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.