on 4,784,506 shares of common stock outstanding as of August 2, 2004.

Name	Shares of Common Stock Beneficially Owned Prior to Offering(1)(2)		Number of Shares Being Offered	Shares Beneficially Owned After Offering(3)	
	Number	Percent		Number	Percent
Xmark Fund, Ltd.(4)	251,286	4.99%	1,852,820	0	*
Xmark Fund, LP(4)	251,286	4.99%	1,480,500	0	*
TNC Partners II, LLC(5)	33,320	*	33,320	0	*
Winchester Global Trust Company Limited as Trustee for Caduceus Capital Trust(6)	251,286	4.99%	1,000,000	0	*
Caduceus Capital II, LP(6)	251,286	4.99%	430,000	0	*
UBS Eucalyptus Fund, LLC(6)	251,286	4.99%	1,000,000	0	*
PW Eucalyptus Fund, Ltd.(6)	251,286	4.99%	120,000	0	*
Finsbury Worldwide Pharmaceutical Trust(6)	251,286	4.99%	1,300,000	0	*
HFC SHC Aggressive(6)	251,286	4.99%	150,000	0	*
HealthCap IV, LP(7)	251,286	4.99%	1,828,600	0	*

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HealthCap IV Bis, LP(7)	251,286	4.99%	1,043,520	0	*
HealthCap IV KB by HealthCap IV GP AB, its General Partner(7)	251,286	4.99%	411,200	0	*
OFCO Club IV by Odlander, Fredrikson & Co. AB, its member(7)	251,286	4.99%	50,000	0	*
Perceptive Life Sciences Master Fund, Ltd.(8)	251,286	4.99%	2,666,660	0	*
North Sound Legacy Fund, LLC(9)	251,286	4.99%	60,000	0	*
North Sound Legacy International, Ltd.(9)	251,286	4.99%	1,280,000	0	*
North Sound Legacy Institutional Fund, LLC(9)	251,286	4.99%	660,000	0	*
Pequot Scout Fund, LP(10)	251,286	4.99%	780,000	0	*
Pequot Navigator Offshore Fund, Inc.(10)	251,286	4.99%	362,000	0	*
Pequot Navigator Onshore Fund, LP(10)	251,286	4.99%	192,000	0	*
SDS Capital Group SPC, Ltd.(11)	251,286	4.99%	1,000,000	0	*
Bay Star Capital II, LP(12)	251,286	4.99%	1,000,000	0	*
ProMed Partners, LP(13)	251,286	4.99%	445,800	13,133	*
ProMed Partners II, LP(13)	251,286	4.99%	82,200	13,133	*
ProMed Offshore Fund, Ltd.(13)	251,286	4.99%	72,000	13,133	*
Paul Scharfer(13)	251,286	4.99%	166,660	13,133	*
David B. Musket(13)	251,286	4.99%	160,000	13,133	*
Ursus Capital, LP(14)	251,286	4.99%	360,000	317,500	6.98%
Ursus Offshore, Ltd.(14)	251,286	4.99%	310,000	317,500	6.98%
Porter Partners, LP(15)	251,286	4.99%	533,320	0	*
EDJ Limited(16)	133,320	2.71%	133,320	0	*
SF Capital Partners, Ltd.(17)	251,286	4.99%	1,368,200	251,243	4.99%
Anders Hove(18)	100,000	2.05%	100,000	0	*
Paul and Theresa Brown 1994 Trust dated 10/8/94(19)	66,660	1.38%	66,660	0	*
Carpenter 1983 Family Trust UA(20)	251,286	4.99%	253,679	0	*
CA-Shoreline Technology Park Limited Partnership(21)	110,000	2.30%	50,000	60,000	1.25%
Total			22,802,459		

*

Percentages are not shown if holdings total less than 1% of total outstanding shares.

(1)

Includes common stock, Preferred Stock on an as-converted basis and common stock issuable upon exercise of Warrants.

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- (2) The conversion of Series A-1 Preferred into common stock and the exercise of the Warrants covered in this table is limited so that no holder of Series A-1 Preferred Stock or Warrants covered by this table may beneficially own (with such holder's affiliates) more than 4.99% of the Company's then-outstanding common stock (the "4.99% limitation"). Each stockholder may waive the 4.99% limitation only upon 61 days' written notice to the Company. The share numbers in this column represent the maximum number of shares of common stock that each selling stockholder subject to the 4.99% limitation could hold upon conversion of its Series A-1 Preferred or exercise of its Warrants, based on 4,784,506 shares of common stock outstanding, and accounting for the shares resulting from the conversion or exercise.
- (3) Assumes the sale of all shares offered hereby.
- (4) Includes (i) 740,250 shares issuable upon the conversion of Preferred Stock held by Xmark Fund, LP; (ii) 926,410 shares issuable upon the conversion of Preferred Stock held by Xmark Fund, Ltd.; (iii) 740,250 shares issuable upon the exercise of warrants held by Xmark Fund, LP; and (iv) 926,410 shares issuable upon the exercise of warrants held by Xmark Fund, Ltd., for a total of 3,333,320 shares which would, in aggregate, represent 41.06% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. Xmark Asset Management, LLC ("XAM"), serves as investment manager for each of Xmark Fund, L.P. and Xmark Fund, Ltd., as well as various other private investment funds. Mitchell D. Kaye is the Manager of XAM, and as such, Mr. Kaye possesses the power to vote and direct the disposition of all securities held by Xmark Fund, L.P. and Xmark Fund, Ltd.
- (5) Includes (i) 16,660 shares issuable upon the conversion of Preferred Stock held by TNC Partners II, LLC; and (ii) 16,660 shares issuable upon the exercise of warrants held by TNC Partners II, LLC. Paul Siesser is the manager of TNC Partners II, LLC and, as such, possesses the power to vote and direct the disposition of all securities held by TNC Partners II, LLC.
- (6) Includes (i) 500,000 shares issuable upon the conversion of Preferred Stock held by Winchester Global Trust Company Limited as Trustee for Caduceus Capital Trust; (ii) 215,000 shares issuable upon the conversion of Preferred Stock held by Caduceus Capital II, LP; (iii) 500,000 shares issuable upon the conversion of Preferred Stock held by UBS Eucalyptus Fund, LLC; (iv) 60,000 shares issuable upon the conversion of Preferred Stock held by PW Eucalyptus Fund, Ltd; (v) 650,000 shares issuable upon the conversion of Preferred Stock held by Finsbury Worldwide Pharmaceutical Trust; (vi) 75,000 shares issuable upon the conversion of Preferred Stock held by HFC SHC Aggressive; (vii) 500,000 shares issuable upon the exercise of warrants held by Winchester Global Trust Company Limited as Trustee for Caduceus Capital Trust; (viii) 215,000 shares issuable upon the exercise of warrants held by Caduceus Capital II, LP; (ix) 500,000 shares issuable upon the exercise of warrants held by UBS Eucalyptus Fund, LLC; (x) 60,000 shares issuable upon the exercise of warrants held by PW Eucalyptus Fund, Ltd; (xi) 650,000 shares issuable upon the exercise of warrants held by Finsbury Worldwide Pharmaceutical Trust; (xii) and 75,000 shares issuable upon the exercise of warrants held by HFC SHC Aggressive, for a total of 4,000,000 shares which would, in aggregate, represent 45.53% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. OrbiMed Advisors LLC and OrbiMed Capital LLC act as investment advisers to certain collective investment funds. Samuel D. Isaly owns a controlling interest in OrbiMed Advisors LLC and OrbiMed Capital LLC. OrbiMed Capital LLC is the investment adviser for Finsbury Worldwide Pharmaceutical Trust and HFC SHC Aggressive.

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OrbiMed Advisors LLC is the investment adviser for Winchester Global Trust Company. OrbiMed Advisors LLC is also the general partner of Capital II, which is the joint venture partner of UBS Eucalyptus Fund, LLC and of PW Eucalyptus Fund, Ltd. As such, Mr. Isaly has the power to vote and to direct the disposition of all the securities held by Winchester Global Trust Company, UBS Eucalyptus Fund, LLC, PW Eucalyptus Fund, Ltd., Finsbury Worldwide Pharmaceutical Trust and HFC SHC Aggressive.

(7)

Includes (i) 521,760 shares issuable upon the conversion of Preferred Stock held by HealthCap IV Bis, LP; (ii) 914,300 shares issuable upon the conversion of Preferred Stock held by HealthCap IV, LP; (iii) 205,600 shares issuable upon the conversion of Preferred Stock held by HealthCap IV KB by HealthCap IV GP AB, its General Partner; (iv) 25,000 shares issuable upon the conversion of Preferred Stock held by OFCO Club IV by Odlander, Fredrikson & Co.; (v) 521,760 shares issuable upon the exercise of warrants held by HealthCap IV Bis, LP; (vi) 914,300 shares issuable upon the exercise of warrants held by HealthCap IV, LP; (vii) 205,600 shares issuable upon the exercise of warrants held by HealthCap IV KB by HealthCap IV GP AB, its General Partner; (viii) and 25,000 shares issuable upon the exercise of warrants held by OFCO Club IV by Odlander, Fredrikson & Co., for a total of 3,333,320 shares which would, in aggregate, represent 41.06% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. HealthCap IV GP S.A. is the general partner of HealthCap IV, L.P. and HealthCap IV Bis, L.P. and possesses, through its board of directors, the power to vote and direct the disposition of all securities held by HealthCap IV, L.P. and HealthCap IV Bis, L.P. The board of directors of HealthCap IV GP S.A., consists of Peder Fredrikson, a Swedish citizen and Francois Kaiser, a Swiss citizen. HealthCap IV GP AB is the general partner of HealthCap IV KB and possesses, through its board of directors, the power to vote and direct the disposition of all securities held by HealthCap IV KB. The board of directors of HealthCap IV GP AB consists of Johan Christenson, Anki Forsberg, Staffan Lindstrand, Magnus Persson, Björn Odlander and Per Samuelsson, each of whom are Swedish citizens. Odlander Fredrikson & Co AB as a member of OFCO Club IV and acting on behalf of the other members of OFCO Club IV has the power to vote and direct the disposition of all securities held by OFCO Club IV. Odlander Fredrikson & Co. AB is in turn controlled by Mr. Fredrikson and Mr. Odlander. Each of HealthCap IV, L.P., HealthCap IV Bis, L.P., HealthCap IV KB and OFCO Club IV are parties to a parallel investment agreement pursuant to which each of them has agreed to invest in parallel. The Odlander, Fredrikson Group acts as investment advisor to each of HealthCap IV, L.P., HealthCap IV Bis, L.P. and HealthCap IV KB.

(8)

Includes 1,333,330 shares issuable upon conversion of Preferred Stock and 1,333,330 shares issuable upon the exercise of warrants for a total of 2,666,660 shares which, in aggregate, would represent 35.79% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. Joseph E. Edelman is the Managing Member of Perceptive Advisors, LLC, the Investment Manager of Perceptive Life Sciences Master Fund, Ltd. ("Perceptive"). As such, Mr. Edelman has sole dispositive and voting authority for all Perceptive's shares.

(9)

Includes (i) 30,000 shares issuable upon the conversion of Preferred Stock held by North Sound Legacy Fund, LLC; (ii) 640,000 shares issuable upon the conversion of Preferred Stock held by North Sound Legacy International, Ltd.; (iii) 330,000 shares issuable upon the conversion of Preferred Stock held by North Sound Legacy Institutional Fund, LLC; (iv) 30,000 shares issuable upon the exercise of warrants held by North Sound Legacy Fund, LLC; (v) 640,000 shares issuable upon the exercise of warrants held by North Sound Legacy International, Ltd.; and (vi) 330,000

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shares issuable upon the exercise of warrants held by North Sound Legacy Institutional Fund, LLC, for a total of 2,000,000 shares which would, in aggregate, represent 29.48% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. North Sound Capital LLC is the investment advisor of North Sound Legacy Fund LLC, North Sound Legacy Institutional Fund LLC, and North Sound Legacy International Ltd. Thomas McAuley is the managing member of North Sound Capital LLC, and is the individual with the power to vote and to direct the disposition of all securities held by North Sound Legacy Fund, LLC, North Sound Legacy International, Ltd. and North Sound Legacy Institutional Fund, LLC.

- (10) Includes (i) 390,000 shares issuable upon the conversion of Preferred Stock held by Pequot Scout Fund, LP; (ii) 181,000 shares issuable upon the conversion of Preferred Stock held by Pequot Navigator Offshore Fund, Inc.; (iii) 96,000 shares issuable upon the conversion of Preferred Stock held by Pequot Navigator Onshore Fund, LP; (iv) 390,000 shares issuable upon the exercise of warrants held by Pequot Scout Fund, LP; (v) 181,000 shares issuable upon the exercise of warrants held by Pequot Navigator Offshore Fund, Inc.; and (vi) 96,000 shares issuable upon the exercise of warrants held by Pequot Navigator Onshore Fund, LP, for a total of 1,334,000 shares which would, in aggregate, represent 21.80% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. Arthur J. Samberg is the sole owner of Pequot Capital Management, Inc., which is the investment manager/advisor to the Pequot Funds, and as such, possesses the sole power to vote and to direct the disposition of all the securities held by Pequot Scout Fund, LP, Pequot Navigator Offshore Fund, Inc. and Pequot Navigator Onshore Fund, LP. Mr. Samberg disclaims beneficial ownership of any of these securities.
- (11) Includes 500,000 shares issuable upon conversion of Preferred Stock and 500,000 shares issuable upon the exercise of warrants for a total of 1,000,000 shares which, in aggregate, would represent 17.29% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. SDS Management, LLC is the investment advisor to SDS Capital Group SPC, Ltd. Steve Derby is the sole managing member of SDS Management, LLC, and as such, is the individual with the power to vote and to direct the disposition of all securities owned by SDS Capital Group SPC, Ltd.
- (12) Includes 500,000 shares issuable upon conversion of Preferred Stock and 500,000 shares issuable upon the exercise of warrants for a total of 1,000,000 shares which, in aggregate, would represent 17.29% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. BayStar Capital Management, LLC is the General Partner of BayStar Capital II, L.P. Lawrence Goldfarb, Steven M. Lamar, and Bay East, L.P. are the managing members of BayStar Capital Management, LLC. Steve Derby is the General Partner of Bay East, L.P. As such, Lawrence

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Goldfarb, Steven M. Lamar, and Steve Derby are the individuals with the power to vote and to direct the disposition of all securities owned by Bay Star Capital II, LP.

- (13) Includes (i) 222,900 shares issuable upon the conversion of Preferred Stock held by ProMed Partners, LP; (ii) 41,100 shares issuable upon the conversion of Preferred Stock held by ProMed Partners II, LP.; (iii) 36,000 shares issuable upon the conversion of Preferred Stock held by ProMed Offshore Fund, Ltd.; (iv) 83,330 shares issuable upon conversion of Preferred Stock held by Paul Scharfer; (v) 80,000 shares issuable upon conversion of Preferred Stock held by David B. Musket; (vi) 222,900 shares issuable upon the exercise of warrants held by ProMed Partners LP; (vii) 41,100 shares issuable upon the exercise of warrants held by ProMed Partners II, LP.; (viii) 36,000 shares issuable upon the exercise of warrants held by ProMed Offshore Fund, Ltd.; (ix) 83,330 shares issuable upon the exercise of warrants held by Paul Scharfer; and (x) 80,000 shares issuable upon the exercise of warrants held by David B. Musket; (xi) 9,800 shares of common stock held by ProMed Partners II LP; and (xii) 3,333 shares of common stock held by David B. Musket, for a total of 939,793 shares which would, in aggregate, represent 16.42% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. ProMed Partners, L.P., ProMed Partners II, L.P. and ProMed Offshore Fund, Ltd. are managed by ProMed Management, Inc. Barry Kurokawa and David B. Musket are the investment managers of ProMed Management, Inc. and as such, Mr. Kurokawa and Mr. Musket possess the power to vote and to direct the disposition of all securities held by ProMed Partners, L.P., ProMed Partners II, L.P., and ProMed Offshore Fund, Ltd.
- (14) Includes (i) 180,000 shares issuable upon the conversion of Preferred Stock held by Ursus Capital LP; (ii) 155,000 shares issuable upon the conversion of Preferred Stock held by Ursus Offshore, Ltd.; (iii) 180,000 shares issuable upon the exercise of warrants held by Ursus Capital, LP; and (iv) 155,000 shares issuable upon the exercise of warrants held by Ursus Offshore, Ltd.; (v) 184,580 shares of common stock held by Ursus Capital LP; and (vi) 132,920 shares of common stock held by Ursus Offshore Ltd., for a total of 987,500 shares which would, in aggregate, represent 19.61% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. Ursus Capital, L.P. is managed by Ursus Capital Management LLC. Mr. Evan Sturza is the sole member of Ursus Capital Management LLC, and possesses the power to vote and to direct the disposition of all securities held by Ursus Capital, L.P. Ursus Offshore, Ltd. is managed by Ursus Capital Management Corp. Evan Sturza is the investment manager of Ursus Capital Management Corp. and possesses the power to vote and to direct the disposition of all securities held by Ursus Offshore Ltd.
- (15) Includes 266,660 shares issuable upon conversion of Preferred Stock and 266,660 shares issuable upon exercise of warrants for a total of 533,320 shares which, in aggregate, would represent 10.03% of the Company's outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company's outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days' written notice to the Company. Jeffrey H. Porter has the