ARTES MEDICAL INC
Form 10-K
March 30, 2007

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2006

OR

o **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 001-33205

Artes Medical, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**33-0870808**
(State of Incorporation)	*(I.R.S. Employer Identification No.)*
5870 Pacific Center Boulevard **San Diego, California** *(Address of Principal Executive Offices)*	**92121** *(Zip Code)*

(858) 550-9999
(Registrant s Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	The NASDAQ Stock Market

Securities registered pursuant to Section 12(g) of the Exchange Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No þ

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 þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer o Non-accelerated filer þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ

The aggregate market value of the common stock held by non-affiliates of the registrant (14,605,371 shares) based on the closing price of the registrant s common stock as reported on the NASDAQ Stock Market on January 31, 2007, was $132,908,876. For purposes of this computation, all officers, directors, and 10% beneficial owners of the registrant have been excluded in that such persons may be deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors, or 10% beneficial owners are, in fact, affiliates of the registrant.

As of March 1, 2007, there were outstanding 16,361,995 shares of the registrant s common stock, par value $.001 per share, and no shares of the registrant s preferred stock.

Documents Incorporated by Reference

Portions of the registrant s definitive proxy statement for the 2007 Annual Meeting of Stockholders are incorporated by reference into Part III of this report. The registrant s 2007 Annual Meeting of Stockholders is scheduled to be held on June 12, 2007. The registrant will file its definitive proxy statement with the Securities and Exchange Commission not later than 120 days after the conclusion of its fiscal year ended December 31, 2006. In addition, certain exhibits filed with our prior registration statement on Form S-1 are incorporated by reference in Part IV of this report.

ARTES MEDICAL, INC.

ANNUAL REPORT ON FORM 10-K
Fiscal Year Ended December 31, 2006

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Forward-Looking Statements:

This Annual Report on Form 10-K, particularly in Item 1. Business and Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations , and the documents incorporated herein by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding our future financial position, business strategy and plans and objectives of management for future operations. Words such as believe, may, could will, estimate, continue, anticipate, intend, expect and similar expressions are in forward-looking statements.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this report, and in particular, the risks discussed under Item 1A. Risk Factors and those discussed in other documents we file with the Securities and Exchange Commission. In light of these risks, uncertainties and assumptions, readers are cautioned not to place undue reliance on such forward-looking statements. These forward-looking statements represent beliefs and assumptions only as of the date of this report. Except as required by applicable law, we do not intend to update or revise forward-looking statements contained in this report to reflect future events or circumstances.

This Annual Report on Form 10-K contains market data and industry forecasts that were obtained from industry publications, third-party market research and publicly available information. These publications generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. While we believe that the information from these publications is reliable, we have not independently verified, and make no representation as to the accuracy of, such information.

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PART I

Item 1. *Business.*

Overview

We are a medical technology company focused on developing, manufacturing and commercializing a new category of injectable aesthetic products for the dermatology and plastic surgery markets. On October 27, 2006, the FDA approved ArteFill, our non-resorbable aesthetic injectable implant for the correction of facial wrinkles known as smile lines, or nasolabial folds, for commercial sale in the United States. We commenced commercial shipments of ArteFill in February 2007. Currently, there are two categories of injectable aesthetic products used for the treatment of facial wrinkles: temporary muscle paralytics, which block nerve impulses to temporarily paralyze the muscles that cause facial wrinkles, and temporary dermal fillers, which are injected into the skin or deeper facial tissues beneath a wrinkle to help reduce the appearance of the wrinkle. Unlike existing temporary muscle paralytics and temporary dermal fillers, which are comprised of materials that are completely metabolized and absorbed by the body, ArteFill is a proprietary formulation comprised of polymethylmethacrylate, or PMMA, microspheres and bovine collagen, or collagen derived from calf hides. PMMA is one of the most widely used artificial materials in implantable medical devices, and is not absorbed or degraded by the human body. Following injection, the PMMA microspheres in ArteFill remain intact at the injection site and provide a permanent support structure to fill in the existing wrinkle and help prevent further wrinkling. As a result, we believe that ArteFill will provide patients with aesthetic benefits that may last for years.

We conducted a controlled, randomized, double-masked, prospective, multi-center U.S. clinical trial of 251 patients, in which 128 patients received ArteFill, and 123 patients received a control of either Zyderm® or Zyplast®, the leading bovine collagen-based temporary dermal fillers at that time. Patients who received ArteFill in our clinical trial showed wrinkle correction that persisted six months after treatment. In contrast, patients who received the collagen control in our clinical trial had returned to their pre-treatment status by their six-month evaluation. As provided in the study protocol, we offered all control group patients the opportunity to be treated with ArteFill at their six-month evaluation, and 91% of these patients accepted our offer. The safety profiles for ArteFill and the collagen control were comparable. In the 111 patients who were treated with ArteFill and remained in the study at 12 months after treatment, ArteFill demonstrated continued safety and wrinkle correction. We did not evaluate the patients who received the collagen control at 12 months after treatment because these patients had either elected to be treated with ArteFill at their six-month evaluation period or had returned to their pre-treatment status. Our promotion of the efficacy benefits of ArteFill is limited to the six-month efficacy evaluation period that we established as the official endpoint in our U.S. clinical trial.

We recently completed a five-year follow-up study of 145 patients who were originally treated with ArteFill in our U.S. clinical trial. In this follow-up study, patients were evaluated for efficacy and safety at a mean of 5.4 years after their last ArteFill injection. With respect to patients who had received treatment for nasolabial fold wrinkles, independent masked observers compared the wrinkle ratings for these patients at five years to baseline (prior to treatment) with an n=119. The results were statistically significant ($p<0.001$), with patients showing continued wrinkle correction at five years compared to baseline. Patients also showed continued improvement, demonstrating statistically significant improvement ($p=0.002$) in wrinkle correction at five years compared to six months after treatment with an n=113. The differences in the number of patients varies based upon the number of patients that returned at each visit and the presence of evaluable photos for masked observer grading. As part of the study, physician investigators and patients were asked to provide their assessment of ArteFill treatment. Over 90% of the physician assessments were either completely successful or very successful; and over 90% of the patient assessments

were either very satisfied or satisfied. We submitted the data from the study to the FDA for review in order to enhance the product labeling for ArteFill.

We market and sell ArteFill to dermatologists, plastic surgeons and cosmetic surgeons in the United States through our direct sales force comprised of 25 sales professionals as of March 1, 2007. We target dermatologists, plastic surgeons and cosmetic surgeons whom we have identified as having performed a large number of procedures involving injectable aesthetic products. These physicians are geographically concentrated in major urban centers in the United States. As part of our marketing and sales program, we train physicians in the technique of injecting ArteFill with the goal of optimizing patient and physician satisfaction with our product.

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Market Opportunity

Market Overview

Aesthetic procedures include non-surgical and surgical treatments to improve or enhance a patient s physical appearance. According to the American Society for Aesthetic Plastic Surgery, or the ASAPS, there were approximately 9.5 million non-surgical aesthetic procedures performed in the United States in 2006, representing a total consumer market of more than $4.5 billion. The leading non-surgical aesthetic procedure in 2006 was the administration of Botox, followed by hyaluronic acid (a type of dermal filler), laser hair removal, microdermabrasion, and chemical peel and the treatment of varicose veins. Women represented 92% of the patients who underwent non-surgical aesthetic procedures in 2006. Most non-surgical aesthetic procedures are considered to be elective procedures, the cost of which must be paid for directly by patients, and is not reimbursable through government or private health insurance.

Based on published membership numbers of professional medical associations, we believe that approximately 24,000 physicians in the dermatology, plastic surgery and cosmetic surgery specialties perform aesthetic procedures in the United States.

Based on our market research, we believe that a majority of injectable aesthetic procedures are performed by approximately 1,000 physicians who are primarily concentrated in major urban centers in California, Florida, New York, Texas, Nevada, Arizona and Illinois.

Injectable Aesthetic Treatment Market

According to the ASAPS, injectable aesthetic treatments are the largest and, for dermal fillers, the fastest growing segment of the non-surgical aesthetic treatment market. Injectable aesthetic products are administered through a syringe into the facial skin or deeper facial tissues in order to reduce the appearance of facial wrinkles and scars and to add fullness to the lips and cheeks. The ASAPS reported that, in 2006, approximately 5.2 million injectable aesthetic procedures were performed in the United States, and U.S. consumers spent approximately $2.5 billion on injectable aesthetic treatments.

Industry research conducted by Medical Insight, Inc. projects that the market for injectable dermal filler treatments will expand at a compound annual growth rate through 2011 of more than 25% in the United States and 20% throughout the rest of the world. We believe the rapid growth in the injectable aesthetic treatment market has been, and will continue to be driven largely by:

- the introduction of new products that offer improved aesthetic benefits and longer lasting results;
- an increasing demand for minimally invasive and cost-effective aesthetic treatments that offer immediate results;
- the aging of the baby boomer demographic segment, which currently represents over 25% of the U.S. population;
- a growing emphasis on self-image driven by the media and an increasingly youth-oriented culture;
- an increasing willingness of physicians to use products beyond their labeled indications; and

a growing trend among physicians to offer elective aesthetic treatments to generate additional income.

Currently, there are two categories of injectable aesthetic products: temporary muscle paralytics and temporary dermal fillers. Temporary muscle paralytics block nerve impulses to temporarily paralyze the muscles that cause facial wrinkles. Temporary dermal fillers are injected into the skin or deeper facial tissues to plump up the skin under a wrinkle or scar or to add fullness to tissues such as lips and cheeks. Because the substances contained in these products are completely metabolized and absorbed by the body over time, repeat injections typically are required to maintain the aesthetic effect.

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The most widely used injectable aesthetic products currently approved by the FDA for use in the United States for the correction of facial wrinkles include:

Product Category	Leading Brands	Ingredient	Approximate Number of Procedures Performed in 2006
Temporary Muscle Paralytics	Botox® Cosmetic	Botulinum toxin type A	3,200,000
Temporary Dermal Fillers	Captique™ Hylaform® Hylaform® Plus	Hyaluronic acid (HA)	1,600,000
	Restylane® CosmoDerm® CosmoPlast® Zyderm® Zyplast®	Human or bovine collagen	160,000
	Radiesse™	Calcium hydroxylapatite (CaHA)	77,000

Physicians also may use other injectable products off-label, beyond their FDA-approved labeled indications, to treat facial wrinkles and scars. For example, physicians used Sculptra®, an injectable filler consisting of a combination of saline and poly-L lactic acid, or PLLA, microspheres approved by the FDA for the restoration and/or correction of the signs of facial fat loss in people with human immunodeficiency virus, or HIV, in approximately 45,000 aesthetic procedures in 2006. Similar to the FDA-approved temporary dermal fillers listed above, the substances contained in Sculptra are completely metabolized and absorbed by the body over time.

Injectable aesthetic treatments usually involve multiple injections into the area to be corrected, and may require more than one office visit to obtain the desired aesthetic effect. Treatments typically are administered in less than 30 minutes. Patients often will receive a local anesthetic or nerve block, typically by injection, to reduce pain during treatment, especially for the treatment of sensitive areas around the lips. The instructions for use of all treatments that contain bovine collagen require physicians to administer a skin test for allergic reactions to bovine collagen approximately 30 days before a patient s first treatment with the bovine collagen-based product. Historically, approximately 3% of patients test positive for bovine collagen allergies. We believe the rate of allergic reactions to bovine collagen is inversely related to the purity of the collagen.

Market Dynamics for Injectable Aesthetic Treatments

The market for injectable aesthetic treatments is characterized by the following:

Rapid market acceptance of innovative and/or longer lasting aesthetic products. Injectable aesthetic products that offer new or improved benefits and/or longer lasting aesthetic effects have often achieved rapid market acceptance. Recent examples include:

Botox. Botox treatments are the most common aesthetic procedure performed in the United States. According to the ASAPS, approximately 3.2 million Botox treatments for aesthetic use were performed in the United

States in 2006. Since 1997, Botox treatments have experienced an annual growth rate of 54%.

Restylane. Launched in January 2004, Restylane, a product comprised primarily of hyaluronic acid, a jelly-like substance that is found naturally in living organisms and acts to hydrate and cushion skin tissue, has become the leading temporary dermal filler approved by the FDA for the correction of facial wrinkles. According to the ASAPS, the number of hyaluronic acid-based procedures has increased significantly over the past three years, from approximately 120,000 procedures in 2003, to 900,000 procedures in 2004, to 1.2 million procedures in 2005 and to 1.6 million procedures in 2006. We believe this increase was mainly attributable to the market launch of Restylane, which provides patients with a moderately longer lasting

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aesthetic benefit compared to prior leading temporary dermal fillers, such as the collagen-based Zyderm and Zyplast, and does not require a skin test prior to treatment like bovine collagen-based products.

Off-label use of available products. Physicians often use injectable aesthetic products beyond their specific FDA-approved indications. Off-label usage is common across medical specialties because physicians often use their professional judgment to decide whether an off-label use is the best treatment option for their patients. The FDA does not regulate the behavior of physicians in their choice of treatment options. The FDA does, however, strictly prohibit a manufacturer s promotion, advertising and labeling of all off-label uses. FDA penalties for promoting products off-label can include adverse publicity, warning letters, fines, civil and criminal penalties, injunctions and product seizures.

The following table highlights common off-label uses for several major injectable aesthetic products as compared to their FDA-approved indications:

Product Formulation	Leading Brand(s)	Approved by the FDA for the Treatment of Facial Wrinkles	FDA-Approved Indications	Common Off-Label Uses
Botulinum toxin type A	Botox	Yes	Moderate to severe frown lines	Forehead wrinkles; crow s feet; and vertical neck bands
Hyaluronic acid	Captique Hylaform Restylane Juvederm	Yes	Moderate to severe facial wrinkles and folds, such as smile lines	Forehead wrinkles; lip augmentation; and acne scars
Bovine or human collagen	CosmoDerm CosmoPlast Zyderm Zyplast	Yes	Soft tissue contour deficiencies such as wrinkles and acne scars	Lip augmentation
Calcium hydroxylapatite (CaHA)	Radiesse	Yes	Vocal cord augmentation, radiographic tissue marking, and oral maxillofacial defects, moderate to severe facial wrinkles and folds, such as nasolabial folds	Frown lines; marionette lines; lip augmentation
Poly-L lactic acid (PLLA)	Sculptra	No	Facial fat loss associated with HIV	Smile lines; marionette lines; and facial contours

Use of injectable aesthetic products as complementary treatments. Physicians commonly offer their patients aesthetic treatments that incorporate multiple products or procedures. For example, physicians commonly use more than one injectable aesthetic product during a single treatment procedure to achieve a desired result, such as combining Botox with a dermal filler. Physicians also increasingly use longer lasting injectable aesthetic products during surgical

procedures, such as facelifts, nose reconstructions and breast reconstruction.

Growing consumer base for injectable aesthetic treatments. Increasing consumer awareness and social acceptance of injectable aesthetic procedures have driven more patients to consider these procedures for the first time. Additionally, during initial patient consultations or following an initial aesthetic treatment, physicians who perform aesthetic procedures commonly inform their patients about other available injectable aesthetic products and cosmetic treatment options.

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Limitations of Current Treatments

All injectable aesthetic products currently approved by the FDA for the treatment of facial wrinkles contain substances that are readily absorbed and completely metabolized by the body, rendering their aesthetic effects relatively short-lived. The following table highlights the time lapse between treatments generally required to maintain a desired aesthetic effect with existing FDA-approved products, as reported by the ASAPS:

Product Categories	Representative Brands	Time Lapse between Treatments
Botulinum toxin type A	Botox Cosmetic	4 to 6 months
Hyaluronic acid	Captique Hylaform Restylane	4 to 12 months
Bovine or human collagen	CosmoDerm CosmoPlast Zyderm Zyplast	3 to 6 months

The temporary duration of these products limits their usefulness to physicians and patients in the following ways:

Patients must undergo repeat injections to sustain aesthetic benefits. In order to sustain the desired aesthetic benefits, patients must undergo repeat injections, which involve additional pain and inconvenience as a result of the multiple facial injections and the recovery time associated with each treatment. Some patients who undergo repeat injections may develop scars and discoloration in the target tissue area, as well as experience a decrease in the aesthetic effect of each successive treatment over time.

Cumulative cost of repeat injections. The cumulative cost of repeat treatments required to maintain the desired aesthetic benefits with currently available injectable aesthetic products may decrease the appeal of these products to patients over time. Based on data from the ASAPS, a patient treated with Botox Cosmetic would need to undergo between 10 to 15 treatments over a five year period to maintain the aesthetic benefit. A patient treated with Restylane would need to undergo between five to 15 treatments to maintain the aesthetic benefit over a similar five year period. Based on pricing data reported by the ASAPS, the cumulative cost to the consumer of these treatments would be at least $5,000 over five years.

Risk to physician practices of patient attrition. The expense, pain and inconvenience of a repeat injection regimen can decrease patient satisfaction with injectable aesthetic treatments and lead patients to discontinue treatments. Based on our market research and discussions with physicians, we believe that a significant percentage of patients suspend or cease injectable aesthetic treatments within one year after their first treatment. Patients who discontinue the use of injectable aesthetic products may stop going to the physician s office altogether, resulting in the physician losing the opportunity to market additional products and services to these patients.

Current products may have limited utility in conjunction with aesthetic surgical procedures. Physicians sometimes use injectable aesthetic products during surgical procedures, such as facelifts, nose reconstructions or other facial reconstruction procedures. The aesthetic effects provided by these products, however, have a much shorter duration than the aesthetic effects provided by surgical procedures. As a result, surgeons have not

widely adopted currently available injectable aesthetic products for use in conjunction with surgical procedures.

Injectable products, such as Sculptra, that are used off-label for the correction of facial wrinkles, present similar limitations because they also contain substances that are completely metabolized and absorbed by the body over time. In addition, the aesthetic correction provided by Sculptra typically is not visible until several weeks after the initial treatment. We also believe that the viscosity of Sculptra limits its off-label use primarily to deep facial contour deficiencies and severe wrinkles.

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Due to these limitations, and given the growth and rapid adoption of new, improved products within the market for injectable aesthetic products, we believe that a significant market opportunity exists for a safe and effective injectable aesthetic product that can provide patients with immediate and enduring aesthetic effects.

Our Solution ArteFill

ArteFill is a novel and proprietary injectable aesthetic implant for the correction of nasolabial folds, or smile lines. In October 2006, the FDA approved ArteFill for commercial sale in the United States, and we commenced commercial shipments of ArteFill in February 2007. ArteFill is the first product in a new category of non-resorbable aesthetic injectable products for the dermatology and plastic surgery markets. Unlike existing temporary muscle paralytics and temporary dermal fillers, which are comprised of materials that are completely metabolized and absorbed by the body, ArteFill is a proprietary formulation comprised of PMMA microspheres and purified bovine collagen. Following injection, the PMMA microspheres in ArteFill remain intact at the injection site and provide a permanent support structure to fill in the existing wrinkle and help prevent further wrinkling. As a result, we believe that ArteFill will provide patients with aesthetic benefits that may last for years. ArteFill has been shown to be safe and effective in our U.S. clinical trials.

We believe that ArteFill will offer the following benefits to physicians and patients:

Enduring aesthetic improvements. We have developed ArteFill to provide patients with aesthetic benefits that we believe may last for years. Based on clinical trial data, the FDA has determined that ArteFill is safe and effective and has allowed us to characterize it as a non-resorbable aesthetic injectable implant. ArteFill is the first non-resorbable injectable aesthetic product approved by the FDA for the treatment of nasolabial folds. Patients who received ArteFill in our clinical trial showed wrinkle correction that persisted six months after treatment. In contrast, patients who received the collagen control in our clinical trial had returned to their pre-treatment status by their six-month evaluation. As provided in the study protocol, we offered all control group patients the opportunity to be treated with ArteFill at their six-month evaluation, and 91% of these patients accepted our offer. In the 111 patients who were treated with ArteFill and remained in our clinical trial at 12 months after treatment, ArteFill demonstrated continued safety and wrinkle correction. We did not evaluate the patients who received the collagen control at 12 months after treatment because at their six-month evaluation period, these patients had either elected to be treated with ArteFill or had returned to their pre-treatment status. Our promotion of the efficacy benefits of ArteFill is limited to the six-month efficacy evaluation period that we established as the official endpoint in our U.S. clinical trial.

We recently completed a 5-year follow-up study of 145 patients who were treated with ArteFill in our U.S. clinical trial. In addition to demonstrating the safety profile of ArteFill, the study showed statistically significant ($p<0.001$) improvement in patient wrinkle correction five years after the patient s last ArteFill treatment, and a statistically significant ($p = 0.002$) improvement in wrinkle correction at the five-year point compared to the six-month evaluation period. We have submitted the data from the study to the FDA for review in order to enhance the product labeling for ArteFill.

Compelling value proposition to patients. We believe patients treated with ArteFill, versus currently available temporary injectable aesthetic products, will incur meaningfully lower cumulative costs over time to maintain the desired aesthetic effect. As a result, we believe ArteFill will present patients with a compelling value proposition because it will allow patients to avoid the cost of repeat injections required by existing temporary injectable aesthetic products.

High levels of patient satisfaction. We believe that the enduring aesthetic improvements provided by ArteFill may generate high levels of patient satisfaction by decreasing the discomfort, cost and inconvenience associated with frequent re-injections, which are required for existing injectable aesthetic products. As a result, we believe that the increased levels of patient satisfaction provided by our product will contribute to longer term physician- patient relationships. As part of our 5-year follow-up study, physician investigators and patients were asked to provide their assessment of ArteFill treatment. Over 90% of the physician assessments were either completely successful or very successful; and over 90% of the patient assessments were either very satisfied or satisfied.

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Differentiated, high value product for physician practices. We believe that the longer lasting aesthetic benefits of ArteFill will enable physicians to offer their patients a premium injectable aesthetic product and generate additional practice revenue per procedure.

Complement to surgical and non-surgical aesthetic treatments. Because of its ability to provide patients with aesthetic benefits that may last for years, we believe that physicians may choose to adopt ArteFill as a valuable complement to the various surgical and non-surgical aesthetic treatments they provide to their patients.

Our Strategy

Our goal is to become a leading medical technology company focused on developing, manufacturing and commercializing a new category of injectable aesthetic products for the dermatology and plastic surgery markets. We plan to achieve this goal through the following strategies:

Establish ArteFill as a leading injectable aesthetic product. ArteFill is the first product in a new category of non-resorbable aesthetic injectable products for the dermatology and plastic surgery markets. We believe ArteFill will provide patients with aesthetic benefits that may last for years. Therefore, we intend to continue to differentiate ArteFill from other injectable aesthetic products and position ArteFill as the premier enduring injectable aesthetic product for the treatment of nasolabial folds. We are and plan to continue to work closely with key opinion leaders to drive physician and patient awareness of the unique benefits of ArteFill.

Provide physicians with comprehensive education and training programs. In connection with the commercial launch of ArteFill, we have implemented a comprehensive physician education and training program to foster consistent and high-quality injection procedures and results. Our education and training program includes web-based training, in-office and off-site training seminars, as well as physician-to-physician training. We believe our education and training programs will enable physicians to improve patient outcomes and satisfaction.

Drive the adoption of our products through a direct sales and marketing effort. We have built a direct sales team of 25 sales professionals as of March 1, 2007. We target dermatologists, plastic surgeons and cosmetic surgeons whom we have identified as having historically performed a significant number of procedures involving injectable aesthetic products. Based on our market research, we believe that a majority of injectable aesthetic procedures are performed by approximately 1,000 physicians concentrated in several major urban centers in the United States. As part of our marketing efforts, we provide physicians with training, marketing programs and practice support services with respect to the use of ArteFill. We also use targeted marketing, advertising and promotional activities to educate consumers about the benefits of ArteFill.

Expand our product offering by acquiring complementary products, technologies or businesses. We may expand our aesthetic product offerings by acquiring complementary products, technologies or businesses that may be sold by our direct sales force to dermatologists, plastic surgeons and cosmetic surgeons. We also plan to explore additional uses of our injectable microsphere platform technology in markets outside of personal aesthetics through collaborative arrangements with strategic partners.

Our Product

ArteFill is composed of PMMA microspheres (20% by volume) suspended in a water-based carrier gel (80% by volume) containing bovine collagen and lidocaine, a local anesthetic. ArteFill is a smooth, opaque, off-white gel. We sell ArteFill in kits containing five sterile pre-filled syringes. We also provide individual skin test kits, with each kit

containing five skin test syringes filled with our manufactured bovine collagen.

PMMA Microspheres

ArteFill is a proprietary combination of round and smooth PMMA microspheres, ranging from 30 to 50 microns in diameter, suspended in a bovine collagen-based solution. PMMA is a biocompatible synthetic

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polymer manufactured to the standards required for use as a long-term medical grade implant. PMMA is one of the most widely used artificial materials in implantable medical devices and has been used for more than 60 years in medical implants such as intraocular lenses and dental prostheses. Scientific studies have shown that PMMA microspheres are both biocompatible and safe for use in humans as soft tissue fillers. These studies also show that human enzymes are unable to metabolize PMMA because of its chemical structure. As a result, PMMA microspheres are not degraded or absorbed by the human body following injection.

The size, shape and smoothness of the PMMA microspheres utilized in a soft tissue filler are important to the product s biocompatibility. Scientific studies have shown that round and smooth microspheres, such as those contained in ArteFill, cause less adverse tissue response compared to other irregular shapes. We believe that PMMA microspheres with diameters of 30 to 50 microns are within the optimal size range for use in soft tissue fillers because PMMA microspheres of this size are small enough to be easily injected through a standard 26-gauge needle, but are large enough to prevent migration from the implantation site and to avoid removal of the microspheres by white blood cells.

We manufacture our PMMA microspheres at our manufacturing facility in Frankfurt, Germany. We have developed a proprietary manufacturing process that generates round and smooth microspheres from medical grade PMMA. This proprietary process ensures that our PMMA microspheres are of the proper size and shape to meet the FDA s stringent quality requirements.

Bovine Collagen

We manufacture the bovine collagen contained in ArteFill at our manufacturing facility in San Diego, California. Bovine collagen has been used by plastic surgeons and dermatologists to treat wrinkles and scars for over 25 years. To ensure both safety and quality, we use a proprietary manufacturing process to produce a highly purified and partly denatured bovine collagen solution from calf hides. Historically, approximately 3% of patients test positive for allergies to bovine collagen-based products. We believe that our collagen is among the most highly purified injectable collagens in the medical industry, and accordingly, may cause a lower incidence rate of allergic reactions in patients, providing us with a competitive advantage over other bovine collagen-based injectable aesthetic products. None of the 391 patients in our U.S. clinical trials tested positive for allergic reactions to our purified bovine collagen.

We plan to conduct a post-market study under an FDA-approved protocol regarding the incidence of allergic reactions to our collagen to determine whether the FDA would approve treatment with ArteFill without a skin test.

We take numerous precautions to help ensure that our bovine collagen is free from BSE. We purchase our supply of calf hides from a herd that is isolated, bred and monitored in accordance with both FDA and USDA guidelines. This closed herd provides a reliable source of raw material, with backup capabilities in case of natural disasters. We purchase only the hides of male calves younger than six months of age. Studies of BSE outbreaks have found that BSE typically manifests itself in female cattle between 40 and 60 months of age. The youngest calf ever detected with BSE was 19 months of age. These studies also have found that BSE is more than 100 times more prevalent in adult females than adult males. We currently have an 18 months supply of calf hides in frozen storage at our manufacturing facility and intend to establish and maintain a supply of calf hides that will last for more than two years. The FDA has required that we continue to monitor the stability of our ArteFill product for a sufficient period of time to support the 18-month expiration date in our product label.

Lidocaine

ArteFill contains a local anesthetic, lidocaine (0.3%). Lidocaine reduces patient discomfort during and after the injection process, making ArteFill injections more convenient for patients and physicians than other injectable aesthetic products that do not contain a local anesthetic.

Storage and handling

We sell ArteFill in kits containing five sterile pre-filled syringes, sealed within a thermoformed tray. These kits must be maintained in refrigerated storage at standard domestic refrigerator temperatures (4º to 8º C) for the

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duration of the product shelf life. We ship each kit inside a container designed to maintain the 4º to 8º C temperature requirement during overnight transit. We believe most physicians who are currently treating their patients with injectable aesthetic products already have refrigerated storage capabilities in their offices.

Our Proprietary Microsphere Technology

ArteFill is based on our proprietary combination of PMMA microspheres and bovine collagen, which we believe serves to stimulate the natural growth of a patient s collagen in the treated area. The bovine collagen in ArteFill provides for the initial correction of a wrinkle and serves to maintain an even distribution of the PMMA microspheres at the injection site, while the PMMA microspheres act as a scaffold for the patient s own collagen deposition. After implantation, the bovine collagen is gradually metabolized and absorbed by the patient s body. At the same time, the collagen-coated PMMA microspheres stimulate fibroblasts, which are cells naturally present in the patient s body, to produce collagen that encapsulates each individual microsphere. The PMMA microspheres are designed not to migrate from the injection site while the patient s own collagen replaces the bovine collagen component of ArteFill. The treated area eventually consists of the patient s own collagen encapsulating each of the PMMA microspheres. We believe that the encapsulation of the PMMA microspheres by the patient s own collagen will provide aesthetic improvements that may last for years.

ArteFill Treatment

ArteFill is administered primarily in an out-patient clinical setting, such as a physician s office. Treatment with ArteFill requires between 15 and 30 minutes. Similar to the application of several widely used temporary dermal fillers, the physician administers ArteFill through a commonly used tunneling injection technique, in which the physician moves the needle linearly beneath the skin wrinkle. The physician can use the thickness of the needle as a gauge to help determine the correct depth of the injection. Because physicians are encouraged to avoid over-correction during the initial injection, patients may require one or two touch-up treatments in intervals of at least two weeks to achieve the desired aesthetic results.

As with all bovine collagen-based products, the instructions for use of ArteFill require physicians to administer a skin test to screen each patient for an allergic reaction to bovine collagen before the patient s first treatment. The skin test involves the physician injecting our purified bovine collagen into the patient s forearm skin and the patient monitoring the treatment area for 28 days. If there are no signs of irritation during the 28-day monitoring period, the patient can proceed with the ArteFill treatment. We believe that our collagen is among the most highly purified injectable collagens in the medical industry and that our collagen accordingly may result in a lower rate of allergic reactions in patients, providing us with a competitive advantage over other bovine collagen-based injectable aesthetic products. We plan to conduct a post-market study under an FDA-approved protocol regarding the incidence of allergic reactions to our collagen to determine whether the FDA would approve treatment with ArteFill without a skin test.

Our Physician Training and Education Program

The goal of our training program is to maximize patient and physician satisfaction with ArteFill by fostering consistent and high-quality injection procedures. As part of our commercial launch, we initiated a a comprehensive training program in order to ensure that physicians are trained to inject ArteFill using a common tunneling injection technique. We intend to offer ArteFill only to physicians who have successfully completed our training program. We have focused and intend to continue to focus on training those physicians whom we have identified as having significant experience in performing injectable aesthetic procedures using the tunneling injection technique. We have designed our training program to be adaptable to each physician s level of prior experience with this technique. Our training program includes the following modules:

Web-based Training. We offer physicians a 30 minute web-based interactive tutorial on ArteFill s scientific background, clinical trial information, injection technique and treatment guidelines.

Training Seminars.

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In-office Training. We offer physicians who have significant experience with the tunneling injection technique a training program in their offices. The training includes an injection technique video, an injection training manual and reference materials.

Hands-on Training. Other physicians participate in a half-day educational program that provides in-depth injection technique training. The program includes live demonstrations and hands-on practice injecting ArteFill using training masks. We also provide training support, an injection training manual and reference materials.

Physician-to-Physician Training. We have established a peer training program, through which physicians who are highly skilled in the tunneling injection technique and have completed our training program may participate in training other physicians.

Sales and Marketing

We commenced commercial shipments of ArteFill in February 2007. We have built a direct sales force in the United States to sell ArteFill into the dermatology and plastic surgery markets. We target dermatologists, plastic surgeons and cosmetic surgeons whom we have identified as having performed a large number of procedures involving injectable aesthetic products. We market ArteFill through our sales and marketing organization, which included 25 sales professionals as of March 1, 2007.

Within the dermatology and plastic surgery markets, we believe that there are approximately 24,000 physicians in the United States, including approximately 14,000 dermatologists, 7,500 plastic and reconstructive surgeons and 2,500 facial/ear-nose-and-throat plastic surgeons. However, we believe that only approximately 5,000 of these physicians offer injectable aesthetic products to their patients.

Furthermore, we believe that a majority of injectable aesthetic procedures are performed by approximately 1,000 physicians who are concentrated in major urban centers in the United States, including California, Florida, New York, Texas, Nevada, Arizona and Illinois. Our initial sales effort has and will continue to target these highly experienced physicians and we expect that the size of our direct sales organization is appropriate to support our commercial launch. We believe that targeting physicians highly experienced with the injection technique used to administer ArteFill will help drive market adoption.

We believe that the advantages of ArteFill over currently available injectable aesthetic treatments for the correction of facial wrinkles will allow us to position ArteFill as a premium injectable aesthetic product. According to our market research, we believe temporary injectable aesthetic products are not meeting all of the needs of patients and physicians for lasting treatment results, value and convenience. Based on its product attributes, we believe ArteFill fills a void that currently exists in the market for injectable aesthetic products. As a result, we market ArteFill to physicians at a premium price, supported by the positioning of ArteFill as the first non-resorbable aesthetic injectable implant for the treatment of nasolabial folds. Based on our market research, we believe patients are willing to pay a premium price for ArteFill when they understand that the cost of ArteFill will be lower than the cumulative costs of the treatment regimen required by currently available temporary injectable aesthetic products.

As part of our marketing strategy, we have developed programs to support physicians and their practices and to foster a mutual commitment to patient satisfaction. Specifically, these programs include:

- technical skill support programs, such as advanced injection training symposia;

promotional materials that provide a physician s patients with information about ArteFill treatments;

marketing programs to assist physicians in developing their patient base for ArteFill; and

participation in our web-based physician locator service.

We market and plan to continue to market ArteFill to physicians through scientific presentations at medical conferences and symposia, advertising in scientific journals, industry trade publications and our website. We have and intend to continue to publish scientific articles to expand physician awareness of our product, and we have and intend to continue offer clinical forums with recognized expert panelists to discuss their experience with ArteFill.

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We are striving to build consumer awareness of ArteFill through physician office marketing programs, health and lifestyle magazine advertisements and our website.

Manufacturing

We have established our 35,000 square foot dedicated manufacturing facility and corporate headquarters in San Diego, California for the production of ArteFill. At this facility, we utilize a proprietary manufacturing process to produce purified and partly denatured bovine collagen from calf hides for the water-based carrier gel, which includes 3.5% purified bovine collagen. Our proprietary process includes viral inactivation, extraction, purification and sterile filtration of the collagen. Our viral inactivation procedure employs two separate validated process steps to inactivate potential viruses in the bovine corium, or inner layer of the calf skin. In addition, we treat our bovine collagen with sodium hydroxide to inactivate potential viruses. We create the final product at this facility by evenly suspending our PMMA microspheres within the water-based carrier gel, which includes 0.3% lidocaine, through our proprietary sterile mixing and syringe filling process. We then package the sterile pre-filled syringes into kits.

We conduct our manufacturing operations at our San Diego facility using sterile and calibrated equipment in dedicated controlled rooms suitable for maintaining product sterility consistent with Good Manufacturing Practice, or GMP, regulations.

Our clean room facilities include equipment sterilizers and a water purification system, and are controlled by an integrated building management system that monitors and regulates air handling and temperature. Our product packaging and labeling capabilities include sealing validations, sterile barriers, transit testing, stability testing, as well as process-validated labeling and barcode generation. We believe our San Diego facility will be capable of supporting our manufacturing, distribution and product development requirements for the foreseeable future.

We currently manufacture our PMMA microspheres at our 3,550 square foot dedicated manufacturing and warehouse facility in Frankfurt, Germany. We utilize a proprietary manufacturing process that generates round and smooth microspheres from medical grade PMMA. The process extracts microspheres ranging from 30 to 50 microns in diameter, and ensures that no more than 1% of the total number of microspheres are smaller than 20 microns in diameter. We then sterilize and package the microspheres and ship them to our San Diego manufacturing facility for final inspection and use in ArteFill. We believe our Frankfurt facility has sufficient capacity to meet our needs for PMMA microspheres for the foreseeable future. We intend to implement redundant capabilities for the production of PMMA microspheres at our San Diego facility. In addition, we plan to further improve and automate our production process in San Diego.

Manufacturing facilities that produce medical devices intended for distribution in the United States and internationally are subject to regulation and periodic unannounced review by the FDA and other regulatory agencies. On October 27, 2006, the FDA issued final certification of our facilities in connection with its approval of ArteFill for sale in the United States. Manufacturing facilities that produce medical devices intended for sale and distribution in the European Economic Community, or EEC, are subject to regulatory requirements of the Medical Devices Directive, or MDD, as well as various International, or ISO, and European National, or EN, standards. In Europe, Notified Bodies are responsible for the enforcement of MDD regulations. In January 2006, KEMA, a European Notified Body, issued to us a quality system certificate indicating that our facilities are in compliance with ISO 13485, the internationally recognized quality system standard for medical device manufacturers.

We have limited experience in manufacturing commercial quantities of ArteFill. While we believe that our current facilities will be sufficient to manufacture an adequate supply to meet the demand for ArteFill through 2008, in order to produce ArteFill in the quantities we anticipate will be necessary to meet future market demand, we will need to increase our manufacturing capacity significantly over the current level.

Material Agreements

We have in place an intercompany manufacturing and supply agreement with our wholly-owned subsidiary, Artes Medical Germany GmbH , or Artes Medical Germany, pursuant to which Artes Medical Germany exclusively manufactures and supplies to us the PMMA microspheres used in ArteFill. Under the terms of this agreement, pricing for the PMMA microspheres is based on Artes Medical Germany s actual documented production costs,

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determined in accordance with generally accepted accounting principles in the United States, subject to adjustment, plus an additional manufacturing profit. This agreement has an indefinite term, but may be terminated by either us or Artes Medical Germany for cause, or by us in the event of a supply failure or for convenience at any time upon ninety days prior written notice of termination to Artes Medical Germany.

We also have in place a supply agreement with Lampire Biological Labs, Inc., or Lampire, pursuant to which Lampire sells to us bovine corium, which we use to produce our highly purified and partly denatured bovine collagen contained in ArteFill. Under the terms of this agreement, pricing is based on unit fees for the acquisition of calves and for processing. Lampire has agreed to process the bovine corium in strict accordance with general and manufacturing process requirements to ensure safety and quality, and to ensure that our bovine collagen is free from BSE. This agreement has an initial term of one year and is subject to automatic renewals of successive one-year periods. Lampire is our sole supplier of bovine corium.

In October 2005, we and Dr. Martin Lemperle entered into a settlement and license agreement with BioForm Medical, Inc. and BioForm Medical Europe B.V., pursuant to which all outstanding disputes and litigation matters among the parties were settled. Under the agreement, we granted to the BioForm entities an exclusive, world-wide, royalty-bearing license under certain of our patents to make and sell implant products containing CaHA particles, and a non-exclusive, world-wide, royalty-bearing license under the same patents to make and sell certain other non-polymeric implant products, and the BioForm entities paid us a technology access fee of $2.0 million for these rights. Under the terms of the agreement, we are entitled to bring suit, at our own expense, to enforce the licensed patents against any third party infringers and to retain any and all damages, including damages for harm to the sales of BioForm, its affiliates or its sublicensees, obtained by us in our efforts to stop the infringement. BioForm has agreed to provide reasonable cooperation to us in connection with any such enforcement action. In the event we are involved in a bankruptcy proceeding or discontinue our business, then BioForm may, at it own expense and for its own benefit, enforce the licensed patents. The settlement and license agreement remains in effect so long as any of the patents licensed under the agreement continues to have at least one valid and enforceable claim that has not expired, lapsed, or been disclaimed or permanently abandoned. We may terminate the license grants under the agreement only if BioForm fails to make timely payment of a royalty amount determined to be due to us by an arbitrator. BioForm may terminate the agreement only if all licensed patents that remain in force are in force solely by virtue of extensions to the original patent terms, and the extensions do not cover any products of BioForm or its sublicensees under the agreement.

In November 2006, we entered into a loan and security agreement with Comerica Bank, pursuant to which we obtained a credit facility consisting of a revolving line of credit in the amount of up to $5.0 million and a term loan in the amount of up to $5.0 million. Interest on the revolving line of credit and the term loan will be at prime plus 2%. The revolving line and term loan mature in November 2007 and 2010, respectively. We are required to maintain a cash balance equal to 1.25 times our indebtedness to Comerica Bank. In addition, the loan and security agreement includes several restrictive covenants, including requirements that we obtain the consent of Comerica Bank prior to entering into any change of control event, incurring other indebtedness or making distributions to our stockholders. To secure the credit facility, we granted Comerica Bank a first priority security interest in our assets and agreed not to encumber our intellectual property rights without the prior consent of Comerica Bank. On November 30, 2006, we drew down the $5.0 million term loan under the credit facility; and on December 28, 2006, we drew down $5.0 million on the line of credit. In connection with the loan and security agreement, we issued Comerica Bank a warrant to purchase 28,235 shares of common stock at an exercise price of $10.63 per share.

Competition

The market for injectable aesthetic products is intensely competitive, subject to rapid change and significantly affected by new product introductions. We compete against other medical technology and pharmaceutical companies who

market aesthetic products. In the United States, we compete primarily with companies that offer temporary injectable aesthetic products approved by the FDA for the correction of facial wrinkles, such as Medicis Pharmaceutical Corporation, Allergan, Inc. and BioForm Medical, Inc. In addition, we compete with companies that offer products that physicians currently use off-label for the correction of facial wrinkles, including Dermik Laboratories, a subsidiary of sanofi-aventis. A number of companies, such as Mentor Corporation, are currently developing new products that may be used for the treatment of facial wrinkles, although we believe none of them

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involve a non-resorbable injectable aesthetic implant. We also compete with companies that offer different treatments for facial wrinkles, including topical cosmeceuticals and creams, chemical peels, laser skin treatments and microdermabrasion.

To compete effectively, we need to demonstrate that ArteFill is a unique and attractive alternative to these other products and treatments. We believe the principal competitive factors in our market include:

safety and efficacy;

immediate and enduring aesthetic results;

cost-effectiveness to patients and physicians;

reduced pain and recovery time before a patient can return to normal activities;

effectiveness of marketing and distribution; and

ability to leverage existing relationships with physicians and distributors.

In addition, in March 2006, Allergan completed its acquisition of INAMED Corporation. As a result of this transaction, the market for injectable aesthetic products experienced a significant concentration of products within a single entity with greater resources and the ability to provide an expanded range of products and services and pricing programs. These companies and others have developed and will continue to develop new products that compete with our products.

Government Regulation

ArteFill is classified as a medical device and is subject to extensive and rigorous regulation by the FDA, as well as by other federal and state regulatory bodies in the United States and comparable authorities in other countries. FDA regulations govern the following activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

product design, development and manufacture;

product safety, clinical testing, labeling and storage;

pre-marketing clearance or approval;

record-keeping procedures;

product marketing, sales and distribution; and

post-marketing surveillance, reporting of deaths or serious injuries and medical device reporting.

FDA s Pre-market Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require either prior 510(k) clearance or PMA from the FDA. Medical devices are classified into one of three classes Class I, Class II, or Class III depending on the degree of risk associated with each medical device and the extent of control

needed to ensure safety and effectiveness. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a pre-market notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices like ArteFill, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring PMA. ArteFill is a Class III device that required approval of a PMA application.

510(k) Clearance Pathway

When a 510(k) clearance is required, we must submit a pre-market notification to the FDA demonstrating that our proposed device is substantially equivalent to a previously cleared and legally marketed 510(k) device or a

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device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA application. By regulation, the FDA is required to clear or deny a 510(k) pre-market notification within 90 days of submission of the application. As a practical matter, clearance often takes significantly longer.

The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously cleared device or use, the FDA will place the device, or the particular use, into Class III. We currently do not have any products in development that would qualify for 510(k) clearance.

Pre-market Approval Pathway

A PMA application must be submitted to the FDA if the device cannot be cleared through the 510(k) process. The PMA application process is much more demanding and uncertain than the 510(k) pre-market notification process. A PMA application must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA s satisfaction the safety and effectiveness of the device. After a PMA application is submitted and the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for review. The FDA has 180 days to review an accepted PMA application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with QSRs. New PMA applications or PMA application supplements are required for a significant modification to the manufacturing process, labeling and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application and may not require as extensive clinical data or the convening of an advisory panel. FDA review of most PMA applications and PMA supplements is subject to payment of a user fee, ranging from $18,000 to $259,000 (in fiscal year 2006), with reduced fees applicable to small business concerns.

Clinical Trials

Clinical trials are almost always required to support a PMA approval and are sometimes required for 510(k) clearance. In the United States, these trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites. Our clinical trials must be conducted under the oversight of an IRB at the relevant clinical trial sites and in accordance with FDA regulations, including but not limited to those relating to good clinical practices. We are also required to obtain patients informed consent that complies with both FDA requirements and state and federal privacy regulations. We, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain approval of the product. Similarly, in Europe the clinical study must be approved by the local ethics committee and in some cases, including studies with high-risk devices, by the Ministry of Health in the applicable country.

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Regulatory Status of ArteFill

In April 2002, we submitted to the FDA a PMA application for our product candidate. We initially named the product used in our clinical trials Artecoll, but later changed the name of our product candidate to ArteFill to reflect refinements that we made to the PMMA microsphere manufacturing process.

In February 2003, an independent expert advisory panel on general and plastic surgery devices recommended that our PMA application be considered approvable. The FDA adopted the recommendations of the panel, and in January 2004 the FDA issued a letter informing us that our PMA application was approvable, subject to the fulfillment of two conditions. The first condition to approval required us to demonstrate that we can manufacture the bovine collagen component of ArteFill at a dedicated manufacturing facility according to FDA quality requirements. The second condition to approval was the submission of a post-market study protocol for examining the potential incidence of delayed granuloma formation in patients treated with ArteFill. A granuloma is an inflammatory reaction to a foreign body that results in redness and hardening of tissue at the injection site. Granuloma formation has been reported to occur in patients treated with all dermal fillers. In the case of temporary dermal fillers, this condition can dissipate when these fillers biodegrade and are reabsorbed by the body. In the case of ArteFill, which is a non-resorbable aesthetic injectable implant containing PMMA microspheres that will not be absorbed or degraded by the human body, it is believed that granuloma formation could occur at any time after injection, although we, the FDA and the medical community currently do not have long-term data regarding the incidence rate of granuloma formation in patients treated with ArteFill. As a result, the FDA has required us to conduct this post-market study to examine whether treatment with ArteFill affects the incidence rate of granuloma formation. We are required to identify the methods by which we will monitor approximately 1,000 patients for granuloma formation for a period of five years after the date of their initial treatment. The FDA has informed us that our proposed protocol is acceptable.

In January 2006, we submitted an amendment to our PMA application to address the conditions set forth in the FDA s approvable letter. In March 2006, the FDA completed inspections of our manufacturing facility and our contract sterilizer in Frankfurt, Germany, with no observations noted. In addition, the FDA completed a comprehensive pre-approval inspection of our primary manufacturing facility in San Diego, California, in April 2006. During this inspection, the FDA noted four minor observations, all of which were corrected and annotated to the inspection report as corrected. On May 3, 2006, the FDA issued an EIR, indicating that its inspection of our manufacturing facilities was completely closed, requiring no further action on the part of our company related to the inspection. On October 27, 2006, the FDA approved ArteFill for the correction of facial wrinkles known as smile lines, or nasolabial folds.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- the FDA s QSRs, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;

- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;

medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and

post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We have registered with the FDA as a medical device manufacturer and have received a manufacturing license from the California Department of Health Services, or CDHS.

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We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDHS, or FDB, to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refunds, recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing our requests for 510(k) clearance or PMA of new products, new intended uses or modifications to existing products;

withdrawing 510(k) clearance or PMAs that have already been granted; and

criminal prosecution.

ArteFill Instructions for Use

In connection with approving our PMA application for ArteFill, the FDA also reviewed and approved our Instructions for Use of ArteFill, or our product label. Our product label provides that ArteFill is indicated for the correction of nasolabial folds in the general population, but is contraindicated for use in patients that:

have a positive reaction to our ArteFill skin test;

have a history of severe allergies manifested by a history or presence of multiple severe allergies;

are allergic or hypersensitive to the anesthetic lidocaine contained in ArteFill;

have a history of allergies to any bovine collagen products;

are prone to thick scar formation and/or excessive scarring; or

are undergoing or planning to undergo desensitization injections to meat products.

ArteFill also is contraindicated for augmentation in the body of the lip.

Our product label further provides that ArteFill should not be used in patients that have skin outbreaks near the injection site until any outbreak clears and cautions that patients may experience increased bruising or bleeding at the injection site if they are taking aspirin or anti-inflammatory drugs or have any medical condition that affects their blood. In addition, physicians, in order to help their patients make an informed treatment decision, should ask patients if they:

have had any treatments for smile lines in the last 6 months;

are receiving ultra-violet light therapy; or

are currently on immuno-suppressive medications or are suffering from any skin disease.

The product label also provides that the most common adverse events associated with ArteFill injections, similar to those observed with other dermal fillers, are lumpiness, persistent swelling or redness and increased sensitivity at the injection site.

Promotion and Advertising Restrictions

We may promote and advertise ArteFill only for the correction of nasolabial folds. We are also limited to promoting the efficacy benefits of ArteFill for six months. However, physicians may prescribe ArteFill for uses that are not described in its FDA-approved labeling and for uses that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, strictly prohibit a manufacturer s communications regarding off-label uses. Companies cannot actively promote FDA-approved devices for off-label uses. If the FDA

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believes we are promoting ArteFill for off-label uses, we could be subject to negative publicity, warning letters, fines, civil and criminal penalties, injunctions and product seizures.

FDA Investigation

In March 2006, the counsel for Dr. Gottfried Lemperle, our former Chief Scientific Officer and a former member of our board of directors, in the Sandor litigation discussed in Legal Proceedings below informed us that she had contacted an investigator in the FDA s Office of Criminal Investigations. She further stated that the FDA investigator informed her that the FDA has an open investigation regarding us, Dr. Gottfried Lemperle and his son, Dr. Stefan Lemperle, our former Chief Executive Officer and a former director, that the investigation had been ongoing for many months, that the investigation would not be completed within six months, and that when the investigation is completed, it could be referred to the U.S. Attorney s Office for criminal prosecution. In November 2006, we contacted the FDA s Office of Criminal Investigations. That office confirmed the ongoing investigation involving the Company, but declined to provide any details of the investigation, including the timing, status, scope or targets of this investigation. For more information, see Legal Proceedings below.

International Regulation

As a manufacturer of Class III medical devices, our manufacturing processes and facilities are subject to regulation and review by international regulatory agencies for products sold internationally. A medical device may only be marketed in the European Union, or the EU, if it complies with the Medical Devices Directive (93/42/EEC), or the MDD, and bears the CE mark as evidence of that compliance. To achieve this, the medical devices in question must meet the essential requirements defined under the MDD relating to safety and performance, and we as manufacturer of the devices must undergo verification of our regulatory compliance by a third party standards certification provider, known as a notified body. In January 2006, we received a quality system certificate from a notified body, demonstrating our compliance with ISO 13485:2003, the internationally recognized quality system standard for medical device manufactures. The ISO 13485:2003 certificate represents the first step toward demonstrating compliance with the appropriate medical and statutory requirements for receipt of the CE mark in the EU and for marketing approval in Canada. After establishing ArteFill in the United States, we plan to explore opportunities to register and sell ArteFill in selected international markets, which would require us to apply for the CE mark and other foreign regulatory approvals. The regulation of our product outside of the United States varies by country. For instance, in Canada and Mexico, ArteFill would be regulated as a medical device, and we may submit for regulatory authorization to commercialize ArteFill in both Canada and Mexico. Certain countries may regulate our product as a pharmaceutical product, which would require us to make extensive filings and obtain regulatory approvals before commercialization. Certain other countries may restrict its import or sale. Other countries have no applicable regulations regarding the import or sale of products similar to ours, creating uncertainty as to what standards we may be required to meet.

Environmental Regulation

Our present and future business has been and will continue to be subject to various other laws and regulations, including state and local laws relating to such matters as safe working conditions and disposal of potentially hazardous substances.

State and Federal Physician and Healthcare Regulation

Physicians are also subject to various state laws and regulations that govern the practice of medicine, prohibit physicians from accepting payment or remuneration for patient referrals or goods or services, restrict referrals for certain services where a physician has a financial relationship with an entity to whom referrals are made, and mandate

certain disclosure requirements for physicians who refer patients to organizations with whom physicians have a significant beneficial interest. These laws include those known as anti-kickback laws and physician self-referral laws. Violations of these laws can lead to fines, civil monetary penalties, incarceration and other administrative sanctions by state or federal agencies. We intend to educate our employees and independent contractors regarding these rules and regulations, and to comply with all applicable laws, rules and regulations that

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may govern the relationships between us and the physicians or healthcare organizations who purchase or administer ArteFill to their patients.

Clinical History

ArteFill is the culmination of more than 20 years of research and development. In 1999, we acquired the U.S. intellectual property rights to ArteFill. In 2004, we acquired all other remaining worldwide intellectual property rights related to ArteFill. These rights included (i) the know-how and trade secrets associated with the bovine collagen manufacturing process used to produce ArteFill and (ii) the know-how, trade secrets and certain assets, including a manufacturing facility in Frankfurt, Germany, relating to the manufacture of the PMMA microspheres contained in ArteFill. Following our acquisition of this technology, we have made further refinements to the PMMA manufacturing process that we believe improve the characteristics and purity of the PMMA microspheres. In addition, to meet the FDA s requirements for final marketing approval of our PMA application and to prepare for commercialization in the United States, we have established our own dedicated QSR compliant manufacturing facility in San Diego, California to produce the bovine collagen used in ArteFill and to complete the manufacturing, packaging and labeling processes for ArteFill.

U.S. Clinical Trial

To support our PMA application, we completed a double-blind, prospective, controlled, randomized, multi-center clinical trial in the United States in 2001. In this trial, patients were randomized (1:1) either to receive ArteFill, or to receive either Zyderm or Zyplast, the leading bovine collagen-based temporary dermal fillers, as a control. A total of 251 subjects (128 ArteFill, 123 control) were treated at eight dermatology or plastic surgery centers in the United States. Follow-up periods for both safety and efficacy were at one, three and six months. Patients treated with ArteFill were also evaluated at 12 months.

The primary effectiveness endpoint was a comparison of the cosmetic correction provided by ArteFill versus the control treatments at the end of a six-month period after injection. The cosmetic correction was evaluated by means of a validated Facial Fold Assessment Scale, or FFA Scale, using standardized photographs as reference. The numerical values for the FFA Scale are presented in the table below.

Facial Fold Assessment Scale Ratings

Score	Description	Depth (Mm)
0	No folds	
1	Folds just perceptible	0.1
2	Shallow folds with some defined edges	0.2
3	Moderately deep folds with some well-defined edges	0.5
4	Deep folds with most edges well-defined and some redundant folds	1.0
5	Very deep folds with most edges well-defined and some redundant folds	2.0

Comparisons to the standardized reference photos were made by masked observers at pre-treatment and at follow-up visits at one month, three months and six months after treatment. FFA Scale improvement was determined by subtracting each patient s FFA score on the applicable evaluation date from the patient s FFA score prior to treatment. Safety was evaluated by comparing the incidence and severity of adverse clinical events during and for 12 months after treatment.

A total of 229 women and 22 men between the ages of 28 and 82 (mean 52.2 years) were enrolled in the study. There were no significant differences in the distribution of age, gender and the facial area treated for the two treatment groups. At six months after treatment, the mean FFA score improvement in subjects who received ArteFill for the treatment of nasolabial folds was 0.8, as compared to a mean FFA score improvement of 0.0 among subjects who received the collagen control treatments. This difference in the level of FFA score improvement in the two groups was statistically significant ($p<0.001$). The difference between the treatments as measured by the improvement in FFA score from baseline was evident beginning three months after treatment.

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In addition, the nasolabial fold area showed significantly greater improvement for subjects treated with ArteFill at 12 months than for subjects treated with collagen control at six months, consistent with the comparison of the two treatment groups at six months.

There were no statistically significant differences between the ArteFill and control groups for treatment of glabellar folds, or frown lines, upper lip lines or mouth corners at six months after treatment. The following graph represents results from our clinical trial comparing ArteFill and Zyderm or Zyplast, based on FFA scale improvement over six months.

At six months after treatment, which was the primary efficacy evaluation endpoint, the wrinkle correction in the patients treated with ArteFill persisted, while the patients treated with the collagen returned to their pre-treatment status. At the six-month evaluation, the control group subjects were offered the opportunity to be treated with ArteFill. Of the 123 subjects in the original control group, 116 completed the six-month evaluation and were offered ArteFill as a crossover treatment. Of these, 106 (91%) chose to be treated with ArteFill. In the 111 patients who were treated with ArteFill and remained in the study at 12 months after treatment, ArteFill demonstrated continued safety and wrinkle correction. We did not evaluate the patients who received the collagen control at 12 months after treatment because these patients had either elected to be treated with ArteFill at their six-month evaluation period or had returned to their pre-treatment status. There were no unexpected or serious adverse events reported in patients treated with ArteFill in the clinical trial. Adverse events reported for ArteFill were similar to but lower in number than the adverse events reported for the control group. Throughout the clinical trial, there were no significant differences in the adverse event rates reported for the two treatments. Based on the results of our clinical trial, on October 27, 2006 the FDA approved ArteFill for the correction of nasolabial folds.

Open Label Trial

Prior to commencing our U.S. clinical trial, we conducted an open label, multi-center, single-arm clinical trial study under a conditional FDA IDE approval. The purpose of this study was to assess the safety of ArteFill for the correction of soft tissue defects in the face. A total of 157 subjects were enrolled and were monitored at three, six and 12 months post-treatment. 126 of the 157 (80.2%) subjects completed the one-year study. There were no implant-related severe illness, trauma or death among the subjects treated with ArteFill. A total of 18 adverse events in 17 subjects were reported, most of which were mild to moderate events. Only one severe adverse event related to treatment with ArteFill was reported. The adverse event, a granuloma, was treated with Cipro and, later, surgical excision of the implant. The only other severe adverse event reported in the study resulted from use of the product in a manner contrary to the study protocol.

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Five-Year Follow-up Study

In our U.S. clinical trial we evaluated patients for 12 months after treatment. This evaluation showed that aesthetic benefits of ArteFill persisted and safety remained throughout the one-year study period. Based on this data, the FDA has determined that ArteFill is safe and effective and has allowed us to characterize it as a non-resorbable aesthetic injectable implant. We believe that the aesthetic effects of ArteFill may last for many years.

We recently completed a five-year follow-up study of 145 patients who were originally treated with ArteFill in our U.S. clinical trial. In this follow-up study, patients were evaluated for efficacy and safety at a mean of 5.4 years after their last ArteFill injection. With respect to patients who had received treatment for nasolabial fold wrinkles, independent masked observers compared the wrinkle ratings for these patients at five years to baseline (prior to treatment) with an n=119. The results were statistically significant ($p<0.001$), with patients showing continued wrinkle correction at five years compared to baseline. Patients also showed continued improvement, demonstrating statistically significant improvement ($p=0.002$) in wrinkle correction at five years compared to six months after treatment with an n=113. The differences in the number of patients varies based upon the number of patients that returned at each visit and the presence of evaluable photos for masked observer grading.

The most common adverse events observed during the study were lumpiness, persistent swelling or redness at the injection site. The adverse events were similar to those seen with other dermal fillers and those observed in other studies with ArteFill.

As part of the study, physician investigators and patients were asked to provide their assessment of ArteFill treatment. Over 90% of the physician assessments were either completely successful or very successful; and over 90% of the patient assessments were either very satisfied or satisfied. We have submitted the data from the study to the FDA for review in order to enhance the product labeling for ArteFill.

Dr. Mark G. Rubin, Assistant Clinical Professor of Dermatology, University of California, San Diego, Division of Dermatology, presented data from the five year follow up study at the 65th annual meeting of the American Academy of Dermatology in Washington, D.C. on February 2, 2007. Dr. Steven Cohen, the lead investigator in our U.S. clinical trial, previously presented preliminary findings of the five-year follow-up study, which included the results of evaluations for 69 patients, at a conference of the American Society of Plastic Surgeons held in San Francisco, California in October 2006. These interim data for the 69 patients have also been published in the September 1, 2006 supplement to *Plastic and Reconstructive Surgery*, a peer-reviewed journal.

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Research and Development

We incurred research and development expenses of $3.6 million, $10.2 million and $8.1 million in fiscal 2004, 2005 and 2006, respectively, primarily related to the development of our manufacturing processes for ArteFill. We currently plan to conduct limited research and clinical development activities to explore potential improvements and enhancements to ArteFill for aesthetic applications. We also plan to explore applications of our injectable microsphere platform technology in non-aesthetic medical applications through collaborative arrangements with strategic partners. These fields may include gastroesophageal reflux disease, female stress urinary incontinence, spinal disc degeneration, sleep apnea and snoring.

Intellectual Property

We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure agreements and other measures to protect our proprietary rights. We currently hold five issued U.S. patents, and have seven pending U.S. patent applications. We also have five issued foreign patents, and multiple foreign patent applications pending in Australia, Canada, Japan, Mexico and Europe. Our primary U.S. patent, No. 5,344,452, which we refer to as the 452 patent, covers our product, ArteFill, and does not expire until September 2011. We have applied for an extension of the term of the 452 patent with the U.S. Patent and Trademark Office, or the U.S. PTO, under Title II of the Drug Price Competition and Patent Term Restoration Act. If the U.S. PTO grants our application, the term of the 452 patent may potentially be extended until September 2016. Our other four U.S. patents have projected expiration dates from April 2, 2021 through February 6, 2023. These other patents are primarily related to injection devices, but do not currently cover or provide patent protection for ArteFill. These other patents may provide patent protection for future products, primarily in the gastroenterology and urology areas. The foreign patents that are counterparts to the 452 patent expire in December 2009. We believe that our 452 patent family protects our rights to ArteFill in the United States, Austria, Belgium, France, Germany, Hong Kong, Italy, Liechtenstein, Luxembourg, the Netherlands, Singapore, Spain, Sweden, Switzerland and the United Kingdom. We also have an Australian patent covering an injection device.

We have obtained registrations for the trademarks ArteFill, Artes, Artes Medical and Enduring Beauty in the United States and certain foreign jurisdictions. In addition, we have filed an application to register the trademark The Art of Soft Tissue Augmentation in the United States and certain foreign jurisdictions, and we have filed applications to register the trademark The First to Last in the United States. All of these applications are pending.

We also rely on trade secrets, technical know-how, contractual arrangements and continuing innovation to protect our proprietary technology and maintain our competitive position. We seek to protect our proprietary information and other intellectual property by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and invention assignment agreements on commencement of their employment or engagement.

In October 2005, in connection with the settlement of all outstanding disputes and litigation matters among us, BioForm Medical, Inc. and BioForm Medical Europe, B.V., we granted to the BioForm entities an exclusive, world-wide, royalty-bearing license under certain of our patents to make and sell implant products containing CaHA particles, and a non-exclusive, world-wide, royalty-bearing license under the same patents to make and sell certain other non-polymeric implant products. See Material Agreements above.

Employees

As of December 31, 2006, we had 110 full-time employees, including five full-time employees located in Frankfurt, Germany. In the United States, we have 24 manufacturing employees, 15 quality assurance and regulatory employees,

35 sales and marketing employees, including 25 sales professionals, eleven employees in research and development and 20 general and administrative employees. During the fourth quarter of 2006, we made a number of changes to our management team. In connection with these changes, we entered into a separation agreement and mutual general release with our former chief executive officer, and confidential settlement and release of claims agreements with two prior members of our management team. For a discussion of our contractual obligations related to these agreements, see Managements Discussion and Analysis of Financial Condition and

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Results of Operations Contractual Obligations. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our existing employees to be good.

Executive Officers

Set forth below are the name, age and position and a brief account of the business experience of each of our executive officers as of March 1, 2007.

Name	Age	Position(s)
Christopher J. Reinhard	54	Executive Chairman of the Board of Directors
Diane S. Goostree	51	President and Chief Executive Officer and Director
Peter C. Wulff	47	Executive Vice President and Chief Financial Officer
Karla R. Kelly, J.D.	53	Chief Legal Officer, General Counsel and Corporate Secretary
Adelbert L. Stagg, Ph.D.	60	Vice President Regulatory Affairs and Chief Compliance Officer
Russell J. Anderson	51	Vice President New Products Engineering
Larry J. Braga	45	Vice President Manufacturing
Susan A. Brodsky-Thalken	53	Vice President U.S. Sales and Training
Frank M. Fazio	38	Vice President Marketing

Christopher J. Reinhard has been our Executive Chairman of the Board of Directors since June 2004. Since December 2003, Mr. Reinhard has also served as Chairman of the Board and Chief Executive Officer of Cardium Therapeutics, Inc., a publicly traded medical technology company. From July 2002 to December 2004, Mr. Reinhard served as Chief Executive Officer of Collateral Therapeutics, Inc., a publicly traded biotechnology company. Prior to the acquisition of Collateral Therapeutics, Inc. by Schering AG in July 2002, Mr. Reinhard worked for Collateral Therapeutics in a variety of roles from June 1995 to July 2002, including Chief Financial Officer and President. Mr. Reinhard holds a B.S. in Finance and an M.B.A. from Babson College.

Diane S. Goostree has been our Chief Executive Officer since November 2006 and our President since March 2006. She also served as our Chief Operating Officer from March 2006 to November 2006. From September 2002 to February 2006, Ms. Goostree was employed with SkinMedica, Inc., a dermatology specialty pharmaceutical company, most recently serving as Senior Vice President, Corporate Development and Operations. From May 2002 to September 2002, Ms. Goostree served as a consultant for SkinMedica, Inc. From November 2000 to May 2002, Ms. Goostree served as Vice President, Business Development at Elan Pharmaceuticals, Inc., a publicly traded biotechnology company. Prior to that, Ms. Goostree worked for Dura Pharmaceuticals, Inc., a publicly traded pharmaceutical company, in a variety of roles, including Regional Sales Director, and most recently as Vice President of Business Development from September 1995 until its acquisition by Elan Pharmaceuticals in November 2000. Ms. Goostree holds a B.S. in Chemical Engineering from the University of Kansas and an M.B.A. from the University of Missouri in Kansas City.

Peter C. Wulff has been our Executive Vice President since February 2007 and our Chief Financial Officer since January 2005. From May 2001 to May 2004, Mr. Wulff served as Vice President Finance, Chief Financial Officer, Treasurer and Assistant Secretary of CryoCor, Inc., a publicly traded medical device company. From November 1999 to May 2001, Mr. Wulff was Chief Financial Officer and Treasurer at Natural Alternatives International, Inc., a publicly traded and international nutritional supplement manufacturer. Mr. Wulff holds a B.A. in both Economics and Germanic Languages and an M.B.A. in Finance from Indiana University. Mr. Wulff is also a Certified Management

Accountant.

Karla R. Kelly, J.D. has been our Chief Legal Officer since June 2006. Prior to that, she was our Vice President, Legal Affairs from December 2005 to June 2006. She also has been our General Counsel and Corporate Secretary since December 2005. Ms. Kelly has provided legal services to us since 1999. Prior to joining us, Ms. Kelly practiced out of her own law firm, Karla R. Kelly, a Professional Law Corporation, from February 2003 to December 2005. From August 1998 to January 2003, Ms. Kelly practiced as Special Counsel with the law firm of

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Luce Forward Hamilton & Scripps LLP in San Diego, California. Ms. Kelly holds a B.A. in Nursing from the College of St. Catherine and a J.D. from the George Washington University National Law Center.

Adelbert L. Stagg, Ph.D. has been our Vice President, Regulatory Affairs and Chief Compliance Officer since March 2005. From August 1998 to March 2005, Dr. Stagg served as Senior Director, Regulatory Affairs of Allergan, Inc., a publicly traded pharmaceutical company. In 1999, Dr. Stagg was the recipient of the Hammer Award from the Vice President of the United States of America for industry leadership in working with the FDA. Dr. Stagg holds a B.A. in both Zoology and History from Andrews University and a Ph.D. in both Physiology and Pharmacology from Duke University. He also completed a postdoctoral fellowship in the department of cardiology at Duke University.

Russell J. Anderson has been our Vice President, New Product Engineering since March 2007, and he previously served as our Vice President, Product Development and Engineering since June 2005. From February 2004 to May 2005, he served as our Vice President, Engineering and Manufacturing. Mr. Anderson was a Project Engineer at NuVasive, Inc., a publicly traded medical device company, from February 2003 to February 2004. From October 2002 to November 2003, Mr. Anderson was also a product development consultant for Boston Scientific Corp. and Target Therapeutics, Inc., both publicly traded medical device companies. From April 2001 to October 2002, Mr. Anderson was Director of Engineering at Novare Surgical Systems, Inc., a privately held medical device company. Mr. Anderson holds a B.S. in Environmental Engineering from California Polytechnic State University and an M.B.A. from California State University in Hayward.

Larry J. Braga has been our Vice President, Manufacturing since June 2005 and previously served as Senior Director, Collagen Manufacturing since June 2004. From April 2000 to May 2004, he served as Director of Manufacturing at Anosys, Inc., a privately held vaccine development company. From November 1997 to April 2000, Mr. Braga served as Senior Process Engineer at Cohesion Technologies Inc., a publicly traded medical device company. Mr. Braga holds a B.S. in biological sciences from California State University in Hayward. He also holds a California pharmacy exemptee license.

Susan A. Brodsky-Thalken has been our Vice President, U.S. Sales and Training since October 2006. From April 2006 to October 2006, she served as our Executive Director, U.S. Marketing and Aesthetic Market Development. From February 2003 to April 2006, Ms. Brodsky-Thalken was a principal at AAP, Inc. providing consulting services to the aesthetic medical device industry. From April 2002 to January 2003, Ms. Brodsky-Thalken served as Vice President, Sales of INAMED Corporation, a publicly traded medical device company. From February 1995 to March 2002, Ms. Brodsky-Thalken served as Regional Sales Director for INAMED Corporation. Ms. Brodsky-Thalken studied Biological Science at San Francisco State University.

Frank M. Fazio has been our Vice President, Marketing since June 2006. From March 2005 to May 2006, Mr. Fazio served as Director, Market Development of INAMED Corporation, a publicly traded medical device company. From May 2002 to March 2005, Mr. Fazio served as Director, Facial Aesthetics of INAMED Corporation. From April 2001 to May 2002, Mr. Fazio was a Principal at AMC Consulting, providing consulting services to companies in the medical device industry. Mr. Fazio holds a B.S. in Molecular and Cellular Biology from the University of Arizona.

Additional Information

Our business was incorporated in Delaware in 1999. Our principal executive offices are located at 5870 Pacific Center Boulevard, San Diego, California 92121, and our telephone number is (858) 550-9999. Our website is located at http://www.artesmedical.com. The information contained in, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

We file and will continue to file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to those reports, electronically with the Securities and Exchange Commission. We make these reports available free of charge on our website under the investor relations page as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities Exchange Commission.

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Materials that we file with the Securities and Exchange Commission may be read and copied at the Securities and Exchange Commission s Public Reference Room at 100 F Street, N.E., Washington, DC 20549. The Securities and Exchange Commission also maintains a website at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding our company that we file electronically with the Securities and Exchange Commission.

Trademarks

Artes Medical®, Artes®, ArteFill®, The Art of Soft Tissue Augmentation™, The First to Last™, ArteFill The First to Last™ logo and Enduring Beauty® are our trademarks. We have rights to these trademarks in the United States and have registrations issued and pending in the United States and other countries. All other service marks, trademarks, trade names and brand names referred to in this report are the property of their respective owners.

Item 1A. ***Risk Factors.***

Set forth below and elsewhere in this report and in other documents that we file with the Securities and Exchange Commission are risks and uncertainties that could cause our actual results to differ materially from the results contemplated by the forward-looking statements contained in this report and the other public statements we make. If any of the following risks actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

We have limited operating experience and a history of net losses and may never achieve or maintain profitability.

We have a limited operating history and have focused primarily on research and development, product engineering, clinical trials, building our manufacturing capabilities and seeking FDA approval to market ArteFill. We received FDA approval to market ArteFill on October 27, 2006, and we commenced commercial shipments of ArteFill during the first quarter of 2007. All of our other product candidates are still in the early stages of research and development. As a result, we have not recorded any product sales revenue as of the fiscal year ended December 31, 2006. We have incurred significant net losses since our inception, including net losses of approximately $12.4 million in 2004, $22.2 million in 2005 and $26.3 million in 2006. At December 31, 2006, we had an accumulated deficit of approximately $79.4 million. For the year ended December 31, 2006, we used net cash in operating activities of $21.6 million. We will need to incur significant sales, marketing and manufacturing expenses in connection with the commercial distribution of ArteFill and expect to incur significant operating losses for the foreseeable future. We cannot predict the extent of our future operating losses and accumulated deficit, and we may never generate sufficient revenues to achieve or sustain profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. Further, because of our limited operating history and because the market for injectable aesthetic products is relatively new and rapidly evolving, we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business. We may not be able to successfully address any or all of the risks, uncertainties and difficulties frequently encountered by early-stage companies in new and rapidly evolving markets such as ours. Failure to adequately do so could cause our business, results of operations and financial condition to suffer.

Our operating results may fluctuate significantly in the future, and we may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.

Our operating results may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

- the level of demand for ArteFill;
- the costs of our sales and marketing activities;
- the introduction of new technologies and competing products that may make ArteFill a less attractive treatment option for physicians and patients;

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our pricing strategy and ability to protect the price of ArteFill against price erosion due to the availability of alternative treatments;

our ability to attract and retain personnel with the skills required for effective operations;

product liability and other litigation;

the amount and timing of capital expenditures and other costs relating to conducting our long-term, post-market safety study for ArteFill, further automating and expanding capacity at our manufacturing facilities and conducting further studies regarding the use of ArteFill for other aesthetic applications;

government regulation and legal developments regarding our products in the United States and in the foreign countries in which we operate;

our ability to receive, and the timing in which we may receive, approval from various foreign regulatory bodies to market ArteFill outside the United States; and

general economic conditions affecting the ability of patients to pay for elective cosmetic procedures.

Because we have only recently commenced commercial shipments of our product, and due to the emerging nature of the injectable aesthetic product market in which we will compete, our historical financial data is of limited value in estimating future operating expenses. Our projected expense levels are based in part on our expectations concerning future revenues. However, our ability to generate any revenues depends on the successful commercial launch of ArteFill. Moreover, the amount of any future revenues will depend on the choices and demand of physicians and patients, which are difficult to forecast accurately. We believe that patients are more likely to pay for elective cosmetic procedures when the economy is strong, and as a result, any material adverse change in economic conditions may negatively affect our revenues. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected shortfall in revenues. Accordingly, a significant shortfall in demand for our products could have an immediate and material adverse effect on our business, results of operations and financial condition. Further, our manufacturing costs and sales and marketing expenses will increase significantly as we expand our operations in connection with the commercialization of ArteFill. To the extent that expenses precede or are not followed by increased revenue, our business, results of operations and financial condition may be harmed.

An investigation by the FDA or other regulatory agencies, including the current investigation by the FDA s Office of Criminal Investigations, which we believe may concern improper uses of our product before FDA approval, could harm our business.

During negotiations with the parties involved in the litigation with Elizabeth Sandor discussed below, Dr. Gottfried Lemperle s counsel informed us that she had contacted an investigator at the FDA s Office of Criminal Investigations to determine whether any investigation of Dr. Gottfried Lemperle was ongoing. She also informed us that the FDA investigator had informed her that the FDA has an open investigation regarding us, Dr. Gottfried Lemperle and Dr. Stefan Lemperle, that the investigation had been ongoing for many months, that the investigation would not be completed within six months, and that at such time the investigation is completed, it could be referred to the U.S. Attorney s Office for criminal prosecution. In November 2006, we contacted the FDA s Office of Criminal Investigation. That office confirmed the ongoing investigation but declined to provide any details of the investigation, including the timing, status, scope or targets of the investigation.

To our knowledge, prior to or following this inquiry, none of our current or former officers or directors had been contacted by the FDA in connection with an FDA investigation. As a result, we have no direct information from the FDA regarding the subject matter of this investigation. We believe that the investigation may relate to the facts alleged in the Sandor litigation and the matters identified in the following correspondence from the FDA. In July 2004, we received a letter from the FDA s Office of Compliance indicating that the FDA had received information suggesting that we may have improperly marketed and promoted ArteFill prior to obtaining final FDA approval. We also received a letter from the FDA s MedWatch program, the FDA s safety information and adverse event reporting program, on April 21, 2005, which included a Manufacturer and User Facility Device Experience Database, or MAUDE, report. The text of the MAUDE report contained facts similar to those alleged by the plaintiff in the Sandor litigation.

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In May 2006, we received the FDA s EIR, for its investigation of our San Diego manufacturing facility. The EIR referenced two anonymous consumer complaints received by the FDA. The first complaint, received by the FDA in December 2003, alleges that Dr. Stefan Lemperle promoted the unapproved use of ArteFill, providing, upon request, a list of local doctors who could perform injections of ArteFill. The second complaint, received by the FDA in June 2004, alleges complications experienced by an individual who had been injected with ArteFill by Dr. Gottfried Lemperle in his home. The second complaint further alleges that Dr. Stefan Lemperle marketed unapproved use of ArteFill.

We responded to the FDA s correspondence in August 2004 and again in May 2006. In our responses, we informed the FDA that based on our internal investigations, Dr. Gottfried Lemperle had used Artecoll, a predecessor product to ArteFill, on four individuals in the United States. In July 2006, the FDA requested us to submit an amendment to our pre-market approval, application for ArteFill containing a periodic update covering the time period between January 16, 2004, the date of our approvable letter, and the date of the amendment. In response to this request, we completed additional inquiries regarding Dr. Gottfried Lemperle s unauthorized uses of Artecoll outside our clinical trials in contravention of FDA rules and regulations. In August 2006, we filed an amendment to our pre-market approval application that included the periodic update requested by the FDA. In the amendment, we informed the FDA that as a result of our additional inquiries, we had identified nine individuals who had been treated with Artecoll in the United States by Dr. Gottfried Lemperle, four of whom we had disclosed to the FDA in our prior correspondence. We also informed the FDA that 16 individuals had been treated with Artecoll by physicians in Mexico or Canada, where Artecoll is approved for treatment, in connection with physician training sessions conducted in those countries. Further, we informed the FDA that Dr. Stefan M. Lemperle, had been injected with Artecoll in the United States in 2004 by his father, Dr. Gottfried Lemperle.

We intend to cooperate fully with any inquiries by the FDA or any other authorities regarding these and any other matters. We have no information regarding when any investigation may be concluded, and we are unable to predict the outcome of the foregoing matters or any other inquiry by the FDA or any other authorities. If the FDA or any other authorities elect to request additional information from us or to commence further proceedings, responding to such requests or proceedings could divert management s attention and resources from our operations. We would also incur additional costs associated with complying with any such requests or responding to any such proceedings. Additionally, any negative developments arising from such requests or the investigation could potentially harm our relationship with the FDA. Any adverse finding resulting from the ongoing FDA investigation could result in a warning letter from the FDA that requires us to take remedial action, fines or other criminal or civil penalties, the referral of the matter to another governmental agency for criminal prosecution and negative publicity regarding our company. Any of these events could harm our business and negatively affect our stock price.

We expect to derive substantially all of our future revenue from sales of ArteFill, and if we are unable to achieve and maintain market acceptance of ArteFill among physicians and patients, our business, operating results and financial condition will be harmed.

We expect sales of ArteFill to account for substantially all of our revenue for at least the next several years. Accordingly, our success depends on the acceptance among physicians and patients of ArteFill as a preferred injectable aesthetic treatment. Even though we have received FDA approval to market ArteFill in the United States, we may not achieve and maintain market acceptance of ArteFill among physicians or patients. ArteFill is the first product in a new category of non-resorbable aesthetic injectable products in the United States. As a result, the degree of market acceptance of ArteFill by physicians and patients is unproven and difficult to predict. We believe that market acceptance of ArteFill will depend on many factors, including:

the perceived advantages or disadvantages of ArteFill compared to other injectable aesthetic products and alternative treatments;

the safety and efficacy of ArteFill and the number and severity of reported adverse side effects, if any;

the availability and success of other injectable aesthetic products and alternative treatments;

the price of ArteFill relative to other injectable aesthetic products and alternative treatments;

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our success in building a sales and marketing organization and the effectiveness of our marketing, advertising and commercialization initiatives;

the willingness of patients to wait 28 days for treatment following the bovine collagen skin test that is required in connection with ArteFill;

our ability to provide additional clinical data to the satisfaction of the FDA regarding the potential long-term aesthetic benefits provided by ArteFill;

our success in training physicians in the proper use of the ArteFill injection technique and the convenience and ease of administration of ArteFill;

the success of our physician practice support programs; and

publicity concerning ArteFill or competing products and alternative treatments.

We cannot assure you that ArteFill will achieve and maintain market acceptance among physicians and patients. Because we expect to derive substantially all of our revenue for the foreseeable future from sales of ArteFill, any failure of this product to satisfy physician or patient demands or to achieve meaningful market acceptance will seriously harm our business.

We face significant competition from companies with greater resources and well-established sales channels, which may make it difficult for us to achieve market penetration.

The market for injectable aesthetic products is extremely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our competitors primarily consist of companies that offer non-permanent injectable aesthetic products approved by the FDA for the correction of facial wrinkles, as well as companies that offer products that physicians currently use off-label for the correction of facial wrinkles. These companies include:

Allergan, Inc., which markets and sells Botox® Cosmetic, a temporary muscle paralytic and the most widely used injectable aesthetic product in the United States, CosmoDerm® and CosmoPlast®, which are human collagen-based temporary dermal fillers, Zyderm® and Zyplast®, which are bovine collagen-based temporary dermal fillers, and Hylaform®, Hylaform® Plus, Captique® and Juvederm™, which are temporary dermal fillers comprised primarily of hyaluronic acid, a jelly-like substance that is found naturally in living organisms and acts to hydrate and cushion skin tissue;

Medicis Pharmaceutical Corporation, which markets and sells Restylane®, the leading temporary dermal filler comprised primarily of hyaluronic acid;

BioForm Medical, Inc., which markets and sells Radiesse™, a calcium hydroxylapatite based derma filler; and

Dermik Laboratories, a subsidiary of sanofi-aventis, which markets and sells Sculptra®, which is approved by the FDA for restoration and/or correction of the signs of facial fat loss in people with human immunodeficiency virus.

Some of these companies are publicly traded and enjoy competitive advantages, including:

superior name recognition;

established relationships with physicians and patients;

integrated distribution networks;

large-scale FDA-approved manufacturing facilities; and

greater financial resources for product development, sales and marketing and patent litigation.

In addition, in March 2006, Allergan completed its acquisition of INAMED Corporation, which was a manufacturer of various temporary dermal fillers. As a result of this transaction, the market for injectable aesthetic products experienced a significant concentration of products within a single entity with greater resources and the

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ability to provide an expanded range of products and services. These companies and others have developed and will continue to develop new products that compete with our products, and the consolidation of such companies may result in competition from entities with even greater financial and other resources.

After establishing ArteFill in the United States, we plan to explore opportunities to register and sell ArteFill in selected international markets. We primarily intend to use third-party distributors in international markets, although we may build direct sales forces to market ArteFill in certain concentrated markets. Due to less stringent regulatory requirements, there are many more injectable aesthetic products available for use in international markets than are approved for use in the United States. As a result, we may face even greater competition in these markets than in the United States.

Many of our competitors spend significantly greater funds on the research, development, promotion and sale of new and existing products. These resources can enable them to respond more quickly to new or emerging technologies and changes in customer requirements. Even if we attempt to expand our technological capabilities in order to remain competitive, research and discoveries by others may make ArteFill a less attractive alternative for physicians and patients. For all the foregoing reasons, we may not be able to compete successfully against our current and future competitors. If we cannot compete effectively in the marketplace, our potential for profitability and our results of operations will suffer.

We have been involved in product litigation in the past, and we may become involved in product litigation in the future, and any liability resulting from product liability or other related claims may negatively affect our results of operations.

Dermatologists, plastic surgeons, cosmetic surgeons and other practitioners who administer ArteFill, as well as patients who have been treated with ArteFill or any of our future products, may bring product liability and other claims against us. In August 2005, Elizabeth Sandor, an individual residing in San Diego, California, filed a complaint against us and Drs. Gottfried Lemperle, Stefan Lemperle and Steven Cohen in the Superior Court of the State of California for the County of San Diego. The complaint, as amended, set forth various causes of action against us, including product liability, fraud, negligence and negligent misrepresentation. The complaint also alleged that Dr. Gottfried Lemperle, our co-founder, former Chief Scientific Officer and a former member of our board of directors, treated Ms. Sandor with Artecoll and/or ArteFill in violation of medical licensure laws, that the product was defective and unsafe because it had not received FDA approval at the time it was administered to Ms. Sandor, and that Ms. Sandor suffered adverse reactions as a result of the injections. In addition, the complaint alleged that Drs. Gottfried Lemperle and Stefan Lemperle, our other co-founder, former Chief Executive Officer and a former director, falsely represented to her that the product had received an approvability letter from the FDA, and was safe and without the potential for adverse reactions. The complaint also alleged medical malpractice against Dr. Cohen, the lead investigator in our U.S. clinical trial, for negligence in treating Ms. Sandor for the adverse side effects she experienced. We notified our directors and officers liability insurance carrier of Ms. Sandor s claims and requested both a defense and indemnification for all claims advanced by Ms. Sandor. Our insurance carrier declined coverage. On June 1, 2006, the parties filed a stipulation to dismiss the case without prejudice and toll the statute of limitations. The court dismissed the case on June 5, 2006 as stipulated by the parties, and Ms. Sandor is allowed to refile her case at any time within 18 months from that date. See Item 1. Business Legal Proceedings contained in this report.

Any negative publicity surrounding these events or any refiling of this case may harm our business and negatively impact the price of our stock. Additionally, if it is determined that Dr. Gottfried Lemperle or Dr. Stefan Lemperle did not act in his individual capacity or that we are liable because of the actions of Dr. Cohen, we may need to pay damages, which would reduce our cash and could cause a decline in our stock price. Further, if any of the individuals injected with Artecoll by Dr. Gottfried Lemperle in the United States, or if any of those individuals injected with Artecoll during the physician training sessions conducted in Mexico and Canada bring claims against our company as

a result of these injections, we may need to pay damages, which would reduce our cash and could cause a decline in our stock price. As of the date of this filing, none of these individuals has filed a claim against our company in connection with an injection of Artecoll, except for Ms. Sandor. There could be other individuals who were injected with Artecoll who are not known to us, who could bring similar claims against our company.

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To limit our product liability exposure, we have developed a physician training and education program. We cannot provide any assurance that our training and education program will help avoid complications resulting from the administration of ArteFill. In addition, although we intend to sell our product only to physicians, we will not be able to control whether other medical professionals, such as nurse practitioners or other cosmetic specialists, administer ArteFill to their patients, and we may be unsuccessful at avoiding significant liability exposure as a result. We maintained limited product liability insurance in an amount of up to $5 million per incident through December 1, 2006, and as of December 1, 2006, we increased our coverage to $20 million per incident, but any insurance we maintain may not sufficient to provide coverage against any asserted claims. In addition, our insurance may not be sufficient to provide coverage for claims which may be asserted in the future by individuals injected with Artecoll by Dr. Gottfried Lemperle or during the physician training sessions conducted in Mexico and Canada. We also may be unable to maintain our insurance or obtain insurance in the future on acceptable terms, or at all. In addition, regardless of merit or eventual outcome, product liability and other claims may result in:

the diversion of management s time and attention from our business and operations;

the expenditure of large amounts of cash on legal fees, expenses and payment of settlements or damages;

decreased demand for ArteFill among physicians and patients;

voluntary or mandatory recalls of our products; or

injury to our reputation.

If any of the above consequences of product liability litigation occur, it could adversely affect our results of operations, harm our business and cause the price of our stock to decline.

We have never commercialized any product, and the successful commercialization of ArteFill will require us to build and maintain a sophisticated sales and marketing organization.

We have no prior experience with commercializing any product, and we will need to deploy and maintain a sophisticated sales and marketing organization in order to successfully commercialize ArteFill. We currently have a direct sales force comprised of 25 sales professionals and plan to target dermatologists, plastic surgeons and cosmetic surgeons whom we have identified as having significant experience with the tunneling injection technique used in ArteFill treatments. Selling ArteFill to physicians will require us to educate them on the comparative advantages of ArteFill over other injectable aesthetic products and alternative treatments. Experienced sales representatives may be difficult to locate and retain, and all new sales representatives will need to undergo extensive training. We anticipate that it will take up to six months for each of our new sales representatives to achieve full productivity. We will need to incur significant costs to continue building our internal sales force. Based on our current operating plan, we expect to incur costs of approximately $8.0 million to $12.0 million over a 12-month period in connection with establishing and building our sales force. There is no assurance that we will be able to recruit and retain sufficiently skilled sales representatives, or that any new sales representatives will ultimately become productive. If we are unable to recruit and retain qualified and productive sales personnel, our ability to commercialize ArteFill and to generate revenues will be impaired, and our business and financial prospects will be harmed.

We have limited manufacturing experience, and if we are unable to manufacture ArteFill in commercial quantities successfully and consistently to meet demand, our growth will be limited.

Prior to receiving FDA approval, we manufactured ArteFill, including the PMMA microspheres used in the product, in limited quantities sufficient only to meet the needs for our clinical studies. To be successful, we will need to manufacture ArteFill in substantial quantities at acceptable costs. We currently have limited resources and manufacturing experience and have only manufactured ArteFill in small quantities. To produce ArteFill in the quantities that we believe will be required to meet anticipated market demand, we will need to increase and automate the production process compared to our current manufacturing capabilities, which will involve significant challenges and may require additional regulatory approvals. The development of commercial-scale manufacturing capabilities will require the investment of substantial additional funds and hiring and retaining additional technical personnel who have the necessary manufacturing experience. For example, we currently use a manual process to fill

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syringes with ArteFill and may need to hire additional personnel for this process in order to meet commercial demand if we are unable to automate the process as intended. The implementation of an automated manufacturing process is a significant manufacturing change that will require development, validation and documentation, and the preparation and submission to the FDA of a Prior Approval Supplement to our PMA application. The FDA s review of a Prior Approval Supplement typically does not require a facility inspection, but the FDA will have six months to review the supplement. We may not successfully complete any required increase or automation of our manufacturing process in a timely manner or at all. If there is a disruption to our manufacturing operations at either facility, we would have no other means of producing ArteFill until we restore and re-qualify our manufacturing capability at our facilities or develop alternative manufacturing facilities. Additionally, any damage to or destruction of our U.S. or German facilities or our equipment, prolonged power outage or contamination at either of our facilities would significantly impair our ability to produce ArteFill. Our lack of manufacturing experience may adversely affect the quality of our product when manufactured in large quantities and therefore result in product recalls. Any recall could be expensive and generate negative publicity, which could impair our ability to market ArteFill and further affect our results of operations. If we are unable to produce ArteFill in sufficient quantities to meet anticipated customer demand, our revenues, business and financial prospects would be harmed. In addition, if our automated production process is not efficient or does not produce ArteFill in a manner that meets quality and other standards, our future gross margins, if any, will be harmed.

The results provided by ArteFill are highly dependent on its technique of administration, and the acceptance of ArteFill will depend on the training, skill and experience of physicians.

The administration of ArteFill to patients requires significant training, skill and experience with the tunneling injection technique. We provide training to physicians in order to ensure that they are trained to inject ArteFill using the tunneling injection technique, and intend to offer ArteFill only to physicians who have completed our training program. However, untrained or inexperienced physicians may obtain supplies of ArteFill from third parties without our authorization and may perform injections using an improper technique, causing suboptimal aesthetic results or adverse side effects in patients.

In addition, even physicians who have been trained by us and have significant experience may administer ArteFill using an improper technique or in areas of the body where it is not approved for use by the FDA. This may lead to negative publicity, regulatory action or product liability claims regarding ArteFill or our company, which could reduce market acceptance of ArteFill and harm our business.

We may experience negative publicity regarding ArteFill or predecessor products sold outside of the United States, which may harm our business.

In the past, predecessor products to ArteFill, such as Artecoll, have generated or received publicity in news and other media. ArteFill is a third-generation product that resulted from product improvements and improvements to the manufacturing process used to generate these predecessor products. Artecoll has been manufactured and marketed outside of the United States under a CE mark by unrelated parties since 1996. Any future publicity regarding our company, ArteFill or predecessor products may include coverage that is negative in nature, which could reduce market acceptance of ArteFill and harm our business or reputation. Such negative publicity may arise from numerous events or concerns, including the following:

- concerns about the safety of ArteFill or the predecessor products;

- negative side effects, or alleged or perceived negative side effects, relating to the use of ArteFill or the predecessor products;

concerns about the safety of competing products, such as temporary muscle paralytics or temporary dermal fillers, or aesthetic treatments generally;

negative side effects, or alleged or perceived negative side effects, relating to the use of these competing products;

any product recalls relating to ArteFill or competing products;

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negative side effects or safety issues resulting from any off-label use of ArteFill;

administration of ArteFill by unlicensed or untrained individuals; and

any lawsuits or administrative actions that we or our officers or directors may be party to or involved in.

Any negative publicity regarding ArteFill, its predecessor products or our company could impair our ability to generate revenues from the sale of ArteFill and harm our business and financial prospects.

Sales of ArteFill could be harmed due to patients allergic reactions to the bovine collagen component of ArteFill, the need to test for such allergic reactions before treatment with ArteFill or patients reluctance to use animal-based products.

ArteFill contains bovine collagen. Although the bovine collagen that we use is purified, patients can experience an allergic reaction. Accordingly, the instructions for use that accompany ArteFill require that all patients must be tested for any such allergies at least 28 days prior to treatment with ArteFill. If patients test positive for allergic reactions to the bovine collagen at higher rates than we expect, sales of ArteFill will be lower than anticipated. The need for a skin test in advance of treatment with ArteFill also may render ArteFill less attractive to patients who seek an immediate aesthetic treatment. The 28-day interval between testing and treatment may also result in the loss of some potential patients who, regardless of test results, fail to reappear for treatment after administration of the skin test. In addition, some potential patients may have reservations regarding the use of animal-based products. As a result of these factors, physicians may recommend alternative aesthetic treatments over ArteFill, which would limit or reduce our sales and harm our ability to generate revenues.

Our ability to manufacture and sell ArteFill could be harmed if we experience problems with the supply of calf hides from the closed herd of domestic cattle from which we derive the bovine collagen component of ArteFill.

We derive the bovine collagen component of ArteFill from calf hides supplied through a herd that is isolated, bred and monitored in accordance with both FDA and United States Department of Agriculture, or USDA, guidelines to minimize the risk of contamination from bovine spongiform encephalopathy, or BSE, commonly referred to as mad cow disease. BSE is a chronic, degenerative disorder that affects the central nervous system.

We currently rely on a sole domestic supplier, Lampire Biological Labs, Inc., for the calf hides from which we produce the purified bovine collagen used in ArteFill. If this herd were to suffer a significant reduction or become unavailable to us through disease, natural disaster or otherwise for a prolonged period, we would have a limited ability to access a supply of acceptable calf hides from a similarly segregated source. In addition, if there were to be any widespread discovery of BSE in the United States, our ability to access bovine collagen may be impaired even if our herd is unaffected by the disease, if third parties begin to demand calf hides from our herd. Although we have not experienced any problems with our supply of calf hides in the past, a significant reduction in the supply of acceptable calf hides due to contamination of our supplier s herd, a supply shortage or interruption, or an increase in demand beyond our current supplier s capabilities could harm our ability to produce and sell ArteFill until a new source of supply is identified, established and qualified with the FDA. Any delays or disruptions in the supply of calf hides would negatively affect our revenues. We currently have an 18 months supply of calf hides in stock and intend to establish and maintain a supply of calf hides that will last for more than two years. If our stockpiled supply is damaged or contaminated, and we are unable to obtain acceptable calf hides in the time frames desired, or at all, our business and results of operations will be harmed.

We are limited to marketing and advertising ArteFill for the treatment of nasolabial folds with efficacy benefits of six months under the label approved by the FDA, and we may not be able to obtain FDA approval to enhance our labeling for ArteFill.

Our U.S. clinical trial demonstrated the efficacy of ArteFill for the treatment of nasolabial folds, or smile lines, at primary efficacy endpoints of up to six months by comparison to the control products. As a result, the FDA requires us to label, advertise and promote ArteFill only for the treatment of nasolabial folds with an efficacy of six months. This limitation restricts our ability to market or advertise ArteFill and could negatively affect our growth. If

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we wish to market and promote ArteFill for other indications or claim efficacy benefits beyond six months, we may have to conduct further clinical trials or studies to gather clinical information for submission to the FDA, which would be costly and take a number of years. In early 2007, we completed a five-year follow-up study of 145 patients who were treated with ArteFill in our U.S. clinical trial. Dr. Mark G. Rubin, presented the results of this study at a meeting of the American Academy of Dermatology in Washington, D.C. in February 2007. We have submitted the results of the five-year follow-up study to the FDA in March 2007 to seek approval to enhance product labeling that would allow us to claim efficacy benefits of ArteFill beyond six months. There can be no assurance, however, that we will be successful in obtaining FDA approval to claim that the aesthetic benefits of ArteFill extend beyond six months or to expand our product labeling to cover additional indications. Without FDA approval to market ArteFill beyond six months, physicians may be slow to adopt ArteFill. Further, future studies of patients injected with ArteFill may indicate that the aesthetic benefits of ArteFill do not meet the expectations of physicians or patients. Such data would slow market acceptance of ArteFill, significantly reduce our ability to achieve expected revenues and could prevent us from becoming profitable.

We are not permitted to market, advertise or promote ArteFill for off-label uses, which are uses that the FDA has not approved. Off-label use of ArteFill may occur in areas such as the treatment of other facial wrinkles, creases and other soft tissue defects. While off-label uses of aesthetic products are common and the FDA does not regulate physicians choice of treatments, the FDA does restrict a manufacturer s communications regarding such off-label use. As a result, we may not actively promote or advertise ArteFill for off-label uses, even if physicians use ArteFill to treat such conditions. This limitation will restrict our ability to market our product and may substantially limit our sales. The U.S. Attorney s offices and other regulators, in addition to the FDA, have recently focused substantial attention on off-label promotional activities and, in certain cases, have initiated civil and criminal investigations and actions related to such practices. If we are found to have promoted off-label uses of ArteFill in violation of the FDA s marketing approval requirements, we could face warning letters, significant adverse publicity, fines, legal proceedings, injunctions or other penalties, any of which would be harmful to our business.

We have increased the size of our company significantly in connection with the commercial launch of ArteFill, and difficulties managing our growth could adversely affect our business, operating results and financial condition.

We have hired a substantial number of additional personnel in connection with the commercial launch of ArteFill, and such growth has and could continue to place a strain on our management and our administrative, operational and financial infrastructure. From January 1, 2005 to December 31, 2006, we have increased the size of our company from 12 to 110 employees, including a direct sales force of 25 sales professionals. Based on our current operating plan, we expect to incur additional costs in connection with commercial launch of ArteFill. We will hire additional sales and manufacturing personnel as necessary to meet customer demand for ArteFill. Our ability to manage our operations and growth requires the continued improvement of operational, financial and management controls, reporting systems and procedures, particularly to meet the reporting requirements of the Securities Exchange Act of 1934. If we are unable to manage our growth effectively or if we are unable to attract additional highly qualified personnel, our business, operating results and financial condition may be harmed.

If changes in the economy and consumer spending reduce demand for ArteFill, our sales and profitability could suffer.

We intend to position ArteFill as a premium-priced product in the injectable aesthetic product market. Treatment with ArteFill is an elective procedure, directly paid for by patients without reimbursement. As a result, sales of ArteFill will require that patients have sufficient disposable income to spend on an elective aesthetic treatment. Adverse changes in the economy may cause consumers to reassess their spending choices and choose less expensive alternative treatments over ArteFill, or may reduce the demand for elective aesthetic procedures in general. A shift of this nature could impair our ability to generate sales and could harm our business, financial condition and results of operations.

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We are dependent on our key management personnel. The loss of any of these individuals could harm our business.

We are dependent on the efforts of our current key management, including Christopher J. Reinhard, our Executive Chairman of the Board of Directors, Diane S. Goostree, our President and Chief Executive Officer and Peter C. Wulff, our Executive Vice President and Chief Financial Officer. We are a party to an employment offer letter agreement with Ms. Goostree. In addition, we have entered into employment agreements with Russell Anderson, our Vice President New Product Engineering and Lawrence Braga, our Vice President Manufacturing. We may terminate our relationships with Ms. Goostree and Messrs. Anderson and Braga at any time, with or without cause. Under each of their agreements, if employment is terminated by us other than for good cause or under certain other circumstances, including a change of control with respect to our company, the executive is entitled to receive, among other things, severance compensation equal to nine months of her then-current base salary, payable in a lump sum, in the case of Ms. Goostree, and three months salary continuation payments at their then-current base salary, in the case of Messrs. Anderson and Braga. All of our other officers and employees are employed at will. Although we are not aware of any present intention of these persons to leave our company, any of our key management personnel or other employees may elect to end their employment with us and pursue other opportunities at any time. We do not have and have no present intention to obtain key man life insurance on any of our executive officers or key management personnel to mitigate the impact of the loss of any of these individuals. The loss of any of these individuals, or our inability to recruit and train additional key personnel, particularly senior sales and marketing and research and development employees, in a timely manner, could harm our business and our future product revenues and prospects. The market for skilled employees for medical technology and biotechnology companies in San Diego is competitive, and we can provide no assurance that we will be able to locate skilled and qualified employees to replace any of our employees that choose to depart. If we are unable to attract and retain qualified personnel, our business will be significantly harmed.

Legal proceedings with a former officer and employee could be costly and could divert our management team s attention from our business and operations.

On November 6, 2006, we filed a demand for arbitration with the American Arbitration Association against Melvin Ehrlich, who served as our President and Chief Operating Officer from January 15, 2004 through April 5, 2004. In the arbitration, we are seeking declaratory relief regarding the number of shares of common stock Mr. Ehrlich is entitled to purchase under a warrant we issued to him in connection with his employment agreement. We believe Mr. Ehrlich vested in and, therefore, is entitled to purchase 26,070 shares of common stock based on the length of time he provided services to our company. These warrant shares have an exercise price of $4.25 per share and are subject to a 180-day market standoff period in connection with our offering. In December 2006, Mr. Ehrlich elected to cashless exercise these warrants, as a result, 7,603 shares of common stock were issued upon completion of the offering. Mr. Ehrlich contends that he is entitled to purchase up to 470,588 shares of common stock, at an average exercise price of $7.44 per share, contingent upon our satisfaction of certain milestones, including the FDA s approval of ArteFill, the FDA s certification of our manufacturing facilities and the completion of the offering. He claims that the language in the warrant allows him to continue to vest in the warrant shares after his employment with us ended, regardless of whether he provided any assistance to us to satisfy the milestones set forth in the warrant. We reject this interpretation of the warrant.

The parties have pursued a settlement of this action, and have negotiated the terms of a proposed settlement agreement in which we will pay Mr. Ehrlich $250,000 and issue Mr. Ehrlich 26,710 shares of common stock and a warrant to purchase 25,000 shares of common stock, at an exercise price of $8.07 per share. The settlement agreement contains a mutual release of claims and a mutual covenant not to sue. The shares of common stock, the warrant and the shares of common stock issuable upon exercise of the warrant are subject to lock-up restrictions that do not expire until June 17,

2007. The settlement agreement is subject to approval by our board of directors, and based on his age, Mr. Ehrlich will have up to seven days to revoke the settlement agreement after he signs it. The Company has made an accrual in the fourth quarter of the fiscal year ended December 31, 2006 based on the terms of the proposed settlement agreement. We cannot assure you that the parties will effect the settlement agreement on the terms outlined above, or at all. If the settlement agreement is not effected, we intend to continue to pursue our declaratory relief action against Mr. Ehrlich. Regardless of merit or eventual outcome, this action may result in the

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expenditure of resources on legal fees, expenses, payment of settlements or damages. Further, this action may divert our management team s time and attention from our business and operations.

We may rely on third parties for our international sales, marketing and distribution activities.

Although we plan initially to market and sell ArteFill to physicians in the United States through our own sales force, we may in the future rely on third parties to assist us in sales, marketing and distribution, particularly in international markets. If and when our dependence on third parties for our international sales, marketing and distribution activities increases, we will be subject to a number of risks associated with our dependence on these third parties, including:

lack of day-to-day control over the activities of third-party contractors;

third-party contractors may not fulfill their obligations to us or otherwise meet our expectations;

third-party contractors may terminate their arrangements with us on limited or no notice or may change the terms of these arrangements in a manner unfavorable to us for reasons outside of our control; and

disagreements with our contractors could require or result in costly and time-consuming litigation or arbitration.

If we fail to establish and maintain satisfactory relationships with these third-party contractors, our revenues and market share may not grow as anticipated, and we could be subject to unexpected costs which would harm our results of operations and financial condition.

To the extent we engage in marketing and distribution activities outside the United States, we will be exposed to risks associated with exchange rate fluctuations, trade restrictions and political, economic and social instability.

If ArteFill is approved for sale in foreign markets and we begin marketing ArteFill in these markets, we will be subject to various risks associated with conducting business abroad. A foreign government may require us to obtain export licenses or may impose trade barriers or tariffs that could limit our ability to build our international presence. Our operations in some markets also may be adversely affected by political, economic and social instability in foreign countries, including terrorism. To the extent that we attempt to expand our sales efforts in international markets, we may also face difficulties in staffing and managing foreign operations, longer payment cycles and problems with collecting accounts receivable and increased risks of piracy and limits on our ability to enforce our intellectual property rights. In addition, for financial reporting purposes, results of operations of our foreign subsidiary will be translated from local currency into U.S. dollars based on average monthly exchange rates. We currently do not hedge our foreign currency transactions and therefore will be subject to the risk of changes in exchange rates. If we are unable to adequately address the risks of doing business abroad and build an international presence, our business, financial condition and results of operations may be harmed.

If we acquire any companies or technologies, our business may be disrupted and the attention of our management may be diverted.

In July 2004, we acquired assets and intellectual property from FormMed Biomedicals AG in connection with the establishment of our manufacturing facility in Germany. This transaction had an effective date as of January 1, 2004. Since the completion of this acquisition, we have spent approximately $750,000 to improve and upgrade the physical facilities, manufacturing processes and quality control systems at that facility to be in compliance with both U.S. and international regulatory quality requirements. We may make additional acquisitions of complementary companies, products or technologies in the future. Any acquisitions will require the assimilation of the operations, products and

personnel of the acquired businesses and the training and motivation of these individuals. Acquisitions may disrupt our operations and divert management s attention from day-to-day operations, which could impair our relationships with current employees, customers and strategic partners. We may need to incur debt or issue equity securities to pay for any future acquisitions. The issuance of equity securities for an acquisition could be substantially dilutive to our stockholders. In addition, our profitability may suffer because of acquisition-related costs or amortization or impairment costs for acquired goodwill and other intangible assets. We may not realize the

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intended benefits of any acquisitions if management is unable to fully integrate acquired businesses, products, technologies or personnel with existing operations. We are currently not party to any agreements, written or oral, for the acquisition of any company, product or technology, nor do we anticipate making any arrangements for any such acquisition in the foreseeable future.

Our business, which depends on a small number of facilities, is vulnerable to natural disasters, telecommunication and information systems failures, terrorism and similar problems, and we are not fully insured for losses caused by such incidents.

We conduct operations in two facilities located in San Diego, California and Frankfurt, Germany. These facilities could be damaged by earthquake, fire, floods, power loss, telecommunication and information systems failures or similar events. Our insurance policies have limited coverage levels of up to approximately $9.1 million for property damage and up to $5.0 million for business interruption in these events and may not adequately compensate us for any losses that may occur. We currently pay annual premiums totaling approximately $40,000 for this coverage. In addition, terrorist acts or acts of war may cause harm to our employees or damage our facilities.

Further, the potential for future terrorist attacks, the national and international responses to terrorist attacks or perceived threats to national security, and other acts of war or hostility have created many economic and political uncertainties that could adversely affect our business and results of operations in ways that we cannot predict. We are uninsured for these types of losses.

We are recording non-cash compensation expense that may result in an increase in our net losses for a given period.

Deferred stock-based compensation represents an expense associated with the recognition of the difference between the deemed fair value of common stock at the time of a stock option grant or issuance and the option exercise price or price paid for the stock. Deferred stock-based compensation is amortized over the vesting period of the option or issuance. At December 31, 2006, deferred stock-based compensation related to option grants and stock issuances totaled approximately $2.7 million. Effective January 1, 2006, we prospectively adopted Statement of Financial Accounting Standards (SFAS) No. 123R, Share-Based Payment (SFAS No. 123(R)). SFAS No. 123(R) required us to reclassify the $2.7 million of deferred stock-based compensation to additional paid-in capital. The $2.7 million will be expensed on a straight-line basis as the options or stock vest, generally over a period of four years. We also record non- cash compensation expense for equity stock-based instruments issued to non-employees. SFAS No. 123(R) now requires us to record stock-based compensation expense for equity instruments granted to employees and directors. In June 2006, we offered certain holders of warrants that were issued in exchange for services an opportunity to amend their warrants to eliminate the automatic expiration upon the closing of our initial public offering, which occurred on December 26, 2006, if not exercised prior, and to allow the warrants to continue in effect under their existing terms until March 15, 2007. In June 2006, we also offered certain holders of warrants that were issued in connection with our prior bridge loan financings an opportunity to amend their warrants to eliminate the automatic expiration upon the closing of our initial public offering if not exercised prior, and to allow the warrants to continue in effect under the terms of the original warrants. Based on the preferences of our warrant holders, we recorded a warrant modification expense of $1,376,000 during the year ended December 31, 2006. Of the warrant modification expense of $1,376,000, $477,000 was recorded as interest expense because these original warrants were issued in connection with financings. The remaining $899,000 was recorded as consulting expense, comprised of $66,000 in research and development expense and $833,000 in selling, general and administrative expense because these original warrants were issued in exchange for services. The impact of these amendments was being charged to expense as of the modification date, as there is no implicit service period associated with the warrants, and no bridge loans remain outstanding. Non-cash compensation expense associated with future equity compensation awards may result in an increase in our net loss, and adversely affect our reported results of operations.

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Changes in, or interpretations of, accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges or require us to change our compensation policies.

Accounting methods and policies for public companies, including policies governing revenue recognition, expenses, accounting for stock options and in-process research and development costs, are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. Changes to, or interpretations of, accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements, including those contained in this report. For example, the Financial Accounting Standards Board has adopted a new accounting pronouncement requiring the recording of expense for the fair value of stock options granted. The impact of the adoption of SFAS No. 123(R) for stock options granted to employees and directors from during the year ended December 31, 2006 was $11,307,000. This amount will be charged to expense over the requisite service period, which is generally four years, on a straight-line basis. The amount charged to expense related to the adoption of SFAS No. 123(R)during the year ended December 31, 2006 was $1,300,000. We rely heavily on stock options to motivate current employees and to attract new employees. As a result of the requirement to expense stock options, we may choose to reduce our reliance on stock options as a motivation tool.

If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees. However, if we do not reduce our reliance on stock options, our reported net losses may increase, which may have an adverse effect on our reported results of operations.

Impairment of our significant intangible assets may reduce our profitability.

The costs of our acquired patents and technology are recorded as intangible assets and amortized over the period that we expect to benefit from the assets. As of December 31, 2006, the net acquired intangible assets comprised approximately 6.0% of our total assets. We periodically evaluate the recoverability and the amortization period of our intangible assets. Some factors we consider important in assessing whether or not impairment exists include performance relative to expected historical or projected future operating results, significant changes in the manner of our use of the assets or the strategy for our overall business, and significant negative industry or economic trends. These factors, assumptions, and changes therein could result in an impairment of our long-lived assets. Any impairment of our intangible assets may reduce our profitability and harm our results of operations and financial condition.

Risks Related to Our Intellectual Property

Our ability to achieve commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection relating to ArteFill and our technology and future products, as well as successfully defending our patents against third party challenges. If we are unable to obtain and maintain protection for our intellectual property and proprietary technology, the value of ArteFill, our technology and future products will be adversely affected, and we will not be able to protect our technology from unauthorized use by third parties.

Our long-term success largely depends on our ability to maintain patent protection covering our product, ArteFill, and to obtain patent and intellectual property protection for any future products that we may develop and seek to market. In order to protect our competitive position for ArteFill and any future products, we must:

- prevent others from successfully challenging the validity or enforceability of, or infringing, our issued patents and our other proprietary rights;

operate our business, including the manufacture, sale and use of ArteFill and any future products, without infringing upon the proprietary rights of others;

successfully enforce our patent rights against third parties when necessary and appropriate; and

obtain and protect commercially valuable patents or the rights to patents both domestically and abroad.

We currently have one U.S. patent and corresponding patents in 14 international jurisdictions that cover our product, ArteFill, and alloplastic implants, which are implants containing inert materials that are compatible for use in or around human tissue, made of smooth, round, injectable polymeric and non-polymeric microspheres, which

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can be used for soft tissue augmentation. The U.S. patent covering this invention, U.S. Patent No. 5,344,452, will expire in September 2011. Although we applied for an extension of the term of this patent until 2016, we cannot assure you that the U.S. Patent and Trademark Office, or the U.S. PTO, will grant the extension for the full five years or at all. In addition, our competitors or other patent holders may challenge the validity of our patents or assert that our products and the methods we employ are covered by their patents. If the validity or enforceability of any of our patents is challenged, or others assert their patent rights against us, we may incur significant expenses in defending against such actions, and if any such challenge is successful, our ability to sell ArteFill may be harmed.

Protection of intellectual property in the markets in which we compete is highly uncertain and involves complex legal and scientific questions. It may be difficult to obtain additional patents relating to our products or technology. Furthermore, any changes in, or unexpected interpretations of, the patent laws may adversely affect our ability to enforce our patent position.

Other risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- our issued patents may not be valid or enforceable or may not provide adequate coverage for our products;
- the claims of any issued patents may not provide meaningful protection;
- our issued patents may expire before we are able to successfully commercialize ArteFill or any future product candidates or before we receive sufficient revenues in return;
- patents issued to us may be successfully challenged, circumvented, invalidated or rendered unenforceable by third parties;
- the patents issued or licensed to us may not provide a competitive advantage;
- patents issued to other companies, universities or research institutions may harm our ability to do business;
- other companies, universities or research institutions may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent;
- other companies, universities or research institutions may design around technologies we have licensed, patented or developed;
- because the information contained in patent applications is generally not publicly available until published (usually 18 months after filing), we cannot assure you that we have been the first to file patent applications for our inventions or similar technology;
- the future and pending applications we will file or have filed, or to which we will or do have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents; and
- we may be unable to develop additional proprietary technologies that are patentable.

Our other intellectual property, particularly our trade secrets and know-how, are important to us, and our inability to safeguard it may adversely affect our business by causing us to lose a competitive advantage or by forcing us to engage in costly and time-consuming litigation to defend or enforce our rights.

We rely on trademarks, copyrights, trade secret protections, know-how and contractual safeguards to protect our non-patented intellectual property, including our manufacturing processes. Our employees, consultants and advisors are required to enter into confidentiality agreements that prohibit the disclosure or use of our confidential information. We also have entered into confidentiality agreements to protect our confidential information delivered to third parties for research and other purposes. There can be no assurance that we will be able to effectively enforce these agreements or that the subject confidential information will not be disclosed, that others will not independently develop substantially equivalent confidential information and techniques or otherwise gain access to our confidential information or that we can meaningfully protect our confidential information.

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Costly and time-consuming litigation could be necessary to enforce and determine the scope and protectability of our confidential information, and failure to maintain the confidentiality of our confidential information could adversely affect our business by causing us to lose a competitive advantage maintained through such confidential information.

Disputes may arise in the future with respect to the ownership of rights to any technology developed with consultants, advisors or collaborators. These and other possible disagreements could lead to delays in the collaborative research, development or commercialization of our products, or could require or result in costly and time-consuming litigation that may not be decided in our favor. Any such event could have a material adverse effect on our business, financial condition and results of operations by delaying or preventing our ability to commercialize innovations or by diverting our resources away from revenue-generating projects.

Pursuant to the terms of an intellectual property litigation settlement, we have licensed some of our technology to a competitor.

In October 2005, we and Dr. Martin Lemperle, the brother of Dr. Stefan M. Lemperle, our former Chief Executive Officer and a former director, entered into a settlement and license agreement with BioForm Medical, Inc. and BioForm Medical Europe B.V., or the BioForm entities, pursuant to which all outstanding disputes and litigation matters among the parties were settled. In connection with the settlement, we granted to the BioForm entities, which are competitors of us, an exclusive, world-wide, royalty-bearing license under certain of our patents to make and sell implant products containing calcium hydroxylapatite, or CaHA, particles and a non-exclusive, world-wide, royalty-bearing license under the same patents to make and sell certain other non-polymeric implant products. These license grants allow BioForm to market and sell its Radiesse and Coaptite® products and other potential future products. Sale of these products by BioForm may impair our ability to generate revenues from sales of ArteFill. In addition, if we become involved in litigation or if third parties infringe or threaten to infringe our intellectual property rights in the future, we may choose to make further license grants with respect to our technology, which could further harm our ability to market and sell ArteFill.

Our business may be harmed, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

A third party may assert that we (including our subsidiary) have infringed, or one of our distributors or strategic collaborators has infringed, his, her or its patents and proprietary rights or challenge the validity or enforceability of our patents and proprietary rights. Our competitors, many of which have substantially greater resources than us and have made significant investments in competing technologies or products, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use and sell future products either in the United States or in international markets. Further, we may not be aware of all of the patents and other intellectual property rights owned by third parties that may be potentially adverse to our interests. Intellectual property litigation in the medical device and biotechnology industries is common, and we expect this trend to continue. We may need to resort to litigation to enforce our patent rights or to determine the scope and validity of a third party s patents or other proprietary rights. The outcome of any such proceedings is uncertain and, if unfavorable, could significantly harm our business. If we do not prevail in this type of litigation, we or our distributors or strategic collaborators may be required to:

- pay actual monetary damages, royalties, lost profits and/or increased damages and the third party s attorneys fees, which may be substantial;

- expend significant time and resources to modify or redesign the affected products or procedures so that they do not infringe a third party s patents or other intellectual property rights; further, there can be no assurance that we

will be successful in modifying or redesigning the affected products or procedures;

obtain a license in order to continue manufacturing or marketing the affected products or services, and pay license fees and royalties; if we are able to obtain such a license, it may be non-exclusive, giving our

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competitors access to the same intellectual property, or the patent owner may require that we grant a cross-license to our patented technology; or

stop the development, manufacture, use, marketing or sale of the affected products through a court-ordered sanction called an injunction, if a license is not available on acceptable terms, or not available at all, or our attempts to redesign the affected products are unsuccessful.

Any of these events could adversely affect our business strategy and the value of our business. In addition, the defense and prosecution of intellectual property suits, interferences, oppositions and related legal and administrative proceedings in the United States and elsewhere, even if resolved in our favor, could be expensive, time consuming, generate negative publicity and could divert financial and managerial resources. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater financial resources.

Our ability to market ArteFill in some foreign countries may be impaired by the activities and intellectual property rights of third parties.

Although we acquired all of the international intellectual property rights related to Artecoll and the ArteFill technology platform in 2004, we are aware that third parties located in Germany, the Netherlands and Canada have in the past, and may be currently, manufacturing and selling products for the treatment of facial wrinkles under the name Artecoll or ArteSense outside the United States. Following the establishment of ArteFill in the United States, we plan to explore opportunities to market and sell ArteFill in select international markets. To successfully enter into these markets and achieve desired revenues internationally, we may need to enforce our patent and trademark rights against third parties that we believe may be infringing on our rights.

The laws of some foreign countries do not protect intellectual property, including patents, to as great an extent as do the laws of the United States. Policing unauthorized use of our intellectual property is difficult, and there is a risk that despite the expenditure of significant financial resources and the diversion of management attention, any measures that we take to protect our intellectual property may prove inadequate in these countries. Our competitors in these countries may independently develop similar technology or duplicate our products, thus likely reducing our sales in these countries. Furthermore, some of our patent rights may be limited in enforceability to the United States or certain other select countries, which may limit our intellectual property rights abroad.

Risks Related to Government Regulation

ArteFill will be subject to ongoing regulatory review, and if we fail to comply with continuing U.S. and foreign regulations, ArteFill could be subject to a product recall or other regulatory action, which would seriously harm our business.

Even though the FDA has approved the commercialization of ArteFill in the United States, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to ArteFill continue to be subject to extensive ongoing regulatory requirements. We are subject to ongoing FDA requirements for submission of safety and other post-market information and reports, including results from any post-marketing studies or vigilance required as a condition of approval. In particular, the FDA has required us to monitor the stability of the bovine collagen manufactured at our U.S. facility for sufficient time to support an 18-month expiration date, and to conduct a post-market study of 1,000 patients to examine the significance of delayed granuloma formation for a period of five years after their initial treatment. The FDA and similar governmental authorities in other countries have the authority to require the recall of ArteFill in the event of material deficiencies or defects in design, manufacture or labeling. Any recall of ArteFill would divert managerial and financial resources and harm our reputation among

physicians and patients.

Additionally, in connection with the ongoing regulation of ArteFill, the FDA or other regulatory authorities may also:

- impose labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contraindications or use limitations that could have a material impact on the future profitability of our product candidates;

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impose testing and surveillance to monitor our products and their continued compliance with regulatory requirements; and

require us to submit products for inspection.

Any manufacturer and manufacturing facilities we use to make our products will also be subject to periodic unannounced review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Material changes to an approved product, including the way it is manufactured or promoted, require FDA approval before the product, as modified, can be marketed. If we fail to comply with applicable regulatory requirements, a regulatory agency may:

issue warning letters;

impose fines and other civil or criminal penalties;

suspend or withdraw regulatory approvals for our products;

refuse to approve pending applications or supplements to approved applications filed by us;

delay, suspend or otherwise restrict our manufacturing, distribution, sales and marketing activities;

close our manufacturing facilities; or

seize or detain products or require a product recall.

If any of these events were to occur, we would have limited or no ability to market and sell ArteFill, and our business would be seriously harmed.

If we, or the supplier of the calf hides used in our collagen, do not comply with FDA and other federal regulations, our supply of product could be disrupted or terminated.

We must comply with various federal regulations, including the FDA s Quality System Regulations, or QSRs, applicable to the design and manufacturing processes related to medical devices. In addition, Lampire Biological Labs, Inc., the supplier of the calf hides used in our collagen, also must comply with manufacturing and quality requirements imposed by the FDA and the USDA. If we or our supplier fail to meet or are found to be noncompliant with QSRs or any other requirements of the FDA or USDA, or similar regulatory requirements outside of the United States, obtaining the required regulatory approvals, including from the FDA, to use alternative suppliers or manufacturers may be a lengthy and uncertain process. A lengthy interruption in the manufacturing of one or more of our products as a result of non-compliance could adversely affect our product inventories and supply of products available for sale which could reduce our sales, margins and market share, as well as harm our overall business and financial results.

The discovery of previously unknown problems with ArteFill may result in restrictions on the product, including withdrawal from manufacture. In addition, the FDA may revisit and change its prior determinations with regard to the safety or efficacy of ArteFill or our future products. If the FDA s position changes, we may be required to change our

labeling or cease to manufacture and market our products. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale of, or to recall ArteFill if concerns about its safety or efficacy develop.

In their regulation of advertising, the FDA and the Federal Trade Commission, or FTC, may issue correspondence alleging that our advertising or promotional practices are false, misleading or deceptive. The FDA and the FTC may impose a wide array of sanctions on companies for such advertising practices, which could result in any of the following:

- incurring substantial expenses, including fines, penalties, legal fees and costs to comply with applicable regulations;

- changes in the methods of marketing and selling products;

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taking FDA-mandated corrective action, which may include placing advertisements or sending letters to physicians rescinding or correcting previous advertisements or promotions; or

disruption in the distribution of products and loss of sales until compliance with the FDA s position is obtained.

If any of the above sanctions are imposed on us, it could damage our reputation, and harm our business and financial condition. In addition, physicians may utilize ArteFill for uses that are not described in the product s labeling or differ from those tested by us and approved by the FDA. While such off-label uses are common and the FDA does not regulate physicians choice of treatments, the FDA does restrict a manufacturer s communications on the subject of off-label use. Companies cannot promote FDA-approved products for off-label uses, but under certain limited circumstances they may disseminate to practitioners articles published in peer-reviewed journals. To the extent allowed by law, we intend to distribute peer- reviewed articles on ArteFill and any future products to practitioners. If, however, our activities fail to comply with the FDA s regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA.

We have a manufacturing facility in Frankfurt, Germany, and will be subject to a variety of regulations in jurisdictions outside the United States that could have a material adverse effect on our business in a particular market or in general.

We presently manufacture the PMMA microspheres used in ArteFill at our manufacturing facility in Germany. In addition, we intend to expand our operations and market ArteFill in other foreign markets, including Canada and selected countries in Europe. We are currently subject to a variety of regulations in Germany and expect to become subject to additional foreign regulations as we expand our operations. Our failure to comply, or assertions that we fail to comply, with these regulations, could harm our business in a particular market or in general. To the extent we decide to commence or expand operations in additional countries, government regulations in those countries may prevent or delay entry into, or expansion of operations in, those markets. For example, the government of the Netherlands has received a request to conduct an investigation into the safety of permanent injectable aesthetic products, which could lead to restrictions on the sale or use of these products, or heighten the requirements for qualifying or licensing these products for sale. Government actions such as these could delay or prevent the introduction of ArteFill in international markets and limit our ability to generate revenues.

We may be subject, directly or indirectly, to state healthcare fraud and abuse laws and regulations and, if we are unable to fully comply with such laws, could face substantial penalties.

Our operations may be directly or indirectly affected by various broad state healthcare fraud and abuse laws. In particular, our activities with respect to ArteFill will potentially be subject to anti-kickback laws in some states, which prohibit the giving or receiving of remuneration to induce the purchase or prescription of goods or services, regardless of who pays for the goods or services. These laws, sometimes referred to as all-payor anti-kickback statutes, could be construed to apply to certain of our sales and marketing and physician training and support activities. In particular, our provision of practice support services such as marketing or promotional activities offered to trained and accredited physicians could be construed as an economic benefit to these physicians that constitutes an unlawful inducement of the physicians to recommend ArteFill to their patients.

If our operations, including our anticipated business relationships with physicians who use ArteFill, are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines and imprisonment. If enforcement action were to occur, our business and financial condition would be harmed.

Risks Related to Our Common Stock

We may be subject to the assertion of claims by our stockholders relating to prior financings, which could result in litigation and the diversion of our management s attention.

Investors in certain of our prior financings may allege that we failed to satisfy all of the requirements of applicable securities laws in that certain disclosures to these investors regarding our capitalization may not have

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been accurate in all material respects, paperwork might not have been timely filed in certain states and/or certain offerings may not have come within a private-placement safe harbor. We believe that any such claims would not succeed because we believe we have complied with these laws in all material respects, such claims would be barred pursuant to applicable statutes of limitations or such claims could be resolved through compliance with certain state securities laws. However, to the extent we do not succeed in defending against any such claims and any such claims are not barred or resolved, they could result in judgments for damages. Even if we are successful in defending these claims, their assertion could result in litigation and significant diversion of our management s attention and resources.

The price of our common stock may be volatile, and any investments in our common stock could suffer a decrease in value.

Prior to our initial public offering in December 2006, there has been no public market for our common stock. An active and liquid trading market for our common stock may not develop or be sustained. The market price for our common stock is likely to be volatile, and the stock markets in general, and the markets for medical technology stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. There have also been periods, sometimes extending for many months and even years, where medical technology stocks, especially of smaller earlier stage companies like us, have been out of favor and trading prices have remained low relative to other sectors.

Price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

- reports of adverse side effects resulting from treatment with ArteFill;
- adverse actions taken by regulatory agencies with respect to open investigations, including the ongoing investigation by the FDA s Office of Criminal Investigations involving Drs. Gottfried and Stefan Lemperle and our company;
- other adverse actions taken by regulatory agencies with respect to our products, manufacturing processes or sales and marketing activities or those of our competitors;
- developments in any lawsuit involving us, our intellectual property or our product or product candidates;
- announcements of technological innovations or new products by our competitors;
- announcements of adverse effects of products marketed or in clinical trials by our competitors;
- regulatory developments in the United States and foreign countries;
- announcements concerning our competitors or the medical device, cosmetics or pharmaceutical industries in general;
- developments concerning any future collaborative arrangements;
- actual or anticipated variations in our operating results;
- lack of securities analyst coverage or changes in recommendations by analysts;

deviations in our operating results from the estimates of analysts;

sales of our common stock by our founders, executive officers, directors, or other significant stockholders or other sales of substantial amounts of common stock;

changes in accounting principles; and

loss of any of our key management, sales and marketing or scientific personnel and any claims against us by current or former employees.

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Litigation has often been brought against companies whose securities have experienced volatility in market price. If litigation of this type were to be brought against us, it could harm our financial position and could divert management s attention and our company s resources.

You could experience substantial dilution of your investment as a result of subsequent exercises of our outstanding warrants and options.

As of December 31, 2006, we had reserved approximately 8.3 million shares of our common stock for potential issuance upon the exercise of warrants and options (including outstanding warrants to purchase common stock, options already granted under our stock option plans, non-plan stock options already granted and shares reserved for future grant under our stock option plans), which represented approximately 39.5% of our common stock on a fully diluted basis (assuming the exercise of all outstanding warrants and options). Of the 8.3 million shares of common stock reserved at December 31, 2006, 2.1 million shares of common stock are reserved for outstanding stock options at a weighted average exercise price of $6.65 per share; 2.5 million shares of common stock are reserved for outstanding warrants to purchase common stock (after considering the impact of the warrant holder elections eliminating the automatic expiration and extending the terms of the warrants upon the closing of our initial public offering), at a weighted average exercise price $7.03 per share; and 3.7 million shares of common stock are reserved for future stock option grants under our 2006 Equity Incentive Plan. The issuance of these additional shares could substantially dilute your ownership interest in our company.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of our certificate of incorporation and bylaws and Delaware law may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing the issuance of blank check preferred stock without any need for action by stockholders;
- providing for a classified board of directors with staggered terms;
- requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;
- eliminating the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder s acquisition of our stock was approved in advance by our board of directors. Together, these charter and statutory provisions could make the removal of management more difficult and may discourage transactions that otherwise could involve payment of a

premium over prevailing market prices for our common stock.

Item 1B. ***Unresolved Staff Comments.***

None.

Item 2. ***Properties.***

We lease a 35,000 square foot building for our corporate, manufacturing and research and development headquarters in San Diego, California under a seven-year lease that expires in December 2011. Our facility includes

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14,000 square feet of clean room space, 15,000 square feet of manufacturing, support and laboratory space and 6,000 square feet of administrative office space. We have a first right of refusal to purchase the facility during the term of the lease, as well as the right to extend the lease term for an additional 5 years. We also sublease 8,000 square feet of additional office space in a building adjacent to our headquarters building under a six-year sublease that expires in March 2011.

In addition, we lease a 3,550 square foot manufacturing and warehouse facility in Frankfurt, Germany, where we manufacture the PMMA microspheres used exclusively in ArteFill. The leases for our Frankfurt facility expire in November 2007, and are subject to automatic one-year extensions unless written notice of termination is given by either party at least six months prior to the beginning of the extension term.

We believe that our existing facilities are adequate to meet our needs for the foreseeable future.

Item 3. ***Legal Proceedings.***

Sandor Litigation

In August 2005, Elizabeth Sandor, an individual residing in San Diego, California, filed a complaint against us, Drs. Gottfried Lemperle, Stefan Lemperle and Steven Cohen in the Superior Court of the State of California for the County of San Diego. The complaint, as amended, set forth various causes of action against us, including product liability, fraud, negligence and negligent misrepresentation, and alleged that Dr. Gottfried Lemperle, our co-founder, former Chief Scientific Officer and a former director, treated Ms. Sandor with Artecoll and/or ArteFill in violation of medical licensure laws, that the product was defective and unsafe because it had not received FDA approval at the time it was administered to Ms. Sandor, and that Ms. Sandor suffered adverse reactions as a result of the injections. In addition, the complaint alleged that Dr. Gottfried Lemperle and his son, Dr. Stefan Lemperle, our other co-founder, former Chief Executive Officer and a former director, falsely represented to her that the product had received an approvability letter from the FDA and was safe and without the potential for adverse reactions. The complaint also alleged medical malpractice against Dr. Cohen, the lead investigator in our U.S. clinical trial, for negligence in treating Ms. Sandor for the adverse side effects she experienced. Ms. Sandor sought damages in an unspecified amount for pain and suffering, medical and incidental expenses, loss of earnings and earning capacity, punitive and exemplary damages, reasonable attorneys fees and costs of litigation. On June 1, 2006, the parties filed a stipulation to dismiss the case without prejudice and toll the statute of limitations. The court dismissed the case on June 5, 2006 as stipulated by the parties, and ms. Sandor is allowed to refile her case at any time within 18 months from that date. The Company has no information with respect to whether or not Ms. Sandor will refile her case prior to that time.

FDA Investigation

During the Sandor litigation discussed above, Dr. Gottfried Lemperle s counsel informed us that she had contacted an investigator in the FDA s Office of Criminal Investigations to determine whether any investigation of Dr. Gottfried Lemperle was ongoing. She also informed us that the FDA investigator informed her that the FDA has an open investigation regarding us, Dr. Gottfried Lemperle and Dr. Stefan Lemperle, that the investigation had been ongoing for many months, that the investigation would not be completed within six months, and that at such time the investigation is completed, it could be referred to the U.S. Attorney s Office for criminal prosecution. In November 2006, we contacted the FDA s Office of Criminal Investigation. That office confirmed the ongoing investigation, but declined to provide any details of the investigation, including the timing, status, scope or targets of the investigation.

To our knowledge, prior to, or following this inquiry, none of our current or former officers or directors had been contacted by the FDA in connection with an FDA investigation. As a result, we have no direct information from the FDA regarding the subject matter of this investigation. We believe that the investigation may relate to the facts alleged

in the Sandor litigation and the matters identified in the following correspondence from the FDA. In July 2004, we received a letter from the FDA s Office of Compliance indicating that the FDA had received information suggesting that we may have improperly marketed and promoted ArteFill prior to obtaining final FDA approval. We also received a letter from the FDA s MedWatch program, the FDA s safety information and adverse event reporting program, on April 21, 2005, which included a Manufacturer and User Facility Device Experience Database, or MAUDE, report. The text of the MAUDE report contained facts similar to those alleged by

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the plaintiff in the Sandor litigation. In May 2006, we received the FDA s EIR for its investigation of our San Diego manufacturing facility. The EIR referenced two anonymous consumer complaints received by the FDA. The first complaint, received by the FDA in December 2003, alleges that Dr. Stefan Lemperle promoted the unapproved use of ArteFill, providing, upon request, a list of local doctors who could perform injections of ArteFill. The second complaint, received by the FDA in June 2004, alleges complications experienced by an individual who had been injected with ArteFill by Dr. Gottfried Lemperle in his home. The second complaint further alleges that Dr. Stefan Lemperle marketed unapproved use of ArteFill.

We responded to the FDA s correspondence in August 2004 and again in May 2006. In our responses, we informed the FDA that based on our internal investigations, Dr. Gottfried Lemperle had used Artecoll, a predecessor product to ArteFill, on four individuals in the United States. In July 2006, the FDA requested us to submit an amendment to our pre-market approval application for ArteFill containing a periodic update covering the time period between January 16, 2004, the date of our approvable letter, and the date of the amendment. In response to this request, we completed additional inquiries regarding Dr. Gottfried Lemperle s unauthorized uses of Artecoll outside our clinical trials in contravention of FDA rules and regulations. In August 2006, we filed an amendment to our pre-market approval application that included the periodic update requested by the FDA. In the amendment, we informed the FDA that as a result of our additional inquiries, we had identified nine individuals who had been treated with Artecoll in the United States by Dr. Gottfried Lemperle, four of whom we had disclosed to the FDA in our prior correspondence. We also informed the FDA that 16 individuals had been treated with Artecoll by physicians in Mexico or Canada, where Artecoll is approved for treatment, in connection with physician training sessions conducted in those countries. Further, we informed the FDA that Dr. Stefan M. Lemperle had been injected with Artecoll in the United States in 2004 by his father, Dr. Gottfried Lemperle.

We intend to cooperate fully with any inquiries by the FDA or any other authorities regarding these and any other matters. We have no information regarding when any investigation may be concluded, and we are unable to predict the outcome of the foregoing matters or any other inquiry by the FDA or any other authorities. In May 2006, we terminated our consulting relationship with Dr. Gottfried Lemperle, and in November 2006, Dr. Stefan Lemperle resigned as a director and employee. Neither Dr. Stefan Lemperle nor Dr. Gottfried Lemperle provide services to us in any capacity.

Mel Ehrlich Litigation

On November 6, 2006, we filed a demand for arbitration with the American Arbitration Association against Melvin Ehrlich, who from January 15, 2004 through April 5, 2004, was our President and Chief Operating Officer. In the arbitration, we are seeking declaratory relief regarding the number of shares of common stoc k Mr. Ehrlich is entitled to purchase under a warrant we issued to him in connection with his employment agreement. We believe Mr. Ehrlich vested in and, therefore, is entitled to purchase 26,070 shares of common stock based on the length of time he provided services to our company. These warrant shares have an exercise price of $4.25 per share, and are subject to a 180-day market standoff period in connection with our proposed offering. Mr. Ehrlich contends that he is entitled to purchase up to 470,588 shares of common stock, at an average exercise price of $7.44 per share, contingent upon our satisfaction of certain milestones, including the FDA s approval of ArteFill, the FDA s certification of our manufacturing facilities and the completion of this offering. He claims that the language in the warrant allows him to continue to vest in the warrant shares after his employment with us ended, regardless of whether he provided any assistance to the Company to satisfy the milestones set forth in the warrant. We reject this interpretation of the warrant. The American Arbitration Association has accepted jurisdiction of the claim, with a final determination of jurisdiction to be finally determined by the arbitrator assigned to this matter.

The parties have pursued a settlement of this action, and have negotiated the terms of a proposed settlement agreement in which we will pay Mr. Ehrlich $250,000 and issue Mr. Ehrlich 26,710 shares of common stock and a warrant to

purchase 25,000 shares of common stock, at an exercise price of $8.07 per share. The settlement agreement contains a mutual release of claims and a mutual covenant not to sue. The shares of common stock, the warrant and the shares of common stock issuable upon exercise of the warrant are subject to lock-up restrictions that do not expire until June 17, 2007. The settlement agreement is subject to approval by our board of directors, and based on his age, Mr. Ehrlich will have seven days to revoke the settlement agreement after he signs it. The Company has made an accrual in the fourth quarter of the fiscal year ended December 31, 2006 based on the terms

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of the proposed settlement agreement. We cannot assure you that the parties will effect the settlement agreement on the terms outlined above, or at all. If the settlement agreement is not effected, we intend to continue to pursue our declaratory relief action against Mr. Ehrlich.

Item 4. ***Submission of Matters to a Vote of Security Holders.***

No matter was submitted to a vote of our security holders during the quarter ended December 31, 2006.

PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.***

Market Information for Common Stock

Our common stock has been listed for trading on the NASDAQ Global Market under the symbol ARTE since December 20, 2006. The following table sets forth high and low sale closing prices per share of common stock during the periods indicated as reported on the NASDAQ Global Market.

2006	**High**	**Low**
Fourth Quarter beginning on December 20, 2006	$ 9.50	$ 7.01
January 1, 2007 to March 15, 2007	9.96	7.35

On March 15, 2007, the closing sale price of our common stock was $7.78 per share. On March 1, 2007, there were approximately 927 record holders of our common stock. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in street name.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, for development of our business and do not anticipate that we will declare or pay cash dividends on our capital stock in the foreseeable future.

Stock Performance Graph

COMPARISON OF CUMULATIVE RETURN*
Among Artes Medical Inc., The NASDAQ Composite Index
And The NASDAQ Medical Equipment Index

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* $100 invested on 12/20/06 in stock on 11/30/06 in index-including reinvestment of dividends. Fiscal year ending December 31.

Recent Sales of Unregistered Securities

In connection with our initial public offering, we effected a 1-for-4.25 reverse stock split of our common stock on December 19, 2006. In addition to the reverse stock split, all outstanding shares of our preferred stock were converted to common stock immediately prior to the closing of our initial public offering on December 26, 2006. Each outstanding share of Series A, Series D and Series E preferred stock was converted into one share of common stock, and as a result of anti-dilution provisions, each one share of Series B preferred stock was converted into 1.35 shares of common stock and each one share of Series C-1 preferred stock was converted into 1.375 shares of common stock. In addition, as a result of the conversion to common stock, all warrants or other rights to purchase the Company s preferred stock outstanding on December 26, 2006 were automatically converted into the right to purchase shares of common stock at the ratios for the particular series of preferred stock set forth above.

All share amounts below have been retroactively adjusted to give effect to a 1-for-4.25 reverse stock split and the conversion to common stock effected in connection with the completion of our initial public offering. During the year ended December 31, 2006, we issued and sold the following securities which were not registered under the Securities Act of 1933:

From January 2006 through March 2006, we issued shares of Series E convertible preferred stock representing 4,092,422 shares of common stock and warrants for Series E convertible preferred stock that represent the right to purchase 531,454 shares of common stock at an exercise price of $10.63 per share to investors for aggregate gross proceeds of approximately $43.5 million in a private placement transaction. In connection with the private placement, we paid cash commissions in an aggregate amount of approximately $3.5 million and issued warrants to purchase shares of Series E convertible preferred stock that represent the right to purchase 324,607 shares of common stock at an exercise price of $10.63 per share to National Securities Corporation in consideration for its services as placement agent. In addition, we reimbursed National Securities Corporation for certain legal and other expenses incurred in connection with the private placement.

In November 2006, we granted a warrant for shares of Series E convertible preferred stock that represents the right to purchase 28,235 shares of common stock at an exercise price of $10.63 per share to Comerica Bank in connection with a loan and security agreement entered into between us an Comerica Bank.

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From March 2006 through December 2006, we granted options to purchase an aggregate of 1,319,857 shares of our common stock at a weighted average exercise price of $8.00 per share to our employees, consultants and directors under our Amended and Restated 2001 Stock Option Plan, or 2001 Plan. During this period, 334,965 of these options were surrendered, resulting in a net of 984,892 options granted.

From January 2006 through December 2006, we issued and sold an aggregate of 99,404 shares of our common stock at a weighted average exercise price of $3.49 per share to our employees, consultants and directors pursuant to exercises of options granted under our 2001 Plan.

From January 2006 through December 2006, we issued an aggregate of 12,793 shares of our common stock in consideration for services provided to us by our employees and consultants.

In May 2006, we issued 2,352 shares of our common stock pursuant to the exercise of a warrant to purchase common stock at an exercise price of $5.31 per share.

In December 2006, we issued 168,580 shares of our common stock pursuant to the cashless exercise of warrants and 107,754 shares of our common stock pursuant to the cash exercise of warrants at a weighted average exercise price of $5.57 per share, in connection with and effective upon the completion of our initial public offering.

The sales and issuances of securities in the transactions described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance upon Section 4(2) of the Securities Act of 1933, as amended, Regulation D promulgated thereunder or Rule 701 promulgated under Section 3(b) of the Securities Act of 1933, as amended, as transactions by an issuer not involving any public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701.

Use of Proceeds

We registered shares of our common stock in connection with our initial public offering under the Securities Act of 1933, as amended. The Registration Statement on Form S-1 (File No. 333-134086) filed in connection with our initial public offering was declared effective by the SEC on December 19, 2006. The offering commenced on December 20, 2006. We sold 4,600,000 shares of our registered common stock in the initial public offering and an additional 690,000 shares of our registered common stock in connection with the underwriters exercise of their over-allotment option. The underwriters of the offering were represented by Cowen and Company, LLC and Lazard Capital Markets LLC and Stifel, Nicolaus & Company, Incorporated.

All 5,290,000 shares of our common stock registered in the offering were sold at the initial public offering price of $6.00 per share, resulting in aggregate gross proceeds to us of $31.7 million. The net offering proceeds received by us, after deducting expenses incurred in connection with the offering, was approximately $25.3 million. These expenses consisted of direct payments of:

approximately $2.2 million in underwriters discounts, fees and commissions; and

approximately $4.2 million in legal, accounting and printing fees and miscellaneous expenses

No payments for such expenses were directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

We have used $5.5 million of the net proceeds of the initial public offering for the intended uses outlined in our prospectus relating to our initial public offering, and as of February 28, 2007, we have approximately $40.7 million in cash, approximately $19.8 million remaining from the proceeds of the offering. We have used $5.1 million to fund our operations, $175,000 to purchase property and equipment and $253,000 to repay our outstanding debt and capital lease obligations. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

Purchases of Equity Securities

There were no share repurchases during the fourth quarter of 2006.

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Item 6. ***Selected Consolidated Financial Data.***

The following selected consolidated financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our audited consolidated financial statements and related notes included elsewhere in this report. We derived the consolidated statement of operations data for the year ended December 31, 2002 and 2003, as well as the consolidated balance sheet data as of December 31, 2002, 2003 and 2004, from our audited consolidated statements not included in this report. We derived the consolidated statements of operations data for the years ended December 31, 2004, 2005 and 2006, as well as the consolidated balance sheet data as of December 31, 2005 and 2006, from our audited consolidated financial statements included elsewhere in this report. Our historical results are not necessarily indicative of operating results to be expected in future periods.

	Years Ended December 31,				
	2002	2003	2004	2005	2006
	(In thousands, except share and per share amounts)				
Consolidated Statements of Operations Data:					
Expenses:					
Research and development	$ 1,457	$ 974	$ 3,634	$ 10,189	$ 8,084
Selling, general and administrative	1,975	2,976	5,155	10,137	17,299
Total expenses	3,432	3,950	8,789	20,326	25,383
Loss from operations	(3,432)	(3,950)	(8,789)	(20,326)	(25,383)
Interest expense, net	(914)	(2,170)	(4,028)	(4,416)	(1,779)
Other income (expense), net			(22)	2,041	363
Loss before benefit for income taxes	(4,346)	(6,120)	(12,839)	(22,701)	(26,800)
Benefit for income taxes			454	458	476
Net loss	$ (4,346)	$ (6,120)	$ (12,385)	$ (22,243)	$ (26,323)
Historical net loss per common share:					
Basic and diluted	$ (4.10)	$ (5.76)	$ (11.20)	$ (18.76)	$ (14.23)
Weighted average shares basic and diluted	1,060,117	1,062,825	1,106,188	1,185,387	1,850,255
Stock-based compensation is included in the following categories:					
Capitalized to inventory	$	$	$	$	$ 263
Research and development			91	256	766

Selling, general and administrative	159	1,042	1,038		4,165
	$ $ 159	$ 1,133	$ 1,294	$	4,931

See our consolidated financial statements and related notes for a description of the calculation of the historical net loss per common share and the weighted-average number of shares used in computing the historical per share data.

	As of December 31, 2006				
	2002	**2003**	**2004**	**2005**	**2006**
			(In thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 55	$ 36	$ 2,269	$ 6,930	$ 46,258
Working capital (deficit)	(2,036)	(2,659)	(3,792)	(2,974)	39,406
Total assets	220	450	10,296	20,320	60,613
Long-term debt and capital lease obligations, less current portion	2,255	371	5,323	66	3,362
Stockholders equity (deficit)	(4,139)	(2,628)	(4,594)	5,537	43,186

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Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations.***

You should read the following discussion and analysis in conjunction with our financial statements and related notes contained elsewhere in this report. This discussion contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of a variety of factors, including those set forth under Item 1A, Risk Factors and elsewhere in this report and those discussed in other documents we file with the Securities and Exchange Commission. In light of these risks, uncertainties and assumptions, readers are cautioned not to place undue reliance on such forward-looking statements. These forward looking statements represent beliefs and assumptions only as of the date of this report. Except as required by applicable law, we do not intend to update or revise forward-looking statements contained in this report to reflect future events or circumstances.

Overview

We are a medical technology company focused on developing, manufacturing and commercializing a new category of injectable aesthetic products for the dermatology and plastic surgery markets. On October 27, 2006, the FDA approved ArteFill, our non-resorbable aesthetic injectable implant for the correction of facial wrinkles known as smile lines, or nasolabial folds. Currently, there are two categories of injectable aesthetic products used for the treatment of facial wrinkles: temporary muscle paralytics, which block nerve impulses to temporarily paralyze the muscles that cause facial wrinkles, and temporary dermal fillers, which are injected into the skin or deeper facial tissues beneath a wrinkle to help reduce the appearance of the wrinkle. Unlike existing temporary muscle paralytics and temporary dermal fillers, which are comprised of materials that are completely metabolized and absorbed by the body, ArteFill is a proprietary formulation comprised of polymethylmethacrylate, or PMMA, microspheres and bovine collagen, or collagen derived from calf hides. PMMA is one of the most widely used artificial materials in implantable medical devices, and is not absorbed or degraded by the human body. Following injection, the PMMA microspheres in ArteFill remain intact at the injection site and provide a permanent support structure to fill in the existing wrinkle and help prevent further wrinkling. As a result, we believe that ArteFill will provide patients with aesthetic benefits that may last for years.

We commenced commercial shipments of ArteFill during the first quarter of 2007. Our strategy is to establish ArteFill as a leading injectable aesthetic product. We plan to drive the adoption of our product through a direct sales and marketing effort to dermatologists, plastic surgeons and cosmetic surgeons in the United States. We initially intend to target dermatologists, plastic surgeons and cosmetic surgeons whom we have identified as having performed a significant number of procedures involving injectable aesthetic products. In connection with our product launch, we intend to provide physicians with comprehensive education and training programs. We believe our education and training programs will enable physicians to improve patient outcomes and satisfaction. After establishing ArteFill in the United States, we plan to explore opportunities to register and sell ArteFill in selected international markets. In addition, we may expand our product offering by acquiring complementary products, technologies or businesses.

Since our inception in 1999, we have incurred significant losses and have never been profitable. We have devoted substantially all of our efforts to product development and clinical trials, to acquire international rights to certain intangible assets and know-how related to our technology, and to establish commercial manufacturing capabilities. To date, we have generated no revenues. As of December 31, 2006, our deficit accumulated during the development stage was approximately $79.4 million.

We have financed our operations through sales of our preferred stock and common stock, options and warrants exercisable for our preferred and common stock, convertible and nonconvertible debt and through the initial public

offering of our common stock. Since inception, we have raised $61.7 million through private equity financings, $1.1 million through the exercise of options and warrants, $28.1 million through convertible and nonconvertible debt, and $25.3 million through the initial public offering of our common stock. In November 2006, we entered into a loan and security agreement with Comerica Bank consisting of a revolving line of credit for up to $5,000,000 and a term loan for up to $5,000,000. At December 31, 2006, $9.9 million was outstanding under the loan and security agreement. As of December 31, 2006, our cash and cash equivalents were $46.3 million.

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Financial Operations Overview

Sales

From our inception in 1999 through the fiscal year ended December 31, 2006, we have not generated any product sales. We commenced commercial shipments and begin generating product sales from ArteFill during the first quarter of 2007.

Cost of Sales

Cost of sales consist primarily of expenses related to the manufacturing and distribution of ArteFill, including expenses related to our direct and indirect manufacturing personnel, quality assurance and quality control, manufacturing and engineering, supply chain management, facilities and occupancy costs. We will also incur expenses related to manufacturing yield losses, product returns and rejects, procurement from our manufacturing materials supply and distribution partners and amortization of deferred stock-based compensation for our direct and indirect manufacturing personnel.

From January 1, 2003 through December 31, 2006, we have not incurred any cost of sales expenses, since we did not commercially manufacture any product during that period. Initially, we expect cost of sales to increase substantially to meet projected sales volume demand for ArteFill. While the direct material costs for ArteFill are expected to represent a small portion of our cost of sales, our manufacturing cost structure includes a large fixed cost component that will be spread out over future production unit volumes. We anticipate the economies of scale of manufacturing our product and future automation efforts will be a significant factor in reducing future unit manufacturing costs to generate improved gross margins.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses are comprised of the following:

- sales and marketing expenses, which primarily consist of the personnel and related costs of our U.S. sales force, customer service, marketing and brand management functions, including direct costs for advertising and promotion of our product; and

- general and administrative costs, which primarily consist of corporate executive, finance, legal, human resources, information systems, investor relations and general administrative functions.

From January 1, 2003 through December 31, 2006, we spent an aggregate of approximately $35.6 million on selling, general and administrative expenses, which represented approximately 61% of total operating expenses. We anticipate substantial increases in our selling, general and administrative expenses as we add personnel to our direct U.S. sales force and expand our other marketing functions. The size of the increase depends on the size of our sales force, as well as the extent of marketing, advertising and promotional efforts either directly or through third parties. We also anticipate increases in general and administrative costs in connection with the commercial launch of ArteFill and costs related to investor relations, financial reporting and corporate governance obligations applicable to publicly held companies.

Research and Development Expenses

A significant majority of our research and development expenses consist of expenses incurred by external service providers for preclinical, clinical trials, technology and regulatory development projects.

Research and development expenses also include costs incurred for process development and validation to scale up our commercial operations to meet cGMP manufacturing requirements prior to final approval from the FDA to market our product. We have also incurred personnel costs related to internal development of our product.

Because we have been focused on obtaining final FDA approval for ArteFill, we currently maintain a limited in-house research and development organization for new product development and have concentrated our resources on manufacturing and process development to meet FDA cGMP requirements. In January 2004, we received an approvable letter from the FDA for our PMA application, indicating that ArteFill is safe and effective for the

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correction of facial wrinkles known as smile lines, or nasolabial folds. In January 2006, we submitted an amendment to our PMA application to address certain conditions to final marketing approval set forth in the FDA s approvable letter, and in April 2006, the FDA completed comprehensive pre-approval inspections of our manufacturing facilities in San Diego, California and Frankfurt, Germany. On May 3, 2006, the FDA issued an EIR, indicating that its inspection of our facilities was completely closed, requiring no further action on the part of our company related to the inspection. On October 27, 2006, the FDA approved ArteFill for commercial sale in the United States.

We expense research and development costs as they are incurred. From January 1, 2003 through December 31, 2006, we spent an aggregate of approximately $22.9 million on research and development expenses, which represented approximately 39% of total operating expenses. We currently plan to conduct limited research and clinical development activities to evaluate the feasibility, safety and efficacy of ArteFill for other aesthetic applications, such as the treatment of acne scars and wounds, and use in aesthetic reconstructive surgery. We also plan to explore applications of our injectable microsphere platform technology in non-aesthetic medical applications through collaborative arrangements with strategic partners.

Amortization of Acquired Intangible Assets

Acquired intangible assets, consisting of core technology and international patents, are recorded at fair market value as of the acquisition date. Fair market value is determined by an independent third party valuation and is amortized over the estimated useful life. This determination is based on factors such as technical know-how and trade secret development of our core PMMA technology, patent life, forecasted cash flows, market size and growth, barriers to competitive entry and existence and the strength of competing products.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates. While our significant accounting policies are described in more detail in Note 1 of the Notes to Consolidated Financial Statements included elsewhere in this report, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements:

Revenue Recognition

From our inception, in 1999 through fiscal year ended December 31, 2006, we have not generated any product sales. We commenced commercial shipments of ArteFill during the first quarter of 2007. We will recognize revenue from product sales when (i) there is persuasive evidence that an arrangement exists, (ii) delivery of the product has occurred and title has transferred to our customers, (iii) the selling price is fixed and determinable and (iv) collection is reasonably assured. Provisions for discounts to customers, returns or other adjustments will be recorded as a reduction of revenue and provided for in the same period that the related product sales are recorded based upon analysis of historical discounts and returns.

When terms of sale are Free on Board, or FOB, shipping point, revenue will be recognized at the time of shipment and when the terms of sale are FOB destination point, revenue will be recognized when the products have reached the destination point and other criteria for revenue recognition have been met.

We expect a substantial amount of our business to be transacted using credit cards. We may offer an early payment discount to certain customers.

We also may provide customers with certain product return rights in the case of damaged or defective product. Once we have experience with actual product sales and customer product returns, we will determine the appropriate reserve for product returns. Our inability to accurately estimate product returns in the future may cause us to defer recognition of revenue.

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Allowance for Doubtful Accounts

Once we have experience in actual collections with our customers, we will analyze the collectibility of our accounts receivable, historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in customer payment terms in evaluating whether an allowance needs to be made during the period. The expense related to the allowance for doubtful accounts is recorded in selling, general and administrative.

Valuation of Inventory

Inventories are stated at the lower of cost or market, with cost being determined under a standard cost method, which approximates a first-in, first-out basis. Our inventories are evaluated and any non-usable inventory is expensed. In addition, we reserve for any inventory that may be excess or potentially non-usable. Charges for such write-offs and reserves are recorded as a component of cost of sales. Changes in demand in the future could cause us to have additional write-offs and reserves.

Impairment of Long-Lived Assets

We review long-lived assets, including property and equipment and intangibles, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. To date, we have not recorded any impairment losses.

Intangible Assets

Intangible assets are comprised of acquired core technology and patents recorded at fair market value less accumulated amortization. Amortization is recorded on the straight-line method over the estimated useful lives of the intangible assets.

Deferred Taxes

Asset Valuation Allowance

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowances recorded against our net deferred tax assets. We have historically had net losses and have not been required to provide for income tax liabilities. We have established a valuation allowance with respect to all of our U.S. deferred tax assets. Changes in our estimates of future taxable income may cause us to reduce the valuation allowance and require us to report income tax expense in amounts approximating the statutory rates.

Deferred Tax Liability

A deferred tax liability was created on the date of purchase of our wholly-owned German-based manufacturing subsidiary as there was no allocation of the purchase price to the intangible asset for tax purposes, and the foreign subsidiary s tax basis in the intangible asset remained zero.

Emerging Issues Task Force, or EITF, Issue No. 98-11, *Accounting for Acquired Temporary Differences in Certain Purchase Transactions That Are Not Accounted for as Business Combinations*, requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability.

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Stock-Based Compensation Expense

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-Based Payment* (SFAS No. 123(R)), which revises SFAS No. 123, *Accounting for Stock-Based Compensation* and (SFAS No. 123), supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). SFAS No. 123(R) requires that share-based payment transactions with employees and directors be recognized in the financial statements based on their grant-date fair value and recognized as compensation expense over the requisite service period. Prior to January 1, 2006, we accounted for our stock-based employee and director compensation plans using the intrinsic value method under the recognition and measurement provisions of Accounting Principles Board Opinion (APB) 25, *Accounting for Stock Issued to Employees*, and related guidance. We adopted SFAS No. 123(R) effective January 1, 2006, prospectively for new equity awards issued subsequent to January 1, 2006, therefore prior period results have not been restated. The adoption of SFAS No. 123(R) in the first quarter of 2006 resulted in the recognition of additional stock-based compensation expense for the year ended December 31, 2006 of $1,300,000. Of this amount, $146,000 has been capitalized to inventory, $139,000 is included in research and development expenses and $1,015,000 is included in selling, general and administrative expenses.

Under SFAS No. 123(R), we calculated the fair value of the stock option grants using the Black-Scholes option-pricing model. For the year ended December 31, 2006, the fair value was based on the following weighted average assumptions: the expected term of 6.0 years; the expected volatility of 60%, the risk free interest rate of 4.55% and 0% for the dividend yield. Future expense amounts for any particular quarterly or annual period could be affected by changes in our assumptions or changes in market conditions.

The weighted average expected term for the year ended December 31, 2006 reflects the application of the simplified method set out in SEC Staff Accounting Bulletin No. 107 (SAB 107), which was issued in March 2005. The simplified method defines the expected term as the average of the contractual term of the options and the weighted average vesting period for all option tranches.

Estimated volatility for the year ended December 31, 2006 also reflects the application of SAB 107 interpretive guidance and, accordingly incorporates historical volatility of similar public entities.

Total unrecognized stock-based compensation costs related to unvested stock option and warrant awards at December 31, 2006 is $9,506,000, all of which arose from the adoption of SFAS No. 123(R). The unrecognized cost is expected to be recognized on a straight-line basis over a weighted average period of four years.

Equity instruments issued to non-employees are recorded at their fair values as determined in accordance with SFAS 123, *Accounting for Stock-Based Compensation*, and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the options vest and are recognized as expense over the related service period.

During the years ended December 31, 2004, 2005, 2006, and for the period from August 24, 1999 (inception) through December 31, 2006, we recognized $1,024,000, $959,000, $535,000, and $2,731,000, respectively, for stock options and warrants issued to non-employees.

Deferred Stock-Based Compensation

Deferred stock-based compensation, which is a non-cash charge, results from employee stock option grants at exercise prices that, for financial reporting purposes, are deemed to be below the estimated fair value of the underlying

common stock on the date of grant. Given the absence of an active market for our common stock through 2005, our board of directors considered, among other factors, the liquidation preferences, anti-dilution protection and voting preferences of the preferred stock over the common stock in determining the estimated fair value of the common stock for purposes of establishing the exercise prices for stock option grants.

As a result of initiating the public offering process, in 2005, and based on discussions with our investment bankers, we have revised our estimate of the fair value of our common stock for periods beginning on and after July 1, 2004 for financial reporting purposes. Our management, all of whom qualify as related parties, determined

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that the stock options granted on and after July 1, 2004 were granted at exercise prices that were below the reassessed fair value of our common stock on the date of grant. We completed the reassessment of the fair value without the use of an unrelated valuation specialist and started with the proposed valuation from our investment bankers, considering a number of accomplishments in 2004 and 2005 that would impact our valuation, including achievement of key clinical milestones, hiring executive officers, and the increased possibility of completing this offering. Accordingly, deferred stock-based compensation of $740,000 was recorded within stockholders equity (deficit) during 2004 which represented the difference between the weighted-average exercise price of $4.25 and the weighted-average fair value of $6.38 on 324,705 options granted to employees during 2004. Deferred stock-based compensation of $2,383,000, net of forfeitures, was recorded within stockholders equity (deficit) during 2005 which represented the difference between the weighted-average exercise price of $5.31 and the weighted-average fair value of $9.18 on 620,000 options granted to employees during 2005.

The deferred stock-based compensation is being amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. The expected future amortization expense for deferred stock-based compensation for stock options granted through December 31, 2006, is $565,000, $527,000 and $371,000 for the years ending December 31, 2007, 2008 and 2009, respectively.

During the years ended December 31, 2004, 2005, 2006, and for the period from August 24, 1999 (inception) through December 31, 2006, we recognized expense of $109,000, $335,000, $719,000, and $1,163,000, respectively, in expense related to deferred stock-based compensation.

Upon the adoption of SFAS No. 123(R) on January 1, 2006, this deferred stock-based compensation was reclassified against additional paid-in capital.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, or GAAP. See our consolidated financial statements and notes thereto included in this report, which contain accounting policies and other disclosures required by GAAP.

Results of Operations

Comparison of Year Ended December 31, 2005 to December 31, 2006

Research and development. Research and development expense decreased by $2.1 million from $10.2 million for the year ended December 31, 2005 to $8.1 million for the year ended December 31, 2006. The decrease was primarily attributable to our transition from the process development stage to the manufacturing of our product. Included in our research and development expenses is $1.2 million of amortization of core technology and patents for each of the years ended December 31, 2005 and December 31, 2006. Also included in research and development expenses for the year ended December 31, 2006 is a one-time warrant modification charge of $0.1 million.

Selling, general and administrative. The following table sets forth our selling, general and administrative expense for the years ended December 31, 2005 and December 31, 2006 (in thousands):

	2005	2006	Amount of Change
Sales and marketing	$ 2,777	$ 6,480	$ 3,703
General and administrative	7,360	10,819	3,459

Total selling, general and administrative	$ 10,137	$ 17,299	$ 7,162

Sales and marketing expense increased by $3.7 million from $2.8 million for the year ended December 31, 2005 to $6.5 million for the year ended December 31, 2006. The increase was primarily attributable to (i) $1.8 million in payroll and travel expenses for additional personnel, (ii) $0.5 million in cash severance payments, (iii) $0.2 million for the development of marketing and promotion programs, (iv) $0.1 million in facilities occupancy costs and staff support and (v) $1.1 million in non-cash compensation expense, including a one-time warrant modification charge of $0.6 million and non-cash severance of $0.3 million.

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General and administrative expense increased by $3.4 million from $7.4 million for the year ended December 31, 2005 to $10.8 million for the year ended December 31, 2006. The increase was primarily attributable to (i) a $0.8 million increase due to additional executive and administrative personnel and related travel expenses, (ii) $0.9 million in cash severance payments, (iii) $0.6 million in facilities occupancy costs, (iv) $1.4 million in non-cash compensation expense, which included a one-time warrant modification charge of $0.2 million and non-cash severance of $0.7 million and (v) $0.3 million in office related expenses offset by (vi) a $0.9 million decrease in professional service fees primarily related to lower legal costs;

Interest expense, net. Net interest expense decreased by $2.6 million from $4.4 million for the year ended December 31, 2005 to $1.8 million for the year ended December 31, 2006. The net decrease was primarily attributable to non-cash interest expense associated with common stock warrants issued with a convertible promissory note offset by an increase in interest income earned on our cash balances. Included in interest expense for the year ended December 31, 2006 is a one-time warrant modification charge of $0.5 million.

Income tax benefit. We recognized an income tax benefit of $0.5 million and $0.5 million for the years ended December 31, 2005 and 2006, respectively. The income tax benefit arose from the amortization of the deferred tax liability attributable to the intangible asset acquired in the purchase of our wholly-owned German-based manufacturing subsidiary. A deferred tax liability was created on the date of purchase as there was no allocation of the purchase price to the intangible asset for tax purposes, and the foreign subsidiary s tax basis in the intangible asset remained zero. EITF 98-11 requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability.

Comparison of Year Ended December 31, 2004 to December 31, 2005

Research and development. Research and development expense increased by $6.6 million from $3.6 million for the year ended December 31, 2004 to $10.2 million for the year ended December 31, 2005. The increase was primarily attributable to (i) an increase of $2.1 million in expenses related to process development, contract service, materials and process validation; (ii) payroll and travel costs of approximately $3.1 million for additional personnel and (iii) facilities occupancy costs of $1.4 million all of which were directly attributable to the scale-up of commercial operations to manufacture our product to meet both FDA cGMP and other regulatory agencies requirements. Included in our research and development expenses is $1.2 million of amortization of core technology and patents for each of the years ended December 31, 2004 and December 31, 2005.

Selling, general and administrative. The following table sets forth our selling, general and administrative expense for the years ended December 31, 2004 and December 31, 2005 (in thousands):

	2004	2005	Amount of Change
Sales and marketing	$ 339	$ 2,777	$ 2,438
General and administrative	4,816	7,360	2,544
Total selling, general and administrative	$ 5,155	$ 10,137	$ 4,982

Sales and marketing expense increased by $2.4 million from $339,000 for the year ended December 31, 2004 to $2.8 million for the year ended December 31, 2005. The increase was primarily attributable to (i) $1.4 million in payroll and travel expenses for additional personnel; (ii) $0.8 million for the development of marketing and promotion programs and (iii) $0.1 million for marketing consultants.

General and administrative expense increased by $2.5 million from $4.8 million for the year ended December 31, 2004 to $7.3 million for the year ended December 31, 2005. The increase was primarily attributable to (i) a $1.4 million increase due to additional executive and administrative personnel and related travel expenses; (ii) $1.0 million in legal expenses and (iii) $0.1 million in other expenses.

Interest expense, net. We recognized net interest expense of $4.4 million for the year ended December 31, 2005, an increase of $0.4 million from $4.0 million for the year ended December 31, 2004. The increase was

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primarily attributable to non-cash interest expense associated with common stock warrants issued with a convertible promissory note.

We recognized other income of $2.1 million for the year ended December 31, 2005, primarily due to a litigation settlement payment.

Income tax benefit. We recognized an income tax benefit of $0.5 million and $0.5 million for the years ended December 31, 2004 and 2005, respectively. The income tax benefit arose from the amortization of the deferred tax liability attributable to the intangible asset acquired in the purchase of our wholly-owned German-based manufacturing subsidiary. A deferred tax liability was created on the date of purchase as there was no allocation of the purchase price to the intangible asset for tax purposes, and the foreign subsidiary s tax basis in the intangible asset remained zero. EITF 98-11 requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 1999, our operations have never been profitable and we have an accumulated deficit of approximately $79.4 million.

We have financed our operations through sales of our preferred stock and common stock, options and warrants exercisable for our preferred and common stock, convertible and nonconvertible debt and through the initial public offering of our common stock. Since inception, we have raised $61.7 million through private equity financings, $1.1 million through the exercise of options and warrants, $28.1 million through convertible and nonconvertible debt, and $25.3 million through the initial public offering of our common stock. In November 2006, we entered into a loan and security agreement with Comerica Bank consisting of a revolving line of credit for up to $5,000,000 and a term loan for up to $5,000,000. At December 31, 2006, $9.9 million was outstanding under the loan and security agreement. As of December 31, 2006, our cash and cash equivalents were $46.3 million.

Cash Flow

Net cash used in operating activities. During the year ended December 31, 2006, our operating activities used cash of approximately $21.6 million, compared to approximately $13.1 million for the year ended December 31, 2005, an increase of $8.5 million. The increase in cash used was due primarily to an increase in the net loss of approximately $3.5 million, primarily attributable to an increase in operating expenses, offset by $1.8 million in adjustments for non-cash expenses and a $6.8 million net increase in operating assets and liabilities primarily due to an increase in inventory offset by payments on accounts payable and accrued expenses.

During the year ended December 31, 2005, our operating activities used cash of approximately $13.1 million, compared to approximately $4.8 million for the year ended December 31, 2004, an increase of $8.3 million. The increase in cash used was due primarily to an increase in the net loss of approximately $9.9 million, primarily attributable to an increase in research and development expenses, offset by $1.4 million in adjustments for non-cash expenses and a $0.2 million net decrease in operating assets and liabilities.

Net cash used in investing activities. Our investing activities used cash of approximately $4.8 million during the year ended December 31, 2006, compared to $7.8 million for the year ended December 31, 2005. Investing activities

during the years ended December 31, 2006 and 2005 were comprised of $1.6 and $4.6 million, respectively, of purchases of plant and production equipment and tenant improvements related to the expansion of our offices and the build-out of our production and manufacturing facilities.

During the year ended December 31, 2005, we used $2.2 million of cash to purchase our German-based manufacturing subsidiary, Artes Medical Germany GmbH (formerly Mediplant GmbH Biomaterials & Medical Devices). During the year ended December 31, 2006 and 2005, we used cash of $3.2 and $1.0 million, respectively, for long-term deposits and other assets, primarily capitalized as initial public offering and private financing costs.

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Our investing activities used cash of approximately $7.8 million during the year ended December 31, 2005, compared to $2.5 million for the year ended December 31, 2004. Investing activities in 2005 and 2004 were comprised of $4.6 million and $0.8 million, respectively, of purchases of plant and production equipment and tenant improvements related to the expansion of our offices and the build-out of our production and manufacturing facilities. We also used $2.3 million and $1.7 million in 2005 and 2004, respectively, of cash to purchase our German-based manufacturing subsidiary, Artes Medical Germany GmbH, and in 2005 we used cash of $1.0 million for long-term deposits and other assets.

Net cash provided by financing activities. Cash provided by financing activities was approximately $65.7 million for the year ended December 31, 2006, compared to approximately $25.5 million for the year ended December 31, 2005. Financing activities during the year ended December 31, 2006 resulted in $29.5 million in net proceeds from the closing of our initial public offering, $31.8 million in proceeds from the issuance of preferred stock, $9.8 million in proceeds from our Comerica Bank loan and security agreement, net of repayments of $0.1 million, $1.1 million in proceeds from the exercise of stock options, repayments of $6.5 million on convertible notes payable and $0.05 million in repayments on capital lease obligations. During the year ended December 31, 2005, our financing activities resulted in $7.0 million in proceeds from the issuance of convertible promissory notes, $11.5 million in proceeds from the issuance of preferred stock, $6.9 million in proceeds from subscriptions for preferred stock, $0.1 million in equipment financing obligations, net of repayments and $0.03 million in proceeds from the exercise of stock options.

Cash provided by financing activities was approximately $25.5 million for the year ended December 31, 2005, compared to approximately $9.6 million for the year ended December 31, 2004. Financing activities in 2005 resulted in $7.0 million in proceeds from the issuance of convertible promissory notes, $11.5 million in proceeds from the issuance of preferred stock, $6.9 million in proceeds from subscriptions for preferred stock and $0.1 million in equipment financing obligations, net of repayments during the year ended December 31, 2005. During the same period in 2004, our financing activities resulted in $6.1 million in proceeds from the issuance of convertible promissory notes and $3.5 million in proceeds from the issuance of preferred stock.

In November 2006, we entered into a loan and security agreement with Comerica Bank, pursuant to which we obtained a credit facility consisting of a revolving line of credit in the amount of up to $5.0 million and a term loan in the amount of up to $5.0 million. Interest on the revolving line of credit and the term loan will be at prime plus 2%. The revolving line and term loan mature in November 2007 and 2010, respectively. We are required to maintain a cash balance equal to 1.25 times our indebtedness to Comerica Bank.

In addition, the loan and security agreement includes several restrictive covenants, including requirements that we obtain the consent of Comerica Bank prior to entering into any change of control event, incurring other indebtedness or making distributions to our stockholders. To secure the credit facility, we granted Comerica Bank a first priority security interest in our assets and agreed not to encumber our intellectual property rights without the prior consent of Comerica Bank. On November 30, 2006, we drew down the $5.0 million term loan under the credit facility and on December 28, 2006, we drew down $5.0 million under the revolving line of credit. We also granted Comerica Bank a warrant to purchase 28,235 shares of common stock, at an exercise price of $10.63 per share.

Funding Requirements

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing resources. We believe that our cash and cash equivalents at December 31, 2006, together with the interest thereon, and the funds available under our credit facility, will be sufficient to meet our anticipated cash requirements with respect to the commercial launch of ArteFill, the automation and scale-up of our manufacturing capabilities and our research

and development activities and to meet our other anticipated cash needs through at least the first quarter of 2008.

Our future capital requirements are difficult to forecast and will depend on many factors, including, among others:

- the costs of establishing and maintaining the sales and marketing organization required for successful commercialization of ArteFill;

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the success of our product launch and growth in sales and related collections;

the costs and effectiveness of our sales, marketing, advertising and promotion activities related to ArteFill, including physician training and education;

the costs related to maintaining and expanding our manufacturing and distribution capabilities;

the costs relating to changes in regulatory policies or laws that affect our operations;

the level of investment in research and development to maintain and improve our competitive position, as well as to maintain and expand our technology platform;

the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

the costs of, and our ability to enter into, foreign distribution agreements in certain concentrated international markets; and

our need or determination to acquire or license complementary products, technologies or businesses.

We may finance future cash needs through the sale of additional equity securities, debt financing and other strategic transactions. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, reduce the scope of, eliminate or divest one or more of our sales and marketing programs, manufacturing capabilities, research and development programs, or our entire business. Due to the uncertainty of financial markets, financing may not be available to us when we need it on acceptable terms or at all. Therefore, we may raise additional capital from time to time when market conditions are favorable, or if strategic considerations require us to do so, even if we have sufficient funds for planned operations. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Contractual Obligations

The following summarizes our long-term contractual obligations as of December 31, 2006:

		Payments Due by Period			
	Total	**2007**	**2008**	**2009**	**After 2009**
			(In thousands)		
Contractual Obligations					
Comerica Bank term loan	$ 4,895,833	$ 1,250,000	$ 1,250,000	$ 1,250,000	$ 1,145,833
Comerica Bank revolving line of credit	5,000,000	5,000,000			
Equipment lease obligations	66,457	45,117	21,340		
Operating lease obligations	5,082,841	984,892	985,714	1,035,940	2,076,295
Other contractual obligations	939,487	939,487			
Total	$ 15,984,618	$ 8,219,496	$ 2,257,024	$ 2,285,940	$ 3,222,128

Our long-term obligations consist primarily of our revolving line of credit and term loan with Comerica Bank that are due in November 2007 and 2010, respectively, facilities leases that expire in March and December 2011 and our equipment financing obligations that expire in April and July 2008.

On November 17, 2006, the Company entered into a separation agreement and mutual general release with Dr. Stefan M. Lemperle in connection with his resignation as a director and as an employee. Pursuant to the agreement, the Company is required to pay $690,000 in cash severance payments. Of the $690,000, $428,000 was paid in 2006 and the balance of $262,000 will be paid monthly through October 2007. Dr. Stefan M. Lemperle is eligible to receive an additional severance payment of $400,000, contingent upon the Company s completion of a qualifying transaction, as defined in the agreement, before March 31, 2007. In connection with the agreement, the Company also amended the terms of the outstanding stock options held by Dr. Stefan M. Lemperle to provide for the full acceleration of all unvested shares under his stock options, and the Company has agreed to issue to Dr. Stefan M.

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Lemperle a warrant to purchase up to 117,647 shares of common stock, subject to certain conditions and in an amount determined in accordance with the terms of the agreement. The Company recorded a non-cash expense charge of $378,000 associated with the accelerated vesting of these options and warrants.

On November 2006, the Company received a notice of demand for arbitration from a former employee in connection with the termination of his employment. On January 31, 2007, the Company entered into a Confidential Settlement and Release of Claims Agreement whereby the Company is required to pay a cash settlement amount of $284,000. The amount was paid in full in February 2007. In addition to the cash settlement, the Company agreed to accelerate the vesting of certain stock options and warrants previously granted to the employee. The Company recorded a non-cash expense charge of $135,000 associated with the accelerated vesting of these options and warrants.

On November 2006, the Company received a notice of demand for arbitration from a former employee in connection with the termination of his employment. On January 10, 2007, the Company entered into a Confidential Settlement and Release of Claims Agreement whereby the Company is required to pay a cash settlement amount of $242,000. Of the $242,000, $39,000 was paid in 2006, $56,000 is due to be paid no later than March 31, 2007 and the balance of $147,000 will be paid monthly through October 2007. In addition to the cash settlement amount the Company agreed to accelerate the vesting of certain stock options previously granted to the employee. The Company recorded a non-cash expense charge of $116,000 associated with the accelerated vesting of these stock options

In November 2006, we entered into a loan and security agreement with Comerica Bank, pursuant to which we obtained a credit facility consisting of a revolving line of credit in the amount of up to $5 million and a term loan in the amount of up to $5 million. Interest on the revolving line of credit and the term loan will be at prime plus 2%. As of December 31, 2006, $9.9 million is outstanding under the revolving line of credit and term loan under the credit facility.

We have entered into employment agreements with Diane Goostree, our President and Chief Executive Officer, Russell Anderson, our Vice President New Products Engineering and Lawrence Braga, our Vice President Manufacturing, pursuant to which we are obligated to make certain severance payments to these individuals in the event their employment with us is terminated under certain circumstances.

On November 6, 2006, we filed a demand for arbitration with the American Arbitration Association against Melvin Ehrlich, who served as our President and Chief Operating Officer from January 2004 to April 2004. We are seeking declaratory relief regarding the number of shares of common stock Mr. Ehrlich is entitled to purchase under a warrant issued to him in connection with his employment agreement. The parties have pursued a settlement of this action, and have negotiated the terms of a proposed settlement agreement in which we will pay Mr. Ehrlich $250,000 and issue Mr. Ehrlich 26,710 shares of common stock and a warrant to purchase 25,000 shares of common stock, at an exercise price of $8.07 per share. The settlement agreement contains a mutual release of claims and a mutual covenant not to sue. The settlement agreement is subject to approval by our board of directors, and based on his age, Mr. Ehrlich will have up to seven days to revoke the settlement agreement after he signs it. The Company has made an accrual in the fourth quarter of the fiscal year ended December 31, 2006 based on the terms of the proposed settlement agreement. We cannot assure you that the parties will effect the settlement agreement on the terms outline above, or at all. If the settlement agreement is not effected, we intend to continue to pursue our declaratory relief action against Mr. Ehrlich.

Related Party Transactions

For a description of our related party transactions, see Related Party Transactions elsewhere in this report.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities.

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Recent Accounting Pronouncements

For information on the recent accounting pronouncements impacting our business, see Note 1 of the Notes to Financial Statements included in this report.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk.***

Interest Rate Risk

Our exposure to interest rate risk is primarily the result of borrowings under our existing credit facility. At December 31, 2006, $9.9 million was outstanding under our credit facility. Borrowings under our credit facility are secured by first priority security interests in substantially all of our tangible and intangible assets. Our results of operations are not materially affected by changes in market interest rates on these borrowings.

The primary objective of our cash management activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. As of December 31, 2006, we had cash and cash equivalents in a bank operating account that provides daily liquidity and through an overnight sweep account that is a money market mutual fund and invests primarily in money market investments and corporate and U.S. government debt securities. Due to the liquidity of our cash, cash equivalents and investment securities, a 1% movement in market interest rates would not have a significant impact on the total value of our cash, cash equivalents and investment securities. We do not have any holdings of derivative financial or commodity instruments, or any foreign currency denominated transactions.

We will continue to monitor changing economic conditions. Based on current circumstances, we do not expect to incur a substantial increase in costs or a material adverse effect on cash flows as a result of changing interest rates.

Impact of Inflation

We believe that our results of operations are not materially impacted by moderate changes in the inflation rate. Inflation and changing prices did not have a material impact on our operations in 2004, 2005, or 2006. Severe increases in inflation, however, could affect the global and U.S. economies and could have an adverse impact on our business, financial condition, and results of operations.

Item 8. ***Consolidated Financial Statements and Supplementary Data.***

Reference is made to the consolidated financial statements, the notes thereto, and the report thereon, commencing on page F-1 of this report, which financial statements, notes, and report are incorporated herein by reference.

Item 9. ***Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.***

None.

Item 9A. ***Controls And Procedures***

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under

Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed in the reports that we file or furnish under the Exchange Act and were effective in ensuring that information required to be disclosed by us in the reports that we file or furnish under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer as appropriate to allow timely decisions regarding required disclosure.

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Changes in Internal Control over Financial Reporting:

During the quarter ending December 31, 2006, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information.***

None.

PART III

Item 10. ***Directors and Executive Officers and Corporate Governance.***

The information required by this Item relating to our directors and our corporate governance is incorporated herein by reference to our definitive Proxy Statement we intend to file pursuant to Regulation 14A of the Exchange Act for our 2007 Annual Meeting of Stockholders. The information required by this Item relating to our executive officers is included in Item 1, Business Executive Officers.

Item 11. ***Executive Compensation.***

The information required by this Item is incorporated herein by reference to our definitive Proxy Statement we intend to file pursuant to Regulation 14A of the Exchange Act for our 2007 Annual Meeting of Stockholders.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

The information required by this Item is incorporated herein by reference to our definitive Proxy Statement we intend to file pursuant to Regulation 14A of the Exchange Act for our 2007 Annual Meeting of Stockholders.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence.***

The information required by this Item is incorporated herein by reference to our definitive Proxy Statement we intend to file pursuant to Regulation 14A of the Exchange Act for our 2007 Annual Meeting of Stockholders.

Item 14. ***Principal Accountant Fees and Services.***

The information required by this Item is incorporated herein by reference to our definitive Proxy Statement we intend to file pursuant to Regulation 14A of the Exchange Act for our 2007 Annual Meeting of Stockholders.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules.***

(a) *Financial Statements and Financial Statement Schedules*

The following documents are filed as part of this report:

(1) Consolidated Financial Statements are listed in the Index to Consolidated Financial Statements on page F-1 of this report, including the report of Ernst & Young LLP, our independent registered public accounting firm.

(2) No financial statement schedules are included in this report because such schedules are not applicable, are not required, or because required information is included in the consolidated financial statements or notes thereto.

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(b) *Exhibits*

Exhibit Number	Exhibit Description
3.4**	Amended and Restated Certificate of Incorporation.
3.6**	Amended and Restated Bylaws.
3.7**	Certificate of Amendment to Amended and Restated Bylaws.
4.1**	Specimen common stock certificate.
4.2**	Amended and Restated Investor Rights Agreement dated June 23, 2006, by and among us and the holders of our preferred stock listed on Schedule A thereto.
4.3#**	Form of warrant to purchase common stock, issued to employees, consultants and service providers.
4.4#**	Amended warrant to purchase up to 650,000 shares of common stock, dated June 9, 2006, issued to Christopher J. Reinhard, as corrected.
4.5**	Form of warrant to purchase common stock, issued to certain investors in a bridge loan financing transaction.
4.6**	Form of warrant to purchase Series C-1 preferred stock, issued to certain investors in a bridge loan financing transaction.
4.7**	Form of warrant to purchase common stock, issued to certain investors in our Series D preferred stock financing.
4.8**	Form of warrant to purchase Series D preferred stock, issued to certain investors in a bridge loan financing transaction.
4.9**	Warrant to purchase 200,000 shares of Series E preferred stock issued to Legg Mason Wood Walker, Inc. on December 22, 2005.
4.10**	Form of warrant to purchase Series E preferred stock issued to certain investors in our Series E preferred stock financing.
4.11**	Form of warrant to purchase Series E preferred stock issued to National Securities Corporation in consideration for placement agent services provided to us in our Series E preferred stock financing.
4.12#**	Amended warrant to purchase up to 150,000 shares of common stock, dated June 9, 2006, issued to Christopher J. Reinhard, as corrected.
4.13#**	Amendment dated June 23, 2006, to warrant to purchase common stock, issued to employees, consultants and service providers, entered into by us and each of the warrant holders listed on Exhibit A thereto.
4.14**	Amendment dated June 23, 2006, to warrant to purchase common stock, issued to certain investors in a bridge loan financing transaction, entered into by us and each of the warrant holders listed on Exhibit A thereto.
4.15**	Amendment dated June 23, 2006, to warrant to purchase Series C-1 preferred stock, issued to certain investors in a bridge loan financing transaction, entered into by us and each of the warrant holders listed on Exhibit A thereto.
4.16**	Amendment dated June 23, 2006, to warrant to purchase common stock, issued to certain investors in our Series D preferred stock financing, entered into by us and each of the warrant holders listed on Exhibit A thereto.
4.17**	Amendment dated June 23, 2006, to warrant to purchase Series D preferred stock, issued to certain investors in a bridge loan financing transaction, entered into by us and each of the warrant holders listed on Exhibit A thereto.
4.18**	Warrant to purchase 28,235 shares of Series E preferred stock issued to Comerica Bank on November 27, 2006.
10.1#**	2000 Stock Option Plan.

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Exhibit Number	Exhibit Description
10.2#**	Form of Non-Qualified Stock Option Agreement under the 2000 Stock Option Plan.
10.3#**	Amended and Restated 2001 Stock Option Plan.
10.4#**	Form of Notice of Option Grant under the Amended and Restated 2001 Stock Option Plan.
10.5#**	Form of Incentive Stock Option Agreement under the Amended and Restated 2001 Stock Option Plan.
10.6#**	Form of Non-Qualified Stock Option Agreement under the Amended and Restated 2001 Stock Option Plan.
10.7#**	2006 Equity Incentive Plan.
10.8.1#**	Form of Notice of Grant of Stock Option under 2006 Equity Incentive Plan.
10.8.2#**	Form of Option Exercise and Stock Purchase Agreement under 2006 Equity Incentive Plan.
10.8.3#**	Form of Restricted Stock Grant Notice under 2006 Equity Incentive Plan.
10.9#**	Director s Agreement, dated June 1, 2004, between us and Christopher Reinhard.
10.10#**	Employment Agreement dated February 15, 2004 between us and Russell Anderson.
10.11#**	Employment Agreement dated June 1, 2004 between us and Lawrence Braga.
10.14#**	Separation Agreement dated March 16, 2006 between us and Gottfried Lemperle.
10.15#**	Form of indemnification agreement between us and each of our directors and executive officers (as amended).
10.16**	Form of consulting agreement for medical/scientific advisory board between us and each of our Medical Advisory Board members.
10.17**	Building Lease Agreement, dated July 26, 2004, between us and Robert Jean Lichter and Gail F. Lichter, Trustees of the Lichter Family Trust First Amended and Restated Declaration of Trust Dated November 7, 1996, and Kenneth R. Satterlee and Candace C. Satterlee, Trustees of the Satterlee Family Trust UTD April 24, 1986, as tenants-in-common.
10.18**	Sublease Agreement, dated June 1, 2005, between us and InfoSonics Corporation.
10.19**	Commercial Space Lease Agreement, dated September 27, 1999, between Ms. Marianne Kämpf and MediPlant GmbH(1).
10.20 **	Purchase Agreement for a Partial Enterprise, dated July 22, 2004, between us and FormMed Biomedicals AG.
10.21 **	Manufacturing and Supply Agreement, dated November 1, 2005, between us and Artes Medical Germany GmbH (formerly MediPlant GmbH Biomaterials and Medical Devices).
10.22 **	Fixed Price Supply Agreement, dated March 1, 2006, between us and Lampire Biological Labs, Inc.
10.23**	Termination and General Release, dated May 11, 2006, between us and Gottfried Lemperle.
10.24**	Settlement Agreement, dated May 12, 2006, between us and Stifel, Nicolaus & Company, Incorporated, as successor in interest to Legg Mason Wood Walker, Incorporated.
10.25 **	Settlement and License Agreement dated October 31, 2005, among us, BioForm Medical, Inc., BioForm Medical Europe B.V. and Dr. Martin Lemperle.
10.26**	Settlement Agreement and Release of Claims dated October 26, 2005, among us, FormMed Biomedicals AG and Dr. Martin Lemperle.
10.27#**	Offer of Employment dated February 13, 2006 between us and Diane Goostree.
10.28**	Separation Agreement and General Release dated November 17, 2006 between us and Stefan M. Lemperle, M. D.
10.29#**	First Amended Offer of Employment dated November 27, 2006 between us and Diane Goostree.

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Exhibit Number	Exhibit Description
10.30**	Loan and Security Agreement dated November 27, 2006 between us and Comerica Bank.
10.31	Confidential Settlement Agreement and Release of All Claims, dated January 10, 2007, between us and William von Brendel.
10.32	Confidential Settlement Agreement and Release of All Claims, dated January 31, 2007, between us and Harald Schreiber
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.
24.1	Powers of Attorney (included on signature page).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.

** Incorporated by reference to the same numbered exhibit filed with or incorporated by reference in our Registration Statement on Form S-1 (File No. 333-134086), dated December 19, 2006.

# Indicates management contract or compensatory plan.

The Commission has granted confidential treatment to us with respect to certain omitted portions of this exhibit (indicated by asterisks). We have filed separately with the Commission an unredacted copy of the exhibit.

(1) In accordance with Rule 12b-12 of the Securities Exchange Act of 1934, this exhibit is an English translation of the original German document.

(c) *Financial Statement Schedules*

No financial statement schedules are included in this report because such schedules are not applicable, are not required, or because required information is included in the consolidated financial statements or notes thereto.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ARTES MEDICAL, INC.

By: /s/ Diane S. Goostree

Diane S. Goostree
President and Chief Executive Officer

Date: March 30, 2007

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Diane S. Goostree and Peter C. Wulff, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title(s)	Date
/s/ Christopher J. Reinhard Christopher J. Reinhard	Executive Chairman of the Board of Directors (principal executive officer)	March 30, 2007
/s/ Diane S. Goostree Diane S. Goostree	President, Chief Executive Officer and Director	March 30, 2007
/s/ Peter C. Wulff Peter C. Wulff	Executive Vice President and Chief Financial Officer (principal financial and accounting officer)	March 30, 2007
/s/ Daren J. Barone Daren J. Barone	Director	March 30, 2007
/s/ John R. Costantino John R. Costantino	Director	March 30, 2007
/s/ Lon E. Otremba	Director	March 30, 2007

Lon E. Otremba

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Artes Medical, Inc.
(a development stage company)

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Artes Medical, Inc.

We have audited the accompanying consolidated balance sheets of Artes Medical, Inc. (a development stage company) as of December 31, 2005 and 2006, and the related consolidated statements of operations, stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2006, and for the period from August 24, 1999 (inception) through December 31, 2006. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements for the period from August 24, 1999 (inception) through December 31, 2000 were audited by other auditors whose report dated June 29, 2001, expressed an unqualified opinion on those statements. The financial statements for the period from August 24, 1999 (inception) through December 31, 2000 include total operating expenses and net loss of $3,099,542 and $3,042,934, respectively. Our opinion on the statements of operations, stockholders equity (deficit), and cash flows for the period August 24, 1999 (inception) through December 31, 2006, insofar as it relates to amounts for prior periods through December 31, 2000, is based solely on the report of other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Artes Medical, Inc. at December 31, 2005 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, and for the period from August 24, 1999 (inception) through December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, Artes Medical, Inc. changed its method of accounting for share-based payments in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004) on January 1, 2006.

/s/ Ernst & Young LLP

San Diego, California
March 27, 2007

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Artes Medical, Inc.
(a development stage company)

Consolidated Balance Sheets

	December 31, 2005	2006
	(In thousands, except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,930	$ 46,258
Prepaid expenses	204	304
Inventory, net	692	4,761
Other assets	374	102
Deferred financing costs	1,011	
Total current assets	9,211	51,425
Property and equipment, net	4,926	5,271
Intellectual property, net	4,770	3,578
Deposits	233	239
Other assets	1,180	100
Total assets	$ 20,320	$ 60,613
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,317	$ 2,218
Accrued compensation and benefits	1,499	1,774
Accrued severance		920
Accrued liabilities	1,585	690
Income taxes payable	70	73
Convertible notes payable (net of discount of $860 at December 31, 2005)	5,665	
Capital lease obligations, current portion	49	45
Revolving credit line		5,000
Term note payable, current portion		1,250
Deferred rent, current portion		49
Total current liabilities	12,185	12,019
Term note payable (net of discount of $305 at December 31, 2006)		3,341
Capital lease obligations, less current portion	66	21
Deferred rent, less current portion	686	678
Deferred tax liability	1,846	1,368
Commitments and contingencies		
Stockholders equity:		

Series A convertible preferred stock, $0.001 par value, 2,050,839 shares and no shares authorized, 2,050,839 shares and no shares issued and outstanding at December 31, 2005 and 2006; liquidation preference of $3,076 and $0 at December 31, 2005 and 2006	2	
Series B convertible preferred stock, $0.001 par value, 679,239 shares and no shares authorized, 679,239 shares and no shares issued and outstanding at December 31, 2005 and 2006; liquidation preference of $2,262 and $0 at December 31, 2005 and 2006	1	
Series C-1 convertible preferred stock, $0.001 par value, 7,052,741 shares and no shares authorized, 4,437,741 and no shares issued and outstanding at December 31, 2005 and 2006; liquidation preference of $12,204 and $0 at December 31, 2005 and 2006	4	
Series D convertible preferred stock, $0.001 par value, 11,500,000 shares and no shares authorized, 10,019,857 and no shares issued and outstanding at December 31, 2005 and 2006, respectively; liquidation preference of $20,040 and $0 at December 31, 2005 and 2006	10	
Series E convertible preferred stock, $0.001 par value, 10,000,000 shares and no shares authorized, 3,463,615 and no shares issued and outstanding at December 31, 2005 and 2006, respectively; liquidation preference of $8,659 and $0 at December 31, 2005 and 2006	3	
Convertible preferred stock, $0.001 par value, 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2006; liquidation preference of $0 at December 31, 2006		
Convertible preferred stock subscribed	6,900	
Common stock, $0.001 par value 150,000,000 and 200,000,000 shares authorized at December 31, 2005 and 2006; 1,229,553 and 16,361,246 shares issued and outstanding at December 31, 2005 and 2006	5	16
Common stock issuable	735	
Additional paid-in capital	53,635	122,572
Deferred stock-based compensation	(2,679)	
Deficit accumulated during the development stage	(53,079)	(79,402)
Total stockholders equity	5,537	43,186
Total liabilities and stockholders equity	$ 20,320	$ 60,613

See accompanying notes.

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Artes Medical, Inc.
(a development stage company)

Consolidated Statements of Operations

	Years Ended December 31,			Period from August 24, 1999 (Inception) through December 31,
	2004	2005	2006	2006
	(In thousands, except share and per share data)			
Expenses:				
Research and development	$ 3,634	$ 10,189	$ 8,084	$ 28,989
Selling, general and administrative	5,155	10,137	17,299	40,898
Loss from operations	(8,789)	(20,326)	(25,383)	(69,887)
Interest income		52	675	841
Interest expense	(4,028)	(4,468)	(2,454)	(14,225)
Other income (expense), net	(22)	2,041	363	2,481
Loss before benefit for income taxes	(12,839)	(22,701)	(26,799)	(80,790)
Benefit for income taxes	454	458	476	1,388
Net loss	$ (12,385)	$ (22,243)	$ (26,323)	$ (79,402)
Loss per share:				
Basic and diluted	$ (11.20)	$ (18.76)	$ (14.23)	
Weighted average shares basic and diluted	1,106,188	1,185,387	1,850,255	

See accompanying notes.

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Artes Medical, Inc.
(a development stage company)

Consolidated Statements of Stockholders Equity

	Convertible Preferred Shares	Convertible Preferred Stock Amount	Common Shares	Common Stock Amount	Common Stock Issuable	Convertible Preferred Stock Subscribed	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Deferred Stock-Based Compensation	Deficit Accumulated During the Development Stage	Total Stockholders Equity
	(In thousands, except share and per share data)										
nce of common stock ash at $0.09 per share		$	735,294	$ 1	$	$	$ 84	$	$	$	$
nce of common stock ervices			173,529				176				
nce of Series A rred stock for cash at 0 per share	112,266						168				
oss and prehensive loss										(896)	(8
nce at December 31,	112,266		908,823	1			428			(896)	(4
nce of Series A rred stock for cash at 0 per share, net of nce costs	1,912,902	2					2,811				2,8
nce of Series A rred stock for services	25,671						114				
nce of Series B rred stock for cash at 8 per share	489,187	1					1,417				1,4
nce of Series B rred stock for services	1,141						4				
nce of common stock ash, in March, May, September			151,294				508				5
nce of stock options to ultants							48				
alized loss on able-for-sale stments								(36)			
oss										(2,147)	(2,
prehensive loss											(2,

nce at December 31,	2,541,167	3	1,060,117	1		5,330	(36)	(3,043)	2,2
s C preferred stock criptions at $7.00 per for cash					682				6
k-based compensation						1			
nce of Series B rred stock in July for at $3.33 per share, net suance costs	188,911					620			6
assification adjustment sses realized in net oss							36	(4,942)	(4,9
prehensive loss									(4,9
nce at December 31,	2,730,078	3	1,060,117	1	682	5,951		(7,985)	(1,3
nce of subscribed s C preferred stock in ch	88,857				(622)	622			
nce of Series C rred stock, in March, ash at $7.00 per share, f issuance costs	21,286					99			
nd due to cancellation ries C preferred stock cribed					(60)				
k-based compensation						6			
nce of warrants in ection with convertible from May to ember						1,489			1,4
nce of Series C rred stock for services arch	2,730					19			
oss and prehensive loss								(4,346)	(4,3
nce at December 31,	2,842,951	3	1,060,117	1		8,186		(12,331)	(4,1
nce of common stock exercise of stock ns in November			17,647			7			
nce of Series C-1 rred stock for services ly	25,000					69			
nce of warrants in ection with convertible						1,126			1,1

s from January through ch							
nce of Series C-1 rred stock for cash, in at $2.75 per share, net suance costs	637,980	1			1,595		1,5
k-based compensation					159		
nce of warrant in June nnection with patent isition					34		
version of Series C rred stock to s C-1 preferred stock ly	174,954						
version of principal and est on promissory s to Series C-1 rred stock in July	3,486,934	3			4,639		4,6
oss and prehensive loss						(6,120)	(6,1
nce at December 31,	7,167,819	7	1,077,764	1	15,815	(18,451)	(2,6

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Artes Medical, Inc.
(a development stage company)

Consolidated Statements of Stockholders Equity (continued)

	Convertible Preferred Shares	Convertible Preferred Stock Amount	Common Shares	Common Stock Amount	Common Stock Issuable	Convertible Preferred Stock Subscribed	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Deferred Stock-Based Compensation	Deficit Accumulated During the Development Stage
				(In thousands, except share and per share data)						
mmon stock of stock ril and			14,117				29			
mmon stock with operty March and			42,352				270			
mmon stock ndered in			4,411				37			
rred stock at $2.00 per						3,543				
ompensation							1,096			
							740		(740)	
rrants in th convertible uary though							5,335			
of deferred									109	
e loss										(12,385)
cember 31,	7,167,819	7	1,138,644	1		3,543	23,322		(631)	(30,836)
mmon stock of stock rch			5,882				25			
mmon stock of warrants h October			23,731				120			

mmon stock ndered in December			51,528		386
mmon stock with eement in			9,768		102
k issuable in guarantee on bt in				735	
ries D k in exchange e notes and st, and cash, 00 per share, e costs	9,754,761	10		(3,543)	14,245
ries D k at $2.00 in ervices in	265,096				367
arrants in th Series D eferred stock					809
arrants in th convertible n January mber					2,007
arrants in th convertible mber					276
ries E k for cash, in 5, at e, net of	3,089,615	3			7,703
rred stock at $2.50 per in December				6,900	
ries E k at $2.50 per nge for reement in	124,000				310
ries E k at $2.50 per nge for convertible n December	250,000				625

ompensation							959		
k									
							2,383	(2,383)	
of deferred									
								335	
e loss									(22,243)
cember 31,									
	20,651,291	20	1,229,553	1	735	6,900	53,639	(2,679)	(53,079)
mmon stock									
of warrants									
ons in March									
mber			114,506				440		
mmon stock									
January									
			8,048				89		
mmon stock									
with									
operty in									
			4,705				49		
ries E									
eferred stock									
are for cash,									
of issuance									
	3,994,000	4				(6,750)	9,367		
ries E									
eferred stock									
are for cash,									
et of issuance									
	5,484,200	6				(150)	12,444		
ries E									
eferred stock									
are for cash,									
of issuance									
	7,712,406	8					16,888		
ries C-1									
eferred stock									
of warrants									
y	50,000						50		
mmon stock									
with									
onvertible									
			70,588		(735)		735		
mmon stock									
blic offering			5,290,000	5			25,279		
arrants upon									
ffering			276,334				583		
arrants to							253		
s E									
eferred stock									

with ement convertible k upon initial g	(37,891,897)	(38)	9,367,512	10			28				
f vesting of or stock nitial public											
							547				
ompensation							2,526				
everance							958				
k											
							(2,679)		2,679		
fication											
							1,376				
e loss											(26,323)
cember 31,		$	16,361,246	$ 16	$	$	$ 122,572	$	$	$	(79,402)

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Artes Medical, Inc.
(a development stage company)

Consolidated Statements of Cash Flows

	Years Ended December 31,			Period from August 24, 1999 (Inception) through December 31,
	2004	2005	2006	2006
	(In thousands)			
Operating activities				
Net loss	$ (12,385)	$ (22,243)	$ (26,323)	$ (79,402)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	1,148	1,742	2,428	5,505
Provision for obsolete inventory	117	120	881	1,118
Benefit for income taxes	(454)	(458)	(478)	(1,390)
Non-cash interest expense associated with issuance of warrants and convertible notes	4,002	4,308	2,350	13,275
Warrant modification expense			899	899
Stock-based compensation	1,133	1,294	4,032	6,673
Issuance of stock for services	38	558	90	1,066
Issuance of stock for settlement and termination agreements		412		412
Issuance of common stock for intellectual property	270		49	319
Loss on disposal of fixed assets	25		43	68
Deferred rent	474	200	42	728
Deferred taxes	(43)	(27)		(70)
Changes in operating assets and liabilities:				
Inventory	(160)	(562)	(4,951)	(5,673)
Prepaid expenses and other assets	(776)	(208)	172	(812)
Accounts payable	1,281	(398)	(1,099)	2,370
Accrued compensation and benefits	(20)	1,346	275	1,805
Accrued severance			920	920
Accrued expenses	471	834	(896)	869
Income taxes payable	43	27	3	73
Net cash used in operating activities	(4,836)	(13,055)	(21,563)	(51,247)
Investing activities				
Purchase of short-term investments				(3,028)
Sale of short-term investments				3,028
Acquisition of intellectual property, net of cash acquired	(1,730)	(2,250)		(3,980)
Purchases of property and equipment	(816)	(4,554)	(1,623)	(7,254)
Deposits and other assets		(950)	(3,156)	(4,411)

Net cash used in investing activities	(2,546)	(7,754)	(4,779)	(15,645)
Financing activities				
Proceeds from term loan payable			4,945	4,945
Payments on term loan payable			(104)	(104)
Proceed from revolving credit line			5,000	5,000
Proceeds from issuance of convertible notes payable	6,093	6,970		17,519
Payments on convertible notes payable	(50)		(6,525)	(6,575)
Proceeds from capital lease obligations		157		157
Payments on capital lease obligations		(41)	(49)	(90)
Proceeds from issuance of note payable				416
Payments on note payable				(416)
Refund on canceled subscribed Series C preferred stock				(60)
Proceeds from subscribed preferred stock	3,543	6,900		11,125
Proceeds from issuance of preferred stock, net		11,456	31,816	49,986
Proceeds from issuance of common stock			29,513	30,108
Proceeds from exercise of stock options and warrants	29	28	1,074	1,139
Net cash provided by financing activities	9,615	25,470	65,670	113,150
Net increase in cash and cash equivalents	2,233	4,661	39,328	46,258
Cash and cash equivalents at beginning of period	36	2,269	6,930	
Cash and cash equivalents at end of period	$ 2,269	$ 6,930	$ 46,258	$ 46,258
Noncash financing activities				
Issuance of subscribed preferred stock	$	$ 3,543	$ 6,900	$ 11,065
Issuance of warrants and common stock in connection with intellectual property acquisition	$ 270	$	$ 49	$ 353
Conversion of convertible notes and interest into convertible preferred stock	$	$ 8,246	$	$ 12,886
Issuance of convertible notes payable as commission for financing	$ 141	$ 203	$	$ 344
Conversion of payables to convertible notes payable	$ 234	$ 95	$	$ 327
Supplemental activities				
Cash paid for income taxes	$ 2	$ 1	$ 1	$ 13
Cash paid for interest	$ 26	$ 160	$ 104	$ 320

See accompanying notes.

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Artes Medical, Inc.
(a development stage company)

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization and Business

Artes Medical, Inc., (the Company), formerly known as Artes Medical USA, Inc., was incorporated in Delaware on August 24, 1999, and is focused on the development, manufacture and commercialization of a new category of injectable aesthetic products for the dermatology and plastic surgery markets. The Company s initial product, ArteFill, is a non-resorbable aesthetic injectable implant for the correction of facial wrinkles known as smile lines, or nasolabial folds. The Company received FDA approval to market ArteFill on October 27, 2006.

The Company is a development stage company, and since inception has been engaged in organizational activities, including research and development, recruiting personnel, establishing office and manufacturing facilities, preparing for ArteFill s regulatory market approval and the related commercial scale-up of ArteFill manufacturing, preparing for ArteFill product marketing and distribution activities, and obtaining financing. Since inception, and through December 31, 2006, the Company has an accumulated deficit of $79.4 million.

On December 26, 2006, the Company closed an initial public offering of its common stock in which it sold 5,290,000 shares of common stock for gross proceeds of $31.7 million. After underwriting discounts, commissions and other offering expenses, the Company received net proceeds of $25.3 million from this offering.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and Artes Medical Germany GmbH (formerly Mediplant GmbH Biomaterials & Medical Devices) since its acquisition effective January 1, 2004. All intercompany accounts have been eliminated in consolidation.

Reverse Stock Split, Conversion to Common Stock and Initial Public Offering

In connection with the Company s initial public offering, the Company effected a 1-for-4.25 reverse stock split of its common stock on December 19, 2006. In addition to the reverse stock split, all outstanding shares of the Company s preferred stock were converted to common stock immediately prior to the closing of the Company s initial public offering on December 26, 2006. Each outstanding share of Series A, Series D and Series E preferred stock was converted into one share of common stock, and as a result of anti-dilution provisions, each one share of Series B preferred stock was converted into 1.35 shares of common stock and each one share of Series C-1 preferred stock was converted into 1.375 shares of common stock. On December 26, 2006, after giving effect to the 1-for-4.25 reverse stock split, and the anti-dilution provisions associated with the Series B and C-1 preferred stock, all of the outstanding shares of preferred stock were automatically converted into 9,367,512 shares of common stock. In addition, as a result of the conversion to common stock, all warrants or other rights to purchase the Company s preferred stock outstanding on December 26, 2006 were automatically converted into the right to purchase shares of common stock at the applicable conversion ratios for the particular series of preferred stock. As of December 31, 2006, there were outstanding warrants to purchase 2,512,542 shares of the Company s common stock at a weighted average exercise price of $7.03. The actions necessary to effect the reverse stock split and the conversion of the preferred stock to common stock were approved by the Company s Board of Directors and the required vote of the Company s stockholders.

The accompanying consolidated financial statements and related notes give retroactive effect to the reverse stock split for all periods presented with respect to outstanding shares of common stock and options and warrants exercisable for common stock. The accompanying consolidated financial statements and related notes do not reflect the conversion to common stock (or the reverse stock split) for all periods presented with respect to outstanding shares of preferred stock and warrants exercisable for preferred stock.

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Artes Medical, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of less than three months when purchased to be cash equivalents.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation.

Fair Value of Financial Instruments

The carrying amount of cash, accounts payable, and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. The Company believes the carrying amount of the notes payable approximate their respective fair values.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Property and Equipment

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (three to seven years) using the straight-line method. Leasehold improvements are amortized over the lesser of the term of the related lease or the useful life of the asset.

Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company will record impairment losses on long-lived assets used in operations when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. While the Company s current and historical operating losses and cash flows are indicators of impairment, the Company believes the future cash flows to be received support the carrying value of its long-lived assets and, accordingly, the Company has not recognized any impairment losses through December 31, 2006.

Deferred Rent

Rent expense is recorded on a straight-line basis over the term of the lease. The difference between rent expense and amounts paid under the lease agreements is recorded as deferred rent in the accompanying consolidated balance sheets. Landlord construction allowances and other such lease incentives are recorded as deferred rent and are amortized on a straight-line basis as a reduction to rent expense.

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Artes Medical, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

Patent Costs

Costs related to filing and pursuing patent applications are expensed as general and administrative expenses as incurred since recoverability of such expenditures is uncertain.

Research and Development Expenses

Research and development costs are expensed as incurred and such costs consist primarily of costs to further the Company s research and development activities and include compensation and other expenses for research and development personnel, costs associated with clinical trials, non-clinical activities, process development activities, regulatory activities, supplies and development materials, costs for consultants, research-related overhead expenses, amortization of purchased technology, and depreciation.

Income Taxes

The Company uses the liability method of accounting for income taxes as required by SFAS No. 109, *Accounting for Income Taxes.*

Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

Foreign Currency Translation and Transactions

The financial statements of foreign subsidiaries having the U.S. dollar as the functional currency, with certain transactions denominated in a local currency, are remeasured into U.S. dollars. The remeasurement of local currency amounts into U.S. dollars creates translation adjustments that are included in stockholder s equity. Transaction and translation gains or losses were not material to the financial statements for any periods presented.

Comprehensive Income (Loss)

SFAS No. 130, *Reporting Comprehensive Income*, requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from nonowner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments and unrealized gains and losses on investments shall be reported net of their related tax effect, to arrive at comprehensive income (loss).

Stock-based Compensation

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-Based Payment* (SFAS No. 123(R)) using the prospective transition method, and therefore, prior period results have not been restated. SFAS No. 123(R), which revises SFAS No. 123, *Accounting for Stock-Based Compensation* and (SFAS No. 123), supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations. Under this transition method, the compensation cost related to all equity instruments granted prior to, but not yet vested as of, the adoption date is recognized based on the grant-date fair value which is estimated in accordance with the original provisions of SFAS No. 123. Compensation costs related to all equity instruments granted after January 1, 2006 is recognized at the grant-date fair values of the awards in accordance with the provisions of SFAS No. 123(R). Additionally, under the provisions of SFAS No. 123(R), the Company is required to include an estimate of the number of awards that will be

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Artes Medical, Inc.
(a development stage company)

Notes to Consolidated Financial Statements (Continued)

forfeited in calculating compensation costs, which is recognized over the requisite service period of the awards on a straight-line basis.

For purposes of calculating the stock-based compensation under SFAS 123(R), the Company estimates the fair value of stock options using a Black-Scholes option-pricing model which is consistent with the model used for pro forma disclosures under SFAS 123 prior to the adoption of SFAS 123(R). The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. In accordance with SFAS 123(R) share-based compensation expense recognized in the statement of operations for the first quarter of 2006 is based on awards ultimately expected to vest and is reduced for estimated forfeitures. Prior to the adoption of SFAS 123(R), the Company used the minimum value method for valuing stock options granted to employees and directors. In the Company s pro forma information required under SFAS 123 for the periods prior to 2006, the Company accounted for forfeitures as they occurred.

The assumptions used to estimate the fair value of stock options granted to employee and directors during the years ended December 31, 2006, 2005 and 2004 are as follows:

	Years Ended December 31,		
	2006 Actual	2005 Pro Forma	2004 Pro Forma
Volatility	60%	0%	0%
Expected term (years)	6.0	4.0	4.0
Risk free interest rate	4.55%	3.00% 4.50%	3.00%
Expected dividend yield	0%	0%	0%

The risk-free interest rate assumption was based on the United States Treasury s rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company s expectation of not paying dividends in the foreseeable future. The weighted average expected life of options was calculated using the simplified method as prescribed by the SEC s SAB No. 107 (SAB No. 107).

This decision was based on the lack of relevant historical data due to the Company s limited historical experience. In addition, due to the Company s limited historical data, the estimated volatility also reflects the application of SAB No. 107, incorporating the historical volatility of comparable companies whose share prices are publicly available.

The weighted average grant-date fair value of stock options granted during the year ended December 31, 2006 was $8.00 per share.

During the year ended December 31, 2006, the Company recorded approximately $1,300,000, as a result of the adoption of SFAS No. 123(R). Of this amount, $146,000 has been capitalized to inventory, $139,000 is included in research and development expenses and $1,015,000 is included in selling, general and administrative expenses.

Total unrecognized stock-based compensation costs related to non-vested stock options granted during the year ended December 31, 2006 was approximately $9,506,000, which related to 3,226,884 options issued and outstanding. This unrecognized cost is expected to be recognized on a straight-line basis over a weighted average period of approximately four years.

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Notes to Consolidated Financial Statements (Continued)

The following table illustrates the effect on net losses as if the Company had applied the fair value recognition provisions of SFAS 123 to determine stock-based compensation for the year ended December 31, 2006:

	Year Ended December 31, 2006 (In thousands, except per share amounts)
Net loss as reported	$ (26,323)
Add: Stock-based compensation included in net loss	719
Deduct: Stock-based employee and director compensation determined under fair value method for all awards	(458)
Pro forma net loss	$ (26,062)
Basic and diluted net loss per share as reported	$ (14.23)
Basic and diluted pro forma net loss per share	$ (14.09)

Equity instruments issued to non-employees are recorded at their fair values as determined in accordance with SFAS 123, *Accounting for Stock-Based Compensation*, and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the options vest and are recognized as expense over the related service period.

During the years ended December 31, 2004, 2005, 2006, and for the period from August 24, 1999 (inception) through December 31, 2006, we recognized $1,024,000, $959,000, $535,000, and $2,731,000, respectively, for stock options and warrants issued to non-employees.

Deferred Stock-Based Compensation

No employee related stock-based compensation expense was reflected in the Company s reported net loss in any period prior to 2004, as all options granted to employees had an exercise price equal to the estimated fair value of the underlying common stock on the date of the grant. Stock-based compensation was recognized in 2004 for warrants granted to a member of the Board of Directors as the exercise price of the warrants was less than the estimated fair value of the underlying common stock on the date of grant.

On September 13, 2005, the Company commenced the initial public offering process, and based on discussions with its investment bankers, reassessed the fair value of its common stock going back to July 1, 2004. The Company s management, all of whom qualify as related parties, determined that the stock options granted from July 1, 2004

forward were granted at exercise prices that were below the reassessed fair value of the common stock on the date of grant. The Company completed the reassessment of its fair value without the use of an unrelated valuation specialist and started with the proposed valuation from its investment bankers, considering a number of accomplishments in 2004 and 2005 that would impact its valuation, including achievement of key clinical milestones, hiring executive officers, and the increased possibility of completing an initial public offering. Accordingly, deferred stock-based compensation of $740,000 was recorded within Stockholders Equity (deficit) during 2004 which represented the difference between the weighted-average exercise price of $4.25 and the weighted-average fair value of $6.38 on 324,705 options granted to employees during 2004. Deferred stock-based compensation of $2,383,000, net of forfeitures, was recorded within Stockholders Equity (deficit) during 2005 which represented the difference between the weighted-average exercise price of $5.31 and the weighted-average fair value of $9.18 on 620,000 options granted to employees during 2005.

The deferred stock-based compensation is being amortized on a straight-line basis over the vesting period of the related awards, which is generally four years.

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During the years ended December 31, 2004, 2005, 2006, and for the period from August 24, 1999 (inception) through December 31, 2006, we recognized $109,000, $335,000, $719,000, and $1,163,000, respectively, in amortization of deferred stock-based compensation which was provided for prior to the adoption of SFAS 123(R).

Unrecognized deferred stock-based compensation related to non-vested stock option and warrant awards granted prior to January 1, 2006 was approximately $1,463,000 at December 31, 2006.

The expected future amortization expense for deferred stock-based compensation for stock options granted through December 31, 2006, is as follows (in thousands):

2007	$ 565
2008	527
2009	371
Total	$ 1,463

Upon the adoption of SFAS No. 123(R) on January 1, 2006, deferred stock-based compensation was reclassified against additional paid-in capital.

The stock-based compensation expense that has been included in the statement of operations for all stock-based compensation arrangements was as follows:

	Years Ended December 31,	
	2005	2006
	(In thousands, except per share amounts)	
Capitalized to inventory	$	$ 263
Research and development expense	$ 256	$ 766
Sales, general and administrative expense	1,092	4,165
	$ 1,348	$ 4,931
Net effect on basic and diluted net loss per share	$ 1.14	$ 2.67

Recently Issued Accounting Standards

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4.* This statement amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify the accounting for abnormal amounts of unallocated overhead resulting from abnormally low production (or idle capacity), freight, handling costs, and wasted material (spoilage). This statement requires that those items be recognized as current-period charges. In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this statement will be effective for inventory costs during the fiscal years beginning after June 15, 2005. The Company is still evaluating the impact the adoption of this statement will have on its financial condition and results of operations.

In June 2006, the FASB issued Interpretation No. 48, or FIN 48, Accounting for Uncertainty in Income Taxes an Interpretation of FAS 109. FIN 48 provides clarification for the financial statement measurement and recognition of tax positions that are taken or expected to be taken in a tax return. FIN 48 is effective in the first quarter of 2007. We are currently evaluating the impact of FIN 48 on our financial statements.

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2. Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per common share is computed by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and the outstanding warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Historical outstanding anti-dilutive securities not included in the diluted net loss per common calculation:

	December 31,		
	2004	2005	2006
Convertible preferred stock	1,712,800	5,307,180	
Warrants to purchase preferred and common stock	1,566,653	2,423,758	2,512,542
Options to purchase common stock	560,470	1,149,000	2,133,842
	3,839,923	8,879,938	4,646,384

3. Acquisitions

On July 22, 2004, the Company acquired worldwide patents and patent rights to polymethylmethacrylate (PMMA) microspheres for polymer and alloplastic implants from a stockholder of the Company for $500,000, excluding direct acquisition related expenses of $34,000. The Company paid $250,000 in December 2003 and the remaining $250,000 in installments through July 2004. The Company took ownership of this intellectual property effective January 1, 2004.

On July 22, 2004, the Company also acquired 100% of the outstanding shares in Artes Medical Germany GmbH (formerly Mediplant GmbH Biomaterials & Medical Devices) (Mediplant) from FormMed Biomedicals AG. FormMed Biomedicals AG s sole stockholder is a Company stockholder.

Mediplant possessed certain related trademarks and manufacturing process know-how, for the manufacture of PMMA materials, an integral component of the Company s product ArteFill. After the acquisition, the Company initiated process development and validation activities. Under the purchase agreement the Company took effective control of Mediplant on January 1, 2004, and began consolidating the financial statements of Mediplant with those of the Company as of that date. The total purchase price for this acquisition was $3,750,000, excluding direct acquisition expenses of $265,000.

The acquisition of the worldwide patents and patent rights to PMMA microspheres for polymer and alloplastic implants and Mediplant were considered linked transactions. Both transactions were considered asset acquisitions and were accounted for under the purchase method of accounting; and, accordingly, the purchased assets and liabilities assumed were recorded at their estimated fair values at the date of the acquisition.

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The following table summarizes the total purchase price, estimated fair values of the assets acquired and liabilities assumed, and the resulting net intangible assets acquired at the date of the acquisition for both of the linked transactions (in thousands):

Total purchase price, including acquisition related expenses		$ 4,549
Allocated to assets and liabilities:		
Tangible net assets acquired:		
Inventory	$ 208	
Other assets	33	
Net tangible assets acquired	241	
Total liabilities assumed	2,847	
Net liabilities assumed		2,606
Net intangible assets acquired		$ 7,155

Based on a third-party valuation, net intangible assets acquired were allocated to patents of $287,000 and core technology of $4,030,000. However, there was no allocation of the purchase price to these intangibles for tax purposes, and Mediplant s tax basis in the intangibles remained zero. EITF 98-11 requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability. Using the prescribed methodology, the Company assigned a value of $6,868,000 to the core technology and $2,838,000 to the related deferred tax liability. The weighted-average useful life of the patents and core technology was estimated to be six years. Accumulated amortization at December 31, 2005 was $96,000 for patents and $2,289,000 for core technology. Accumulated amortization at December 31, 2006 was $144,000 for patents and $3,434,000 for core technology. Amortization expense for patents and core technology is estimated to be $1,192,000 for each year from 2007 to 2009.

MediPlant Acquisition Settlement Agreement

In October 2005, the Company, FormMed Biomedicals AG, and Dr. Martin Lemperle, one of the Company s founders, entered into a settlement agreement to accelerate the two installment payments due under the original purchase agreement dated July 22, 2004, and to settle and mutually release all parties regarding reimbursement of certain production and development costs incurred by FormMed prior to the date of the purchase agreement and reimbursement to Dr. Martin Lemperle of certain legal expenses. Upon final settlement of the litigation with one of the Company s competitors (see Note 5) and receipt of the settlement amount in 2005, the Company paid FormMed $750,000 as the final payment and secured the release of certain tangible and intangible assets held in escrow, as required pursuant to the terms of the original MediPlant purchase agreement.

The Company agreed to pay FormMed 428,000 Euro for the prior production and development costs on a payment schedule through June 30, 2006. In addition, the Company issued FormMed 7,214 shares of Company common stock as consideration for accrued interest. The Company agreed to pay Dr. Martin Lemperle 150,000 Euro by June 30, 2006 for all legal costs incurred as a result of the settlement and litigation agreements with a competitor (see Note 5). In addition, the Company issued Dr. Martin Lemperle 2,549 shares of Company common stock as consideration for accrued interest.

All parties agreed that both the cash payments and common stock grant covers in full all prior period production, development and legal costs incurred by FormMed and Dr. Martin Lemperle

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4. Balance Sheet Details

Other Assets

Other current assets consist primarily of a receivable for tenant improvement allowances provided by the Company s landlord. Other noncurrent assets consist of capitalized direct financing costs which are amortized to interest expense and various deposits with vendors and professional service providers.

Deferred Financing Costs

Deferred financing costs consist of amounts related to the issuance of common stock and common stock warrants issued in connection with a modification of terms of certain convertible notes payable. These amounts will be expensed to interest expense using the effective interest method over the modified term of the agreement.

Inventory

Inventory consists of raw materials used in the manufacture of ArteFill. Inventory is carried at the lower of cost or market. Cost is determined using the average-cost method with provisions made for obsolete or slow moving goods.

Inventory consisted of the following at (in thousands):

	December 31, 2005	2006
Raw materials	$ 590	$ 727
Work in process	320	1,619
Unpackaged finished goods	19	3,169
	929	5,515
Less: reserve for obsolete inventory	(237)	(754)
Total	$ 692	$ 4,761

Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31, 2005	2006

Furniture and fixtures	$ 385	$ 588
Office equipment	471	734
Lab equipment	1,820	2,464
Leasehold improvements	2,894	3,351
	5,570	7,137
Less accumulated depreciation and amortization	(644)	(1,866)
Total	$ 4,926	$ 5,271

Total depreciation expense for the years ended December 31, 2004, 2005 and 2006, and the period from August 24, 1999 (inception) through December 31, 2006, was $42,000, $549,000, $1,235,000 and $1,926,000, respectively.

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5. Commitments and Contingencies

On November 27, 2006, the Company entered into a loan and security agreement with Comerica Bank, pursuant to which the Company obtained a credit facility with Comerica Bank, consisting of a revolving line of credit in the amount of up to $5,000,000 and a term loan in the amount of up to $5,000,000. Interest on the revolving line and the term loan accrues at prime plus 2%. The revolving line and term loan mature on November 27, 2007 and 2010, respectively. The agreement requires the Company to meet certain liquidity ratios and imposes certain restrictions on mergers, acquisitions and distributions. In addition the Company granted the bank a warrant to purchase 120,000 shares of Series E preferred stock at an exercise price of $2.50 per share. The fair value of the warrant plus the related beneficial conversion feature totaled $253,000; this amount plus an additional $54,000 of actual loan costs was recorded as debt discount and will be amortized over the life of the term loan using the effective interest method. The debt is secured by substantially all of the assets of the Company.

The following is a summary of the credit facility at December 31, 2006 (in thousands):

Comerica Bank revolving line of credit	$ 5,000
Comerica B term loan	4,896
	9,896
Less current portion	6,250
	3,646
Debt discount	(305)
Long-term debt	$ 3,341

Annual maturities of the credit facility for the next five years are as follows: $6,250, $1,250, $1,250, and $1,146.

The Company leases equipment under various equipment financing arrangements ranging in term from one to three years with interest rates ranging from 8.5% to 9.3%.

Future principal payments under the Company s equipment financing arrangements are as follows (in thousands):

Years ended December 31,	
2007	$ 45
2008	21
Total	$ 66

The Company executed a building lease, which commenced January 1, 2005 and expires in December 2011. On June 1, 2005, the Company executed a building lease for additional office space. The lease began on June 1, 2005 and expires on March 30, 2011. Various types of office equipment are also being leased under operating leases.

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Future annual minimum rental payments under the Company s operating leases are as follows (in thousands):

Years ended December 31,	
2007	$ 985
2008	986
2009	1,036
2010	1,086
2011	990
Total minimum lease payments	$ 5,083

Rent expense was $435,000, $954,000, $919,000 for the years ended December 31, 2004, 2005 and 2006, respectively, and $2,714,000 for the period from August 24, 1999 (inception) through December 31, 2006.

The Company is subject to various legal actions and proceedings in the normal course of business. While the ultimate outcome of these matters cannot be predicted with certainty, management does not believe these matters will have a material adverse effect on the Company s financial statements.

Litigation Settlement Agreement

On October 31, 2005, the Company and Dr. Martin Lemperle, one of the Company s founders, resolved all of their outstanding disputes and litigation matters with an independent company competing in the aesthetics market (the Competitor). According to the terms of the settlement agreement, the Company has granted the Competitor an exclusive, world-wide license under certain of its patents to make and sell implant products containing Calcium Hydroxylapatite particles, and a nonexclusive, world-wide license under the same patents to make and sell certain other nonpolymeric implant products. The Competitor paid the Company $2,058,000 in November 2005 for the settlement plus past royalties. This amount is included in other income in the 2005 consolidated statements of operations.

Settlement Agreements

In November 2005, the Company and a legal firm entered into a settlement agreement regarding disputed legal expenses incurred prior to 2004 while the legal firm was representing the Company on a certain litigation matter. The Company paid $225,000 in 2005 for a negotiated amount of unpaid legal expenses in exchange for a full and mutual release of claims between the two parties.

In March 2006, the Company entered into a separation agreement with a founder in connection with his retirement and resignation. Under the terms of the agreement, the Company agreed to pay a cash bonus of $70,000 for his performance during fiscal year 2005 and to retain him as a consultant for an initial term of up to 24 months beginning March 15, 2006, subject to an extension for an additional 12 months under certain circumstances. In connection with

the separation agreement, the parties also entered into a voting agreement, pursuant to which the founder agreed to vote all shares of voting capital stock owned by him as directed by a majority of the board of directors on all matters presented for a vote of the stockholders. In May 2006, the Company terminated the consulting arrangement as permitted under the terms of the separation agreement and the Company paid a lump sum payment of $366,667, the amount to which the founder would have been entitled had he completed the initial term of the separation agreement.

In May 2006, the Company paid $500,000 to Stifel, Nicolaus & Company, Incorporated in connection with a settlement agreement related to a dispute arising out of an engagement agreement between the parties.

On November 2, 2006, the Company received a notice of demand for arbitration from a former employee in connection with the termination of his employment. On January 31, 2007, the Company entered into a Confidential

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Notes to Consolidated Financial Statements (Continued)

Settlement and Release of Claims Agreement whereby the Company is required to pay a cash settlement amount of $284,000. The amount was paid in full in February 2007. In addition to the cash settlement amount, the Company agreed to accelerate the vesting of certain stock options and warrants previously granted to the employee. The Company recorded a non-cash expense charge of $135,000 associated with the accelerated vesting of these options and warrants.

On November 16, 2006, the Company received a notice of demand for arbitration from a former employee in connection with the termination of his employment. On January 10, 2007, the Company entered into a Confidential Settlement and Release of Claims Agreement whereby the Company is required to pay a cash settlement amount of $242,000. Of the $242,000, $39,000 was paid in 2006, $56,000 is due to be paid no later than March 31, 2007 and the balance of $147,000 will be paid monthly through October 2007. In addition to the cash settlement amount, the Company agreed to accelerate the vesting of certain stock options previously granted to the employee. The Company recorded a non-cash expense charge of $116,000 associated with the accelerated vesting of these stock options.

On November 17, 2006, the Company entered into a separation agreement and mutual general release with Dr. Stefan M. Lemperle in connection with his resignation as a director and as an employee. Pursuant to the agreement, the Company is required to pay $690,000 in cash severance payments. Of the $690,000, $428,000 was paid in 2006 and the balance of $262,000 will be paid monthly through October 2007. Dr. Stefan M. Lemperle is eligible to receive an additional severance payment of $400,000, contingent upon the Company s completion of a qualifying transaction, as defined in the agreement, before March 31, 2007. In connection with the agreement, the Company also amended the terms of the outstanding stock options held by Dr. Stefan M. Lemperle to provide for the full acceleration of all unvested shares under his stock options, and the Company has agreed to issue to Dr. Stefan M. Lemperle a warrant to purchase up to 117,647 shares of common stock, subject to certain conditions and in an amount determined in accordance with the terms of the agreement. The Company recorded a non-cash expense charge of $378,000 associated with the accelerated vesting of these options and warrants.

On November 6, 2006, the Company filed a demand for arbitration with the American Arbitration Association against Melvin Ehrlich, who served as the Company s President and Chief Operating Officer from January 2004 to April 2004. The Company is seeking declaratory relief regarding the number of shares of common stock Mr. Ehrlich is entitled to purchase under a warrant issued to him in connection with his employment agreement. The parties have pursued a settlement of this action, and have negotiated the terms of a proposed settlement agreement in which the Company will pay Mr. Ehrlich $250,000 and issue Mr. Ehrlich 26,710 shares of common stock and a warrant to purchase 25,000 shares of common stock, at an exercise price of $8.07 per share. The settlement agreement contains a mutual release of claims and a mutual covenant not to sue. The settlement agreement is subject to approval by the Company s board of directors, and based on his age, Mr. Ehrlich will have up to seven days to revoke the settlement agreement after he signs it. The Company has made an accrual in the fourth quarter of the fiscal year ended December 31, 2006 based on the terms of the proposed settlement agreement.

FDA Investigation

In March 2006, the counsel for Dr. Gottfried Lemperle, our former Chief Scientific Officer and a former member of our board of directors, in the Sandor litigation discussed in Legal Proceedings below informed us that she had contacted an investigator in the FDA s Office of Criminal Investigations. She further stated that the FDA investigator informed her that the FDA has an open investigation regarding us, Dr. Gottfried Lemperle and his son, Dr. Stefan

Lemperle, our former Chief Executive Officer and a former director, that the investigation had been ongoing for many months, that the investigation would not be completed within six months, and that when the

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investigation is completed, it could be referred to the U.S. Attorney s Office for criminal prosecution. In November 2006, we contacted the FDA s Office of Criminal Investigations. That office confirmed the ongoing investigation involving the Company, but declined to provide any details of the investigation, including the timing, status, scope or targets of this investigation.

6. Convertible Notes Payable

In 2000 and 2001, the Company issued unsecured convertible notes payable to stockholders of the Company in the amount of $1,510,000 (2000 Notes). The 2000 Notes bore interest at an annual rate of 8%. In July 2003, $1,477,000 of principal and $335,000 in accrued interest was converted into 659,069 shares of Series C-1 preferred stock at a conversion rate of $2.75 per share.

The remaining $33,000 of principal that was not converted and $12,000 of accrued interest is included in convertible notes payable on the December 31, 2004 and the $33,000 of principal and $15,000 of accrued interest is included in convertible notes payable on the December 31, 2005 consolidated balance sheets. For the years ended December 31, 2004, 2005 and 2006, and for the period from August 24, 1999 (inception) to December 31, 2006, the Company recorded $4,000, $4,000, $1,000 and $353,000 of interest expense associated with the 2000 Notes, respectively.

In 2002 and 2003, the Company issued unsecured convertible notes payable to stockholders of the Company in the amount of $2,615,000 (2002 Notes). The 2002 Notes bore interest at an annual rate of 12%. In July 2003, $2,615,000 of principal and $213,000 in accrued interest was converted into 2,827,864 shares of Series C-1 preferred stock at a conversion rate of $1.00 per share.

For the years ended December 31, 2004, 2005 and 2006, and for the period from August 24, 1999 (inception) to December 31, 2006, the Company recorded $0, $0, $0 and $213,000 of interest expense associated with the 2002 Notes, respectively.

In December 2003 and throughout 2004, the Company received bridge loan financing by issuing unsecured convertible notes payable (2004 Notes) in the amount of $6,736,000. The 2004 Notes bore interest at an annual rate of 8%. In May 2005, $6,736,000 of principal and $501,000 in accrued interest was converted into 5,789,801 shares of Series D preferred stock at a conversion rate of $1.25 per share. For the years ended December 31, 2004, 2005 and 2006, and for the period from August 24, 1999 (inception) through December 31, 2006, the Company recorded $322,000, $179,000, $0 and $501,000 of interest expense associated with the 2004 Notes, respectively.

In connection with the 2004 Notes, the Company issued warrants to purchase 634,016 shares of common stock to the holders of the 2004 Notes during the year ended December 31, 2004. The warrants are fully vested and have an exercise price of $5.31. The proceeds from the 2004 Notes were allocated to the carrying values of the notes and the warrants on the basis of their relative fair values on the date of issuance.

In accordance with EITF 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments, the Company initially recorded its convertible debt net of a discount for the (i) the estimated fair value of the warrants issued in the amount of $2,667,500 and (ii) the intrinsic value of the related beneficial conversion feature in the same amount for a total of $5,335,000. The estimated fair value of the warrants was determined in accordance with the Black-Scholes

valuation model. The discount associated with the warrants and beneficial conversion feature is being amortized to interest expense over the term of the outstanding convertible notes payable. Interest expense related to the warrants and beneficial conversion features was $3,555,000, $1,780,000, $0 and $5,335,000 for the years ended December 31, 2004, 2005 and 2006, and for the period from August 24, 1999 (inception) to December 31, 2006.

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In May 2005, the Company received $6,970,000 in proceeds by issuing unsecured convertible promissory notes (2005 Bridge Loan) that were to accrue simple interest at 10% per annum until the maturity date of November 3, 2005. At the sole discretion of the Company, the maturity date was subject to a one-time extension to February 3, 2006. The Company exercised its right of the one-time extension, the applicable interest rate increased to 12% retroactively to the date of issuance of the 2005 Bridge Loan. At the closing of the next equity financing, the holders of the 2005 Bridge Loan elected not to convert all or a portion of the outstanding principal and accrued but unpaid interest into the new equity shares at the per share price of those shares but rather to be repaid the balance due under the 2005 Bridge Loan.

Simultaneously upon issuance of the 2005 Bridge Loan, the Company issued warrants to purchase Series D convertible preferred stock equal to 30% of the principal amounts of the 2005 Bridge Loan divided by the warrant exercise price of $2.00 per share, or warrants to purchase 1,045,500 shares of Series D convertible preferred stock. The warrants expire in May 2010.

In accordance with EITF 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments, the Company initially recorded its convertible debt net of a discount for the (i) the estimated fair value of the warrants issued in the amount of $1,003,500 and (ii) the intrinsic value of the related beneficial conversion feature in the same amount for a total of $2,007,000. The estimated fair value of the warrants was determined in accordance with the Black-Scholes valuation model. The discount associated with the warrants and beneficial conversion feature is being amortized to interest expense over the term of the outstanding convertible notes payable.

Interest expense related to the warrants and beneficial conversion features was $1,772,000, $235,000 and $2,007,000 for the years ended December 31, 2005 and 2006, and for the period from August 24, 1999 (inception) to December 31, 2006, respectively.

On September 30, 2005, outstanding principal amount of $970,000 and accrued interest of $39,000 under the convertible notes issued in the 2005 Bridge Loan converted into 403,412 shares of Series E convertible preferred stock at a rate of $2.50 per share.

The Company had $492,000 in accrued interest included in convertible notes payable on the December 31, 2005 balance sheet.

On December 30, 2005, the Company entered into an amendment of the 2005 Bridge Loan with an investor who held convertible promissory notes representing an outstanding principal amount of $5,500,000, whereby the Company paid, in January 2006, a total of $3,246,000, consisting of $3,000,000 of outstanding principal and $246,000 of accrued interest, upon the second closing of the Series E Financing. In February 2006, upon the third closing of the Series E Financing, the Company paid an additional $2,738,000, consisting of $2,500,000 of outstanding principal and $238,000 of accrued interest, the final amount due under the 2005 Bridge Loan.

Per the note amendment, the investor waived both its conversion and redemption options under the original note and extended the due date of the remaining outstanding principal of $2,500,000 from February 3, 2006 to February 15, 2006. As additional consideration, the Company granted the investor a stock grant of 250,000 shares of Series E convertible preferred stock in December 2005. In addition, three Company directors personally guaranteed the

remaining outstanding principal under the amended note agreement. In exchange for the personal guarantees, the Company issued each of these three directors 23,529 shares of common stock. At December 31, 2005, the common stock had not yet been issued and is included as common stock issuable in the 2005 consolidated balance sheet and the consolidated statement of stockholders equity.

7. Stockholders Equity

On December 26, 2006, the Company closed an initial public offering of its common stock in which it sold 5,290,000 shares of common stock at $6.00 per share for gross proceeds of $31.7 million. After underwriting

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discounts, commissions and offering expenses, the Company received net proceeds of $25.3 million. Upon the closing of the offering, all outstanding shares of convertible preferred stock converted into 9,367,512 shares of common stock.

Convertible Preferred Stock

In May 2005, the Company issued 5,789,801 shares of Series D convertible preferred stock at $1.25 per share and 4,230,055 shares of Series D convertible preferred stock at $2.00 per share for a total of $15,197,000 and interest accrued to the holders of the 2004 convertible notes payable (2004 Notes) of $500,000. The total investment was comprised of $8,460,000 in subscriptions for a total of 4,230,055 shares of Series D convertible preferred stock and $7,237,000 of convertible promissory notes payable (2004 Notes), including accrued interest of $500,000, which converted into a total of 5,789,801 shares of Series D convertible preferred stock.

The Company issued warrants to purchase an aggregate of 198,310 shares of common stock, at an exercise price of $8.50 per share, to certain purchasers of Series D convertible preferred stock. The warrants may be exercised any time for a period of five years. The purchasers that were issued shares of Series D convertible preferred stock in connection with the conversion of promissory notes previously issued by the Company did not receive such warrants.

In August 2005, the Company obtained stockholder approval to open an offering to sell approximately ten million shares of Series E convertible preferred stock at $2.50 per share for gross proceeds of $25 million (the Series E Financing).

The Series E Financing closed in five rounds from December 2005 through March 2006, resulting in gross proceeds of $50.7 million, including the conversion of $1,009,000 of the outstanding 2005 Bridge Loan and related accrued interest.

On December 22, 2005, the first round closed with total proceeds of $7.7 million, including the conversion of $970,000 of the outstanding 2005 Bridge Loan and $39,000 of accrued interest, resulting in the issuance of 3,213,615 shares of Series E convertible preferred stock. Cash proceeds were received of $6.7 million for the purchase of 2,686,203 shares. An additional 403,412 shares were issued for the conversion of $1,009,000 of the outstanding 2005 Bridge Loan including accrued interest of $39,000.

In December 2005, the Company engaged a placement agent to secure the sale of up to $10 million in additional Series E convertible preferred stock. A purchaser of less than $5.0 million of Series E convertible preferred stock would receive a warrant to purchase one share of Series E convertible preferred stock for each five shares of Series E convertible preferred stock purchased, or 20% of the amount purchased. A purchaser of $5.0 million or more of Series E convertible preferred stock would receive a warrant to purchase one share of Series E convertible preferred stock for each 14.0 shares of Series E convertible preferred stock purchased, or 30% of the amount purchased. The warrants have an exercise price of $10.63 per share. The warrants may be exercised any time for a period of five years.

On January 6, 2006, the Company closed the second round of its Series E Financing. Upon closing, total gross proceeds of $6,750,000 were received resulting in the issuance of 2,700,000 shares of Series E convertible preferred stock and warrants for the future purchase of 702,000 shares of Series E convertible preferred stock at $2.50 per share. The warrants expire January 6, 2011. In addition, the Company issued a warrant for the future purchase of

16,875 shares of common stock at $5.31 per share. This warrant expires January 6, 2011.

On January 13, 2006, the Company closed the third round of Series E Financing. Upon closing, total gross proceeds of $3,235,000 were received resulting in the issuance of 1,294,000 shares of Series E convertible preferred stock and warrants for the future purchase of 536,440 shares of Series E convertible preferred stock at $2.50 per

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share. The warrants expire January 13, 2011. In addition, the Company issued a warrant for the future purchase of 8,088 shares of common stock at $5.31 per share. This warrant expires January 13, 2011.

On February 14, 2006, the Company closed its fourth round of Series E Financing. Upon closing, total gross proceeds of $13,711,000 were received resulting in the issuance of 5,484,200 shares of Series E convertible preferred stock and warrants for the future purchase of 948,420 shares of convertible Series E convertible preferred stock at $2.50 per share. The warrants expire February 14, 2011. In addition, the Company issued a warrant for the future purchase of 5,727 shares of common stock at $5.31 per share. This warrant expires February 14, 2011.

On March 28, 2006, the Company closed the fifth and final round of Series E Financing. Upon closing, total gross proceeds of $19,281,000 were received resulting in the issuance of 7,712,406 shares of Series E convertible preferred stock and warrants for the future purchase of 1,451,582 shares of Series E convertible preferred stock at $2.50 per share. The warrants expire March 28, 2011.

In October 2005, the Company entered into a termination agreement with certain financial advisors. In exchange for the termination agreement the Company issued 124,000 shares of Series E convertible preferred stock at $2.50 per share. The Company expensed $310,000 as stock-based compensation during the year ended December 31, 2005 related to this termination agreement.

As of December 31, 2005, the Company had received $6.9 million in subscriptions for Series E convertible preferred stock.

At December 31, 2004, 2005 and 2006, the Company was authorized to issue 25,000,000, 35,000,000 and 10,000,000 shares of preferred stock, respectively.

	December 31,					
	2004			2005		
	Shares Designated	Shares Issued and Outstanding	Aggregate Liquidation Preference (In thousands)	Shares Designated	Shares Issued and Outstanding	Aggregate Liquidation Preference (In thousands)
Series A	2,050,839	2,050,839	$ 3,076	2,050,839	2,050,839	$ 3,076
Series B	679,239	679,239	2,262	679,239	679,239	2,262
Series C-1	7,052,741	4,437,741	12,204	7,052,741	4,437,741	12,204
Series D	11,000,000			11,500,000	10,019,857	20,040
Series E				10,000,000	3,463,615	8,659
	20,782,819	7,167,819	$ 17,542	31,282,819	20,651,291	$ 46,241

Conversion

In connection with the Company s initial public offering, the Company effected a 1-for-4.25 reverse stock split of its common stock on December 19, 2006. In addition to the reverse stock split, all outstanding shares of the Company s preferred stock were converted to common stock immediately prior to the closing of the Company s initial public offering on December 26, 2006. Each outstanding share of Series A, Series D and Series E preferred stock was converted into one share of common stock, and as a result of anti-dilution provisions, each one share of Series B preferred stock was converted into 1.35 shares of common stock and each one share of Series C-1 preferred stock was converted into 1.375 shares of common stock.

On December 26, 2006, after giving effect to the 1-for-4.25 reverse stock split, and the anti-dilution provisions associated with the Series B and C-1 convertible preferred stock, all of the outstanding shares of convertible preferred stock were automatically converted into 9,367,512 shares of common stock.

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Dividends

The holders of the Series A, B, C-1, D and E convertible preferred stock were entitled to receive noncumulative dividends at $0.12, $0.26, $0.22, $0.16 and $0.20 per share, respectively, per annum only when and if declared by the Board of Directors. The Board of Directors had not declared any dividends on any series of preferred stock prior to the conversion of the Company s preferred stock on December 26, 2006.

Voting Rights

The holders of the Series A, B, C-1, D and E convertible preferred stock were entitled to the number of votes equal to the number of shares of common stock into which each share of preferred stock was convertible on the record date for the vote, and had voting rights and powers equal to the common stock.

Liquidation

The holders of the Series A, B, C-1, D and E convertible preferred stock were entitled to receive liquidation preferences at the rate of $1.50, $3.33, $2.75, $2.00 and $2.50 per share, respectively. Liquidation payments were to be made in preference to any payments to the holders of common stock and made with the following priority to the preferred stockholders: Series B, Series A, Series C-1, Series D and then Series E.

Anti-Dilution Provisions

The issuance of Series C-1 convertible preferred stock in 2003 triggered the anti-dilution provisions of Series B convertible preferred stock. The common shares that the outstanding Series B preferred shares converted into increased by 111,585 to 790,824 shares of common stock.

The issuance of Series D convertible preferred stock in 2005 triggered the anti-dilution provisions of the Series B and Series C-1 convertible preferred stock. The common shares that the outstanding Series B preferred shares converted into increased by 125,444 shares to 919,368 shares of common stock and the common shares that the outstanding Series C-1 preferred shares converted into increased by 1,664,097 shares to 6,101,838 shares of common stock.

Stock Option Plans

In 2006, the Company adopted the 2006 Equity Incentive Plan (the 2006 Plan) for eligible employees, officers, directors, advisors, and consultants that provides for the grant of incentive and nonstatutory stock options and other awards. The Company has 5,882,353 shares of common stock options authorized under the 2006 Plan. Terms of the stock option agreements, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the 2006 Plan. Options granted by the Company generally vest over four years and vested options are exercisable from the date of grant for a period of ten years. The exercise price of the incentive stock options must equal at least the fair market value of the stock on the date of grant.

In 2001, the Company adopted the 2001 Stock Option Plan (the 2001 Plan) for eligible employees, officers, directors, advisors, and consultants that provides for the grant of incentive and nonstatutory stock options. The 2001 Plan

superseded the Company s 2000 Stock Option Plan (the 2000 Plan). Following the adoption of the 2001 Plan, no further option grants were made under the 2000 Plan. Terms of the stock option agreements, including vesting requirements, are determined by the Board of Directors, subject to the applicable provisions of the 2000 Plan or 2001 Plan. Options granted by the Company generally vest over four years and vested options are exercisable from the date of grant for a period of ten years. The exercise price of the incentive stock options must equal at least the fair market value of the stock on the date of grant. All the shares of stock that remained available for issuance and not subject to outstanding options under the 2000 Plan and 2001 Plan became part of the available pool of shares under the 2006 Plan. No further option grants will be made under the 2000 Plan or 2001 Plan.

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The exercise price of nonstatutory stock options under the 2000 Plan and the 2001 Plan must equal at least 85% of the fair market value of the stock on the date of grant. The exercise price of any incentive stock option granted to a 10% stockholder may be no less than 110% of the fair value of the Company s common stock on the date of grant. As of December 31, 2006, there were 25,880 and 2,078,082 options outstanding under the 2000 Plan and 2001 Plan, respectively, and 29,880 options granted outside the 2000 Plan and 2001 Plan.

The Company recorded stock-based compensation for options granted to nonemployees of $112,000, $107,000, $156,000 and $484,000 for the years ended December 31, 2004, 2005 and 2006, and for the period from August 24, 1999 (inception) through December 31, 2006, respectively. The fair value of each option was determined using the Black-Scholes valuation model and periodically re-measured and recognized over the related service period. The following table summarizes stock option activity under the Company s stock option plans, as well as outside of these plans (shares in thousands):

	Options	Weighted-Average Exercise Price
August 24, 1999 (inception)		
Granted	71	$ 0.43
Outstanding, December 31, 1999	71	0.43
Granted	187	1.36
Canceled	(29)	2.34
Outstanding, December 31, 2000	229	1.15
Granted	94	1.53
Canceled	(6)	0.64
Outstanding, December 31, 2001	317	1.28
Granted	11	1.49
Canceled	(8)	1.40
Outstanding, December 31, 2002	320	1.28
Granted	118	6.38
Exercised	(18)	0.43
Canceled	(46)	6.38
Outstanding, December 31, 2003	374	2.30
Granted	391	4.25
Exercised	(14)	2.04
Canceled	(191)	2.34

Outstanding, December 31, 2004	560	3.57
Granted	611	5.31
Exercised	(6)	4.25
Canceled	(16)	5.31
Outstanding, December 31, 2005	1,149	4.46
Granted	1,320	8.00
Exercised	(99)	3.49
Canceled	(236)	4.91
Outstanding, December 31, 2006	2,134	6.65

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The following table summarizes information about options outstanding at December 31, 2006 under the 2000 and 2001 Plans and outside the Plans:

	Options Outstanding			Options Exercisable	
Grant Exercise Price	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$0.43 - $ 0.64	29,880	3.0 years	$ 0.52	27,306	$ 0.50
$1.49 - $ 2.34	88,231	4.6 years	1.74	77,324	1.71
$4.25 - $ 6.38	1,005,291	8.7 years	5.15	414,050	5.06
$7.86 - $10.63	1,010,440	9.6 years	8.75	174,717	8.54
	2,133,842	8.9 years	6.65	693,397	5.38

On December 26, 2006, upon the closing of the Company s initial public offering, stock options to purchase 78,855 shares of common stock granted to Outside Directors became fully vested. The Company took a charge of $547,000 related to the acceleration of these stock options.

Warrants

In February and May 2000, the Company issued in aggregate 16,666 fully vested warrants to purchase common stock at an exercise price of $6.38 per share in connection with services provided to obtain financing. The warrants expire ten years from the date of grant. The value of the warrants was estimated using the Black-Scholes valuation model and was not material to the financial statements. As of December 31, 2006, 12,745 warrants to purchase common stock have been exercised.

In June 2003, the Company issued a warrant to purchase 6,470 fully vested shares of common stock to a member of the Board of Directors at an exercise price of $5.40 per share in connection with services provided to facilitate the acquisition of certain worldwide patents and patent rights. The warrant expires in June 2014. The value of the warrant was estimated using the Black-Scholes valuation model and $34,000 was capitalized as intellectual property in the December 31, 2004 balance sheet and is being amortized over six years. The following assumptions were utilized in the model: expected dividend yield of 0%, expected volatility of 75%, risk-free interest rate of 4%, and contractual life of ten years. As of December 31, 2006, 649 shares of common stock were issued as the result of the cashless exercise of 6,470 warrants to purchase common stock.

In connection with the 2002 Notes, the Company issued 1,125,505 and 1,489,495 warrants to purchase Series C-1 preferred stock to the holders of the 2002 Notes during the years ended December 31, 2002 and 2003, respectively.

The warrants are fully vested and have an exercise price of $1.00. The proceeds from the 2002 Notes were allocated to the carrying values of the notes and the warrants on the basis of their relative fair values at the date of issuance.

The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk-free interest rate of 3%, and contractual life of five years. As the fair value of the warrants exceeded the carrying value of the 2002 Notes, the allocated discount related to the warrants was limited to the amount of the proceeds from the 2002 Notes. As a result, $1,126,000 and $1,489,000 was recorded as a debt discount in 2002 and 2003, respectively. The discount was amortized over the term the 2002 Notes were outstanding, which resulted in interest expense of $745,000 and $1,870,000 in the years ended December 31, 2002 and 2003, respectively. The discount was fully amortized at December 31, 2003, as the 2002 Notes had been converted to Series C-1 preferred stock. As of December 31, 2006, 11,764 warrants to purchase Series C-1 preferred stock have been exercised.

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In connection with the 2004 Notes, the Company issued warrants to purchase 633,914 shares of common stock to the holders of the 2004 Notes during the year ended December 31, 2004. The warrants are fully vested and have an exercise price of $5.31.

The proceeds from the 2004 Notes were allocated to the carrying values of the notes and the warrants on the basis of their relative fair values on the date of issuance. Due to the value ascribed to the warrants, the Company also recorded a beneficial conversion equal to the value ascribed to the warrants. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk free interest of 3%, and contractual life of five years. As a result, $5,335,000 was recorded as a debt discount in 2004. The debt discount is being amortized over the period during which the 2004 Notes are outstanding, which resulted in interest expense of $3,555,000 and $1,780,000 in the years ended December 31, 2004 and 2005, respectively. As of December 31, 2006, warrants to purchase 2,822 shares of common stock have been exercised.

In 2004, the Company issued a warrant to a member of the Board of Directors to purchase 152,941 shares of common stock at an exercise price of $5.31 per share. The warrant expires in 2009. 117,647 of the warrant shares were immediately vested and the remaining 35,294 warrant shares vested at 735 shares per month, subject to full acceleration of vesting upon the Company s receipt of final marketing approval for ArteFill.

The value ascribed to the 117,647 warrant shares was estimated using the Black-Scholes valuation model and resulted in $495,000 expensed to compensation for the year ended December 31, 2004. The 35,294 warrants were deemed to be employee warrants. As these warrants were issued with an exercise price less than the deemed fair market value of the underlying shares at grant date, the Company recorded the intrinsic value of $38,000 as deferred compensation and is amortizing to compensation expense over the term of the vesting period.

In September and November 2004, the Company issued in aggregate 99,998 fully vested warrants to purchase common stock at exercise prices ranging from $4.25 to $8.50 per share in connection with various consulting services provided to the Company. The warrants expire from four to ten years from the date of grant. The value of the warrants was estimated using the Black-Scholes valuation model and resulted in $417,000 expensed to compensation for the year ended December 31, 2004. As of December 31, 2006, 11,763 have been exercised for cash.

In September 2004, the Company issued 17,343 fully vested warrants to purchase common stock at exercise prices of $5.31 and $10.63 per share in lieu of interest on an outstanding accounts payable balance. The warrants expire in five years. The value of the warrants was estimated using the Black-Scholes valuation model and resulted in $72,000 expensed to interest for the year ended December 31, 2004. In connection with a settlement agreement in October 2005 these warrants were canceled.

In November 2004, the Company issued 8,234 fully vested warrants to purchase common stock at an exercise price of $8.50 in connection with Series D subscriptions as direct financing related costs. There was no net impact to the consolidated financial statements. The warrants expire November 22, 2009 and as of December 31, 2006, no warrants have been exercised.

In September 2004, the Company issued 23,529 fully paid warrants to purchase common stock in connection with services provided by an employee to the Company. The warrants were to vest monthly in an equal amount over a 12-month period. The Company recorded $100,000 of compensation expense in 2004 based on the fair value of the warrants as the warrants vested. On May 17, 2005, the 15,685 vested warrants were exercised. On October 12, 2004, 7,058 warrants were exercised.

In connection with the 2005 Bridge Loans, in 2005 the Company issued warrants equal to 30% of the principal amount of the Notes divided by the exercise price of $2.00 per share or warrants to purchase 1,045,500 shares of Series D convertible preferred stock.

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The warrants may be exercised any time for a period of five years. The proceeds from the 2005 Bridge Loan were allocated to the carrying values of the notes and the warrants on the basis of their relative fair values on the date of issuance. Due to the value ascribed to the warrants, the Company also recorded a beneficial conversion equal to the value ascribed to the warrants. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk free interest of 3.0%, and contractual life of five years. As a result, $2,007,360 was recorded as a debt discount in 2005 and $1,772,000 was amortized in 2005. As of December 31, 2006, 176,470 warrants to purchase Series D preferred stock were cashless exercised, no shares were issued as a result of the net issuance.

In 2005, certain purchasers of Series D convertible preferred stock received a warrant to purchase one share of common stock for each five shares of Series D convertible preferred stock purchased, or 198,310 warrants to purchase common stock at an exercise price of $8.50 per share. The warrants vest immediately and may be exercised any time for a period of five years. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk free interest of 3.0%, and contractual life of five years. As a result, $809,000 was recorded as equity issuance costs in 2005 with no net impact on the financial statements. As of December 31, 2006, 70,775 warrants to purchase common stock were cashless exercised, no shares were issued as a result of the net issuance.

On December 22, 2005, the Company issued warrants to purchase up to 200,000 shares of Series E convertible preferred stock at $2.50 per share. These warrants were issued pursuant to a settlement agreement.

The warrants vest immediately and may be exercised any time for a period of seven years. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk free interest of 4.5%, and contractual life of seven years. As a result, $364,000 was recorded as stock-based compensation. As of December 31, 2006, no warrants have been exercised.

On December 22, 2005, the Company issued warrants to purchase up to 4,543 shares of common stock at $5.31 per share. These warrants were issued pursuant to a settlement agreement. The warrants vest immediately and may be exercised any time for a period of five years. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk free interest of 4.5%, and contractual life of five years. As a result, $35,000 was recorded as stock-based compensation. As of December 31, 2006, no warrants have been exercised.

On December 30, 2005, the Company entered into an amendment of the 2005 Bridge Loan with an investor (See Note 6). In connection with the amendment, the Company issued warrant to a member of the Board of Directors to purchase 35,294 shares of common stock at an exercise price of $5.31 per share. The warrant expires in 2010. All of the warrant shares were fully vested upon issuance of the warrant. The value ascribed to the 35,294 warrant shares was estimated using the Black-Scholes valuation model and resulted in $276,000 capitalized as deferred financing costs at December 31, 2005. The deferred financing costs will be expensed as additional interest over the period in which the loan will be repaid under the amendment.

In June 2006, the Company offered certain holders of warrants that were issued in exchange for services an opportunity to amend their warrant agreements to eliminate the automatic expiration upon the closing date of the Company s initial public offering if not exercised prior, and to allow the warrants to continue in effect under the amended agreement until March 15, 2007. In return, the warrant holders agreed to eliminate their ability to do cashless exercises of their warrants.

In June 2006, the Company also offered certain holders of warrants that were issued in connection with bridge loans an opportunity to amend their warrant agreements to eliminate the automatic expiration upon the closing date of the Company s initial public offering if not exercised prior, and to allow the warrants to continue in effect under the term of the original warrant agreements. In return, the warrant holders agreed to eliminate their ability to do

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cashless exercises of their warrants. The bridge loans have been either repaid or converted to convertible preferred stock in prior periods.

In June 2006, in connection with the offer to amend the terms of the warrant agreements, certain medical/scientific advisory members received accelerated vesting of their unvested warrants.

In June 2006, the Company amended the warrant agreements of certain key individuals to eliminate the automatic expiration upon the closing date of the Company s initial public offering if not exercised prior, and to allow the warrants to continue in effect under the terms of the original warrant agreements.

These offers remained open until June 23, 2006. Based on the warrant holders preferences, the Company recorded a warrant modification expense of $1,376,000 during the year ended December 31, 2006. Of the warrant modification expense of $1,376,000, $477,000 was recorded as interest expense because these original warrants were issued in connection with financings. The remaining $899,000 was recorded as consulting expense, comprised of $66,000 in research and development expense and $833,000 in selling, general and administrative expense because these original warrants were issued in exchange for services.

On November 27, 2006, the Company entered into a loan and security agreement with Comerica Bank, pursuant to which the Company has obtained a credit facility with Comerica Bank, consisting of a revolving line of credit in the amount of up to $5,000,000 and a term loan in the amount of up to $5,000,000. Interest on the revolving line and the term loan accrues at prime plus 2%. The revolving line and term loan mature on November 27, 2007 and 2010, respectively. The agreement requires the Company to meet certain liquidity ratios and imposes certain restrictions on mergers, acquisitions and distributions. In addition the Company granted the bank a warrant to purchase 120,000 shares of Series E preferred stock at $2.50. The fair value of the warrant plus the related beneficial conversion feature totaled $253,000, this amount plus an additional $54,000 of actual loan costs was recorded as debt discount and will be amortized over the life of the term loan using the effective interest method. The debt is secured by substantially all of the assets of the Company.

As of December 31, 2006, after giving effect to a 1- for- 4.25 reverse stock split of the Company s outstanding common stock and the conversion of all outstanding shares of the Company s preferred stock into common stock (taking into account the anti-dilution provisions of the Series B convertible preferred stock and the Series C-1 convertible preferred stock) in connection with the initial public offering of the Company s common stock, warrants to purchase 2,512,542 shares of the Company s common stock, at a weighted average exercise price of $7.03 were outstanding.

Common Shares Reserved for Issuance

The following table summarizes common shares reserved for future issuance on exercise or conversion of the following:

	December 31, 2005	December 31, 2006

Convertible preferred stock as adjusted for anti-dilution provisions in conjunction with Series B and Series C-1 shares issued	5,307,180	
Warrants for common and preferred stock	2,423,758	2,512,542
Common stock options outstanding previous to 2001 Plan	58,117	55,760
Common stock options outstanding under 2001 Plan	1,090,880	2,078,082
Common stock options available for future grant	1,256,176	3,661,341
Total common shares reserved for issuance	10,136,111	8,307,725

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8. Income Taxes

At December 31, 2006, the Company had federal and California tax net operating loss carryforwards of approximately $62,000,000 and $62,000,000, respectively. The federal and state tax loss carryforwards begin to expire in 2019 and 2009, respectively, unless previously utilized.

Pursuant to Internal Revenue Code Sections 382 and 383, use of the Company s net operating loss and tax credit carryforwards may be subject to an annual limitation if cumulative changes in ownership of more than 50% occur within a three-year period.

Significant components of the Company s deferred tax assets are shown below. A valuation allowance has been established to offset the U.S. deferred tax assets, as realization of such assets has not met the more likely than not threshold required under SFAS No. 109.

	December 31,	
	2005	2006
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 17,146	$ 24,885
Reserves and other	2,200	3,840
Total deferred tax assets	19,346	28,725
Valuation allowance for deferred tax assets	(19,346)	(28,447)
		278
Deferred tax liabilities:		
Foreign intangible	(1,831)	(1,368)
Other	(15)	(278)
Total deferred tax liabilities	(1,846)	(1,646)
Net deferred tax liabilities	$ (1,846)	$ (1,368)

The components of the benefit (expense) for income taxes are as follows (in thousands):

	Years Ended December 31,		
	2004	2005	2006
Current:			

Federal	$	$	$
State			
Foreign	(43)	(37)	
	(43)	(37)	
Deferred:			
Federal			
State			
Foreign	497	495	476
	497	495	476
	$ 454	$ 458	$ 476

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Reconciliation of the statutory federal income tax benefit to the Company s effective tax benefit (in thousands):

	December 31,		
	2004	2005	2006
Tax benefit at federal statutory rate	$ 4,365	$ 7,718	$ 9,114
State, net of federal benefit	749	1,324	1,541
Tax credits			308
Foreign tax	454	458	476
Change in valuation allowance excluding change applicable to purchased intangibles	(4,034)	(8,202)	(9,101)
Change in valuation allowance applicable to purchased intangibles	84	5	
Other foreign loss	(452)	(457)	(408)
Other permanent differences	(712)	(388)	(1,454)
Benefit for income taxes	$ 454	$ 458	$ 476

9. Employee Benefit Plan

Effective January 1, 2000, the Company adopted a defined contribution 401(k) profit sharing plan (the Plan) covering substantially all employees that meet certain age requirements. Employees may contribute up to 100% of their compensation per year (subject to a maximum limit by federal law). The Plan does allow for employer matching. To date, no employer match has been made.

10. Related-Party Transactions

The Company receives services from entities affiliated with stockholders of the Company. The Company paid $0, $0, $0, and $389,000 during the years ended December 31, 2004, 2005, 2006, and for the period from August 24, 1999 (inception) through December 31, 2006, respectively, for those services.

During the year ended December 31, 2005, the Company paid $2,250,000 in payments to a related party under the Mediplant purchase agreement (see Note 3).

On December 30, 2005, the Company entered into an amendment of the 2005 Bridge Loan with an investor (see Note 6). Per the note amendment, the investor waived both its conversion and redemption options under the original note and extended the due date of the remaining outstanding principal. Three Company directors personally guaranteed the remaining outstanding principal under the amended note agreement. In exchange for the personal guarantees, the three Company directors were each granted 23,529 shares of common stock. At December 31, 2005, the common stock had not yet been issued and is included as common stock issuable in the 2005 consolidated balance sheet and the consolidated statement of stockholders equity. On January 3, 2006, the common shares were issued.

11. Subsequent Events

On January 31, 2007, the Company entered into a Confidential Settlement and Release of Claims Agreement whereby the Company is required to pay a cash settlement amount of $284,000. The amount was paid in full in February 2007. In addition to the cash settlement, the Company agreed to accelerate the vesting of certain stock options and warrants previously granted to the employee. The Company recorded a non-cash expense charge of $135,000 associated with the accelerated vesting of these options and warrants.

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Notes to Consolidated Financial Statements (Continued)

On January 10, 2007, the Company entered into a Confidential Settlement and Release of Claims Agreement whereby the Company is required to pay a cash settlement amount of $242,000. Of the $242,000, $39,000 was paid in 2006, $56,000 is due to be paid no later than March 31, 2007 and the balance of $147,000 will be paid monthly through October 2007. In addition to the cash settlement amount the Company agreed to accelerate the vesting of certain stock options previously granted to the employee. The Company recorded a non-cash expense charge of $116,000 associated with the accelerated vesting of these stock options.

On November 6, 2006, the Company filed a demand for arbitration with the American Arbitration Association against Melvin Ehrlich, who served as the Company s President and Chief Operating Officer from January 2004 to April 2004. The Company is seeking declaratory relief regarding the number of shares of common stock Mr. Ehrlich is entitled to purchase under a warrant issued to him in connection with his employment agreement. The parties have pursued a settlement of this action, and have negotiated the terms of a proposed settlement agreement in which the Company will pay Mr. Ehrlich $250,000 and issue Mr. Ehrlich 26,710 shares of common stock and a warrant to purchase 25,000 shares of common stock, at an exercise price of $8.07 per share. The settlement agreement contains a mutual release of claims and a mutual covenant not to sue. The settlement agreement is subject to approval by the Company s board of directors, and based on his age, Mr. Ehrlich will have up to seven days to revoke the settlement agreement after he signs it. The Company has made an accrual in the fourth quarter of the fiscal year ended December 31, 2006 based on the terms of the proposed settlement agreement.

12. Quarterly Information (Unaudited)

The following quarterly information includes all adjustments which management considers necessary for a fair statement of such information. For interim quarterly financial statements, the provision for income taxes is estimated using the best available information for projected results for the entire year.

	2006			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(In thousands, except per share data)			
Research and development	$ 2,949	$ 1,530	$ 1,219	$ 2,386
Selling, general and administrative	3,194	4,868	3,401	5,836
Loss from operations	(6,143)	(6,398)	(4,620)	(8,222)
Net loss	$ (7,981)	$ (6,186)	$ (4,402)	$ (7,754)
Net loss per share Basic and diluted	$ (6.14)	$ (4.59)	$ (3.17)	$ (2.32)
Shares used in calculating net loss per share Basic and diluted	1,300,634	1,347,993	1,387,036	3,348,081

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Notes to Consolidated Financial Statements (Continued)

	2005			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(In thousands, except per share data)			
Research and development	$ 1,557	$ 2,356	$ 2,841	$ 3,435
Selling, general and administrative	1,482	2,239	3,002	3,414
Loss from operations	(3,039)	(4,595)	(5,843)	(6,849)
Net loss	$ (4,516)	$ (5,620)	$ (6,729)	$ (5,378)
Net loss per share Basic and diluted	$ (3.96)	$ (4.78)	$ (5.61)	$ (4.44)
Shares used in calculating net loss per share Basic and diluted	1,139,497	1,176,822	1,200,269	1,210,372