ARTES MEDICAL INC
Form 424B4
December 20, 2006

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Filed Pursuant to Rule 424(b)(4)
Registration No. 333-134086

PROSPECTUS

4,600,000 Shares
Common Stock

Prior to this offering, there has been no public market for our common stock. The initial public offering price of our common stock is $6.00 per share. Our common stock has been approved for quotation on the Nasdaq Global Market under the symbol ARTE.

We have granted the underwriters an option to purchase, on the same terms and conditions set forth below, a maximum of 690,000 additional shares if the underwriters sell more than 4,600,000 shares in this offering.

Certain of our existing stockholders have indicated an interest in purchasing up to approximately 800,000 shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, our underwriters may determine not to sell shares in this offering to our existing stockholders, or our stockholders may decide not to purchase shares in this offering.

Investing in our common stock involves risks. See Risk Factors beginning on page 9.

	Price to Public	Underwriting Discounts and Commissions	Proceeds to Artes Medical, Inc.
Per share	$6.00	$0.42	$5.58
Total	$27,600,000	$1,932,000	$25,668,000

Delivery of the shares of common stock will be made on or about December 26, 2006.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Cowen and Company Lazard Capital Markets

Stifel Nicolaus

The date of this prospectus is December 19, 2006.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate as of the date on the front cover of this prospectus only, regardless of the time of delivery of this prospectus or of any sale of our common stock. Our business prospects, financial condition and results of operations may have changed since that date.

No action is being taken in any jurisdiction outside of the United States to permit a public offering of the common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in any jurisdiction outside of the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

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PROSPECTUS SUMMARY

This prospectus summary highlights selected information appearing elsewhere in this prospectus. Because this is only a summary, it does not contain all the information that may be important to you. You should carefully read this prospectus in its entirety before investing in our common stock, especially the risks of investing in our common stock, which we discuss later in Risk Factors, and our financial statements and related notes beginning on page F-1. Unless the context requires otherwise, the words Artes, we, the *Company, us and our refer to Artes Medical, Inc. and our subsidiary, Artes Medical Germany GmbH (formerly MediPlant GmbH Biomaterials & Medical Devices).*

Artes Medical, Inc.

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 U.S. Food and Drug Administration, or 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 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 are currently conducting ongoing evaluations of the patients who received ArteFill in our U.S. clinical trial and qualify for long-term follow-up. The evaluation of the first 69 patients indicates that these patients have experienced sustained aesthetic improvement five years after their initial treatment with ArteFill and have expressed high levels of satisfaction with their ArteFill treatment. The lead investigator in our U.S. clinical trial presented the preliminary findings of our five-year follow-up patient evaluations, which included the results of evaluations for these 69 patients, at a conference of the American Society of Plastic Surgeons held in San Francisco, California in October 2006. The interim data have also been published in the September 1, 2006 supplement to *Plastic and Reconstructive Surgery*, a peer-reviewed journal.

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We intend to commence commercial shipments of ArteFill during the first quarter of 2007. We plan to sell ArteFill to dermatologists, plastic surgeons and cosmetic surgeons in the United States primarily through a direct sales force initially comprised of up to 25 sales professionals. We initially intend to target dermatologists, plastic surgeons and cosmetic surgeons whom we have identified as having performed a large 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 who are concentrated in major urban centers in the United States. In connection with our product launch, we will train physicians in the technique of injecting ArteFill with the goal of optimizing patient and physician satisfaction with our product. After establishing ArteFill in the United States, we plan to explore opportunities to register and sell ArteFill in selected international markets.

Injectable Aesthetic Market Opportunity

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, injectable aesthetic treatments are the largest and 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 2005, approximately 4.9 million injectable aesthetic procedures were performed in the United States, and U.S. consumers spent approximately $2.2 billion on injectable aesthetic treatments. Based on market research conducted by Medical Insight, Inc., we believe that physicians purchased approximately $600 million of injectable aesthetic products for these treatments. Most aesthetic procedures are considered elective procedures, the cost of which must be paid for directly by patients, and are not reimbursable through government or private health insurance.

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. However, the substances contained in these products are completely metabolized and absorbed by the body over time, resulting in significant limitations, including:

- repeat injections required for patients to sustain aesthetic benefits;
- cumulative cost of repeat injections;
- risk to physician practices of patient attrition; and
- limited utility in conjunction with aesthetic surgical procedures.

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 this projected growth is based in part on the introduction of new longer-lasting products, an increasing demand for minimally invasive and cost-effective treatments that offer immediate results, a favorable demographic shift due to the aging of the baby boomers, and a growing emphasis on self-image driven by the media and an increasingly youth-oriented culture.

ArteFill Our Injectable Aesthetic Product

ArteFill is a novel and proprietary aesthetic injectable implant for the correction of nasolabial folds, or smile lines. In October 2006, the FDA approved ArteFill for commercial sale in the United States. 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 comprised of a proprietary combination of PMMA microspheres and purified bovine collagen. Following injection, the microspheres remain intact at the injection site and provide a permanent support structure to fill in the

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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 believe that ArteFill will offer the following benefits:

- enduring aesthetic improvements;
- compelling value proposition to patients;
- high levels of patient satisfaction;
- differentiated, high value product for physician practices; and
- complement to surgical and non-surgical aesthetic treatments.

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;
- provide physicians with comprehensive education and training programs;
- drive the adoption of ArteFill through a direct sales and marketing effort; and
- expand our product offering by acquiring complementary products, technologies or businesses.

Risks Associated with Our Business

Our business is subject to numerous risks, as discussed more fully in the section entitled Risk Factors immediately following this prospectus summary. From inception through September 30, 2006, we had an accumulated deficit of approximately $71.6 million. We expect to continue to incur significant losses in the future as we commercialize ArteFill, and we may never generate sufficient revenues to achieve or sustain profitability. Because we have limited operating experience and plan to enter into the rapidly evolving market for injectable aesthetic products, we may not be able to successfully predict or react to relevant industry developments and business trends. Although the FDA has approved ArteFill for sale in the United States, we will not be able to achieve our business objectives if we cannot effectively build and use our sales and marketing organization to achieve sufficient market acceptance of ArteFill. We also face significant competition from companies with greater resources and well-established sales channels, which may make it difficult for us to achieve market penetration. In addition, ArteFill will be subject to ongoing regulatory review, and any failure to comply with continuing regulation by the FDA or other regulatory bodies could subject ArteFill to a product recall or other regulatory action, which would seriously harm our business.

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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 prospectus.

Artes Medical®, Artes®, our logo, ArteFill®, The Art of Soft Tissue Augmentation™, The First to Last™, 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 prospectus are the property of their respective owners.

This prospectus 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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The Offering

Common stock offered by us	4,600,000 shares
Common stock to be outstanding after this offering	15,634,343 shares
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $21.9 million, or approximately $25.7 million if the underwriters exercise their over-allotment option in full, based on the initial public offering price of $6.00 per share. We intend to use the net proceeds from this offering to build our sales and marketing organization and implement promotional and advertising campaigns related to the commercial launch of ArteFill; to conduct our long-term, post-market safety study of ArteFill; to further automate and expand capacity at our manufacturing facilities; and to conduct further studies to evaluate the feasibility, safety and efficacy of ArteFill for other aesthetic applications. We intend to use the remainder of the net proceeds from this offering for working capital and for other general corporate purposes. See Use of Proceeds.
Nasdaq Global Market symbol	ARTE

The number of shares of our common stock to be outstanding immediately after this offering is based on:

- 10,758,441 shares of common stock outstanding as of September 30, 2006 after giving effect to the conversion of all outstanding shares of our preferred stock into 9,367,511 shares of common stock, which will become effective at the closing of this offering;
- 107,754 shares of our common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, at a weighted average exercise price of $5.58 per share, which the warrant holders have elected to exercise in cash, contingent and effective upon the closing of this offering; and
- 168,148 shares of our common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, which the warrant holders have elected to exercise through a cashless exercise provision of the warrants, contingent and effective upon the closing of this offering, based on the initial public offering price of $6.00 per share. No shares of common stock will be issued to warrant holders who have elected to exercise their warrants through cashless exercise provisions if the exercise price of their warrants exceeds the initial public offering price of $6.00 per share. If not exercised through a cashless exercise, these warrants would have been exercisable for 767,583 shares of common stock, at a weighted average exercise price of $5.47 per share.

The number of shares of our common stock outstanding immediately after this offering excludes:

- 1,869,676 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2006, at a weighted average exercise price of $5.85 per share;
- 335,246 shares of our common stock issuable upon the exercise of outstanding stock options granted after September 30, 2006, at a weighted average exercise price of $10.63 per share;
- 3,640,843 shares of our common stock available for future grant under our 2006 Equity Incentive Plan, which number excludes the cancellation of 121,355 outstanding stock options canceled after September 30, 2006, at a weighted average exercise price of $6.30 per share, which will become effective upon the closing of this offering, and the annual increases in the number of shares authorized under this plan beginning January 1, 2007;

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2,490,189 shares of our common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, at a weighted average exercise price of $6.98 per share; and

28,235 shares of common stock issuable upon the exercise of a preferred stock warrant granted after September 30, 2006, at an exercise price of $10.63 per share.

Unless otherwise indicated, all information in this prospectus assumes:

that the underwriters do not exercise their option to purchase up to 690,000 additional shares of our common stock to cover over-allotments, if any;

the completion of a 1-for-4.25 reverse split of our outstanding common stock immediately before the closing of this offering;

the conversion, upon the closing of this offering, of all of the outstanding shares of preferred stock into 9,367,511 shares of common stock;

no options, warrants or shares of common stock were issued after the date of this prospectus, and no outstanding options or warrants were exercised after September 30, 2006;

the amendment and restatement of our certificate of incorporation and bylaws, which will become effective at the closing of this offering;

the adoption of our 2006 Equity Incentive Plan, which will become effective upon the closing of this offering; and

that none of the estimated offering expenses payable by us on the closing of this offering have been paid. However, as of September 30, 2006, we have paid in cash approximately $2.7 million of these expenses.

Certain of our existing stockholders have indicated an interest in purchasing up to approximately 800,000 shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, our underwriters may determine not to sell shares in this offering to our existing stockholders, or our stockholders may decide not to purchase shares in this offering.

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Summary Consolidated Financial Data

The following summary consolidated financial data should be read in conjunction with Selected Consolidated Financial Data, 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 prospectus. We derived the summary consolidated statements of operations data for the years ended December 31, 2003, 2004 and 2005 and the summary consolidated balance sheet data as of December 31, 2005 from our audited consolidated financial statements included elsewhere in this prospectus. The summary consolidated financial data at September 30, 2006 and for the nine months ended September 30, 2005 and 2006 are derived from our unaudited consolidated financial statements, which are included elsewhere in this prospectus. Our historical results are not necessarily indicative of our future results.

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
	(in thousands, except per share data)			(unaudited)	
Consolidated Statements of Operations Data:					
Expenses:					
Research and development	$ 974	$ 3,634	$ 10,189	$ 6,754	$ 5,698
Selling, general and administrative	2,976	5,155	10,137	6,723	11,463
Total expenses	3,950	8,789	20,326	13,477	17,161
Loss from operations	(3,950)	(8,789)	(20,326)	(13,477)	(17,161)
Interest expense, net	(2,170)	(4,028)	(4,416)	(3,518)	(1,907)
Other income (expense), net		(22)	2,041	(11)	351
Loss before benefit for income taxes	(6,120)	(12,839)	(22,701)	(17,006)	(18,717)
Benefit for income taxes		454	458	141	148
Net loss	$ (6,120)	$ (12,385)	$ (22,243)	$ (16,865)	$ (18,569)
Historical net loss per common share:					
Basic and diluted	$ (5.76)	$ (11.20)	$ (18.76)	$ (14.38)	$ (13.81)
Weighted average shares - basic and diluted	1,062,825	1,106,188	1,185,387	1,172,419	1,344,503
Pro forma net loss per common share (unaudited):					
Basic and diluted			$ (5.15)		$ (1.88)
Weighted average shares - pro forma basic and diluted (unaudited)			4,319,411		9,885,002

Stock-based compensation is included in the following categories:

Capitalized to inventory	$	$	$	$	$ 214
Research and development		91	256	113	267
Selling, general and administrative	159	1,042	1,038	389	1,324
	$ 159	$ 1,133	$ 1,294	$ 502	$ 1,805

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The following table presents a summary of our consolidated balance sheet as of September 30, 2006:

on an actual basis;

on a pro forma as adjusted basis to give effect to the conversion of all outstanding shares of convertible preferred stock, as of September 30, 2006, into shares of common stock; the issuance of 107,754 shares of our common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, at a weighted average exercise price of $5.58 per share, which the warrant holders have elected to exercise in cash, contingent and effective upon the closing of this offering; the issuance of 168,148 shares of our common stock upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, which the warrant holders have elected to exercise through a cashless exercise provision of the warrants, contingent and effective upon the closing of this offering, based on the initial public offering price of $6.00 per share; and the sale of the shares of our common stock we are offering in this offering at the initial public offering price of $6.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

	As of September 30, 2006	
	Actual	Pro forma as adjusted
	(in thousands) (unaudited)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents(1)	$ 12,789	$ 34,683
Working capital	12,403	34,297
Total assets	29,745	51,639
Current portion of capital lease obligations	44	44
Long-term debt and capital lease obligations, less current portion(2)	31	31
Convertible preferred stock	38	
Common stock	1	16
Additional paid-in capital	94,144	116,061
Deficit accumulated during the development stage	(71,648)	(71,648)
Total stockholders equity	22,535	44,429

(1) The pro forma as adjusted amount does not include the impact of approximately $2.7 million of estimated offering costs already paid in cash by us as of September 30, 2006.

(2) The pro forma as adjusted amount does not include the draw down of $5.0 million under the Company s term loan credit facility, which occurred in November 2006. See Note 11 of Notes to Consolidated Financial Statements.

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RISK FACTORS

Any investment in our common stock involves a substantial risk of loss. You should consider carefully the risks and uncertainties described below, together with all the other information contained in this prospectus, before you decide whether to purchase our common stock. The risks and uncertainties described below are not the only ones we face. Our business, financial condition or results of operations could be materially harmed by any of these risks. In that case, the trading price of our common stock could decline, and you may lose part or all 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 currently have no products in commercial distribution. We received FDA approval to market ArteFill on October 27, 2006, and we intend to commence 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 revenues to date. 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 $18.6 million for the nine months ended September 30, 2006. At September 30, 2006, we had an accumulated deficit of approximately $71.6 million. For the nine months ended September 30, 2006, we used net cash in operating activities of $16.5 million. We will need to incur significant sales, marketing and manufacturing expenses in connection with the commercial launch 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. Before investing, you should consider an investment in our stock in light of the risks, uncertainties and difficulties frequently encountered by early-stage companies in new and rapidly evolving markets such as ours. We may not be able to successfully address any or all of these risks. 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;
- 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

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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 not 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 to commercialize 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, our former Chief Scientific Officer and a former member of our board of directors, informed us that his counsel had contacted an investigator in the FDA s Office of Criminal Investigations to determine whether any investigation of Dr. Gottfried Lemperle was ongoing. In March 2006, Dr. Gottfried Lemperle s counsel informed us that an investigator at the FDA 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.

To our knowledge, prior to or following this inquiry, neither Dr. Gottfried Lemperle, Dr. Stefan Lemperle nor any of our current officers or directors has 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 following correspondence from and to 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. In addition, we 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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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. Artecoll has been manufactured and sold by unrelated third parties outside the United States under a CE mark since 1996. In 2004, we acquired all worldwide intellectual property rights related to Artecoll and a facility used to produce PMMA microspheres. Following this acquisition, we requested these third parties to cease manufacturing and distributing their product named Artecoll. We have never manufactured, sold or received any revenues from Artecoll. We initially named the product used in our clinical trials as Artecoll, but later changed the name of our product candidate to ArteFill to reflect refinements that we have made to the PMMA microsphere manufacturing process following our acquisition of the rights to Artecoll.

We also stated in our correspondence to the FDA that we found no evidence that any of the Artecoll used in the U.S. clinical study was used improperly before or after receipt of the approvable letter from the FDA in January 2004. We also informed the FDA that we could not conclusively determine the source of the Artecoll used on the four individuals, that Dr. Gottfried Lemperle s use of Artecoll was not part of a study or any activity sponsored by us and that Dr. Gottfried Lemperle had resigned from his position as Chief Scientific Officer and as a member of our board of directors. In addition to our correspondence to the FDA, we also informed the FDA of these matters during its inspection of our manufacturing facilities in San Diego, California in April 2006. In May 2006, we received the FDA s Establishment Inspection Report, or 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. In May 2006, we terminated Dr. Gottfried Lemperle s consulting relationship with us. Dr. Gottfried Lemperle no longer provides services to us in any capacity.

In July 2006, the FDA requested us to submit an amendment to our pre-market approval, or PMA, 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. The FDA requested our periodic update to include, among other things, all information available to us regarding individuals who had been treated with Artecoll outside our clinical trials and any adverse events these individuals had experienced. 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, our then-serving Chief Executive Officer and director, had been injected with Artecoll in the United States in 2004 by his father, Dr. Gottfried Lemperle. Prior to the time we conducted the additional inquiries to prepare our periodic update for the FDA, Dr. Stefan M. Lemperle had failed to disclose to us, or to the FDA, that he had been injected with Artecoll in contravention of FDA rules and regulations. In October 2006, our board of directors removed Dr. Stefan Lemperle from the position of Chief Executive Officer, and in November 2006, Dr. Stefan Lemperle resigned as a director and employee. Dr. Stefan Lemperle no longer provides services to us in any capacity. We received FDA approval to market ArteFill on October 27, 2006.

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

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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;

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 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 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

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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™, which is approved by the FDA for vocal cord augmentation, radiographic tissue marking and the treatment of oral and maxillofacial defects, or the loss of facial structure and skin tissue, and is currently under review by the FDA for other uses, including aesthetic applications; 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 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.

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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 case was dismissed on June 5, 2006, and the plaintiff is allowed to refile the case at any time within 18 months from that date. See Business Legal Proceedings.

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 the 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 the 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 the Company, who could bring similar claims against the Company.

To limit our product liability exposure, we have decided to restrict sales of ArteFill to physicians who have successfully completed our physician training program. We cannot provide any assurance that such a training program will help avoid complications resulting from the administration of ArteFill. In addition, although we plan 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 currently maintain limited product liability insurance in an amount of up to $5 million per incident and as of December 1, 2006 we will have additional coverage of $20 million per incident, but any insurance we obtain may not provide adequate coverage against any asserted claims. In addition, such additional insurance may not 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 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;

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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 a sophisticated sales and marketing organization.

We have no prior experience with commercializing any product, and we will need to deploy a sophisticated sales and marketing organization in order to successfully commercialize ArteFill. We are building a direct sales force to be comprised of up to 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 all sales representatives will need to undergo extensive training. We anticipate that it will take up to six months for our sales representatives to achieve full productivity. We will need to incur significant costs to build 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 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. We plan to manufacture ArteFill in commercial quantities at our facility in San Diego, California. We currently manufacture the PMMA microspheres used in ArteFill at our facility in Frankfurt, Germany and intend to implement redundant capabilities for the production of PMMA microspheres at our San Diego facility. 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 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

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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 intend to provide training to physicians in order to ensure that they are trained to inject ArteFill using the tunneling injection technique, and plan 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. Side effects that may occur as a result of improper injection technique include:

swelling or redness;

lumpiness at the injection site; and

the development of a granuloma, or an inflammatory reaction to a foreign body that results in redness and hardening of tissue at the injection site.

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;

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.

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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.

ArteFill is not yet supported by long-term clinical data and may therefore prove to be less effective than initially thought.

We currently lack published long-term clinical data for completed trials supporting the aesthetic benefits of ArteFill beyond six months. We are currently conducting ongoing, five-year follow-up evaluations of patients who received ArteFill in our U.S. clinical trial and who qualify for long-term follow-up. When completed, we intend to submit the results of these five-year follow-up evaluations to the FDA and to a peer-reviewed scientific journal for publication. Dr. Steven Cohen, the lead investigator in our U.S. clinical trial, presented the 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. The interim data for the 69 patients have also been published in the September 1, 2006 supplement to *Plastic*

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and Reconstructive Surgery, a peer-reviewed journal. There can be no assurance that we will be successful in obtaining FDA approval to claim that the aesthetic benefits of ArteFill extend beyond six months.

In addition, without published peer-reviewed data for completed trials regarding the safety and efficacy of 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 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 November 27, 2006, we have increased the size of our company from 12 to 109 employees. 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 internal sales force and sales management to market ArteFill. Thereafter, 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 after we become subject to those requirements. 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.

Under the label approved by the FDA, we are limited to marketing and advertising ArteFill for the treatment of nasolabial folds with efficacy benefits of six months.

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 we wish to market and promote ArteFill for other indications or claim efficacy benefits beyond six months, we would have to conduct further clinical trials or studies to gather clinical information for the FDA, which would be costly and take a number of years. Even if we submitted additional clinical data to the FDA to support other PMA applications or additional follow-up study data to support extended efficacy claims, there can be no assurance that we would be successful in obtaining approval to market ArteFill for other indications or to claim efficacy benefits beyond six months. In addition, we will not be 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.

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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 will be 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.

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 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 Product Development and 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 our former officers and employees 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 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 us to satisfy the milestones set forth in the warrant. We reject this interpretation

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of the warrant and plan to pursue our request for declaratory relief vigorously and to defend against any claims Mr. Ehrlich asserts.

Following discussions at a series of weekly board meetings in October 2006, our board approved a plan on October 26, 2006 to reduce our operating costs and to reorganize our business operations, including our sales and marketing organization, to focus our efforts on the U.S. market and on physician-based training and sales programs. In connection with this cost reduction plan and reorganization, we terminated the employment of William von Brendel, our former Vice President of Worldwide Sales and International Markets, Harald T. Schreiber, our former Chief Creative Officer, and a manager in our sales and marketing organization on October 27, 2006. In connection with their termination, we believe we have paid all amounts owed to Messrs. von Brendel and Schreiber under the terms of their employment agreements. On the date of their termination, we also offered to pay Messrs. von Brendel and Schreiber three months severance and to extend the expiration date of their respective stock options from 90 days to one year after the date of termination of their employment, in exchange for their execution of a general release.

On November 2, 2006, we were served with a demand for arbitration with the American Arbitration Association by Mr. Schreiber pursuant to the dispute resolution provisions in his employment agreement. Mr. Schreiber seeks compensatory damages of an unspecified amount and alleges several causes of action, including wrongful termination, fraud, breach of contract and the implied covenant of good faith and fair dealing, and hostile work environment. We believe that many of Mr. Schreiber s claims contradict the terms of his employment agreement, and we deny his allegations. To avoid the costs of arbitration, we have issued a settlement offer to Mr. Schreiber. There can be no assurance that our offer will be acceptable to Mr. Schreiber, or that we will reach a settlement with Mr. Schreiber. If we do not reach an agreement with Mr. Schreiber, we will defend the case vigorously.

On November 16, 2006, we were served with a demand for arbitration with the American Arbitration Association by Mr. von Brendel pursuant to the dispute resolution provisions in his employment agreement. Mr. von Brendel seeks compensatory damages of an unspecified amount and alleges various causes of action, including wrongful termination and breach of contract, fraud and the implied covenant of good faith and fair dealing. We deny Mr. von Brendel s allegations and believe that many of his claims contradict the terms of his employment agreement. To avoid the costs of arbitration, we have issued a settlement offer to Mr. von Brendel. There can be no assurance that our offer will be acceptable to Mr. von Brendel, or that we will reach an agreement with Mr. von Brendel. If we do not reach an agreement with Mr. von Brendel, we will defend the case vigorously.

We maintain employment practices liability insurance in an amount of up to $2.0 million in the aggregate for claims made during any one-year insurance period. Our insurance carrier has agreed to provide coverage and defense for these actions, subject to customary reservation of rights. We cannot assure you that our insurance carrier will provide coverage for all outstanding claims, or any employment-related claims asserted in the future based on our recent management changes, or that any coverage will be adequate to cover these claims. In addition, regardless of merit or eventual outcome, our existing actions, and any potential actions resulting from our recent management changes, may result in the expenditure of a significant amount of cash on legal fees, expenses, payment of settlements or damages. Further, these actions 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 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.

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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, 2005, 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 date of our initial public offering if not exercised prior, and to allow the warrants to continue in effect under their existing terms until March 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 date of our public offering if not exercised prior, and to allow the warrants to continue in effect under the terms of the original warrants. The warrant holders were given the option to amend their warrants until June 23, 2006. Based on the preferences of our warrant holders, we recorded a warrant modification expense of $1,376,000 during the nine months ended September 30, 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. As a result of these amendments, warrants to purchase approximately 2,490,189 shares of common stock will be outstanding after completion of our initial public offering. 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.

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

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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 prospectus. 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 January 1, 2006 through September 30, 2006 was $8,763,600. 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 nine months ended September 30, 2006 was $749,000. 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 September 30, 2006, the net acquired intangible assets comprised approximately 13.0% 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 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

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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. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our confidential information, and failure to maintain the confidentiality of our

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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. While these products are currently approved only for vocal cord augmentation, radiographic tissue marking and the treatment of oral and maxillofacial defects in the United States, we believe that Radiesse is under review by the FDA for the treatment of facial wrinkles and is available for such use outside the United States. If BioForm obtains FDA approval to develop, market and sell Radiesse, Coaptite or any other CaHA implant product for indications similar to ArteFill, our ability to generate revenues from sales of ArteFill may be impaired. 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 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 and the Netherlands have in the past, and may be currently, manufacturing and selling products for the treatment of facial wrinkles under the name Artecoll 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.

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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;
- 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

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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;
- 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.

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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 regrading our capitalization may not have 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 you may not be able to sell your shares at or above the initial offering price.

Prior to this offering, 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 following this offering. The market price for our common stock may decline below the initial public offering price and our stock price is likely to be volatile. You may not be able to sell your shares at or above the initial public offering price. 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;

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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.

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.

We will have broad discretion in how we use the net proceeds from this offering, and we may not use them effectively.

Our management will have considerable discretion in the application of the net proceeds of the offering. We currently intend to use the net proceeds from this offering to fund expenses related to building our sales and marketing organization and implementing promotional and advertising campaigns related to the commercial launch of ArteFill, conducting our long-term, post-market safety study of approximately 1,000 patients treated with ArteFill, further automating and expanding capabilities at our manufacturing facilities and conducting further studies to evaluate the feasibility, safety and efficacy of ArteFill for other aesthetic applications and use in aesthetic reconstructive surgery, and for working capital and general corporate purposes. We may also use a portion of the net proceeds to acquire or to invest in businesses, products or technologies that we believe are complementary to our own, or to obtain the right to use such complementary technologies. However, our plans may change and we could spend the net proceeds in ways that do not necessarily enhance the value of our common stock.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

If you purchase shares in this offering, the value of your shares based on our actual book value will immediately be less than the offering price you paid. This reduction in the value of your equity is known as dilution. This dilution occurs in large part because our earlier investors paid substantially less than the initial public offering price when they purchased their shares. Investors purchasing common stock in this offering will, therefore, incur immediate dilution of $3.41 in net tangible book value per share of common stock, based on the initial public offering price of $6.00 per share. Investors may incur additional dilution upon the exercise of outstanding stock options and outstanding warrants. In addition, if we raise funds by issuing additional securities, the newly issued shares will further dilute your percentage ownership of our company.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. If there are substantial sales of our common stock, the price of our common stock could decline.

Sales of substantial amounts of our common stock in the public market after the offering could adversely affect the price of our common stock. After this offering, we will have 15,634,343 shares of common stock outstanding. All of the shares offered under this prospectus will be freely tradable without restriction or further registration under the federal securities laws, unless purchased by our affiliates as that term is defined in Rule 144 under the Securities Act of 1933. The remaining 11,034,343 shares outstanding upon the closing of this offering may be sold pursuant to Rule 144, 144(k) or 701 of the Securities Act, unless the holders of these shares are subject to the lock-up agreements, or other contractual arrangements, discussed below. The holders of an aggregate of 11,606,882 shares of our outstanding common stock and shares of common stock issuable upon the exercise of outstanding warrants will have rights to cause us to file a registration statement on their behalf and to include their shares in registration statements that we may file on behalf of other stockholders. Sales by our current stockholders of a substantial number of shares after this offering, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. After the completion of this offering, substantially all of our current stockholders will be bound by a 180-day lock-up agreement, or other contractual

arrangements, that prohibits these holders from selling or transferring their stock for 180 days following the offering, other than in specific circumstances. However, Cowen and Company, LLC and Lazard Capital Markets LLC, on behalf of the underwriters, at their discretion, can waive the restrictions of the lock-up agreement, and we can waive the restrictions of the contractual arrangements, at an earlier time without prior notice or announcement and allow our stockholders to sell their shares of our common stock in the public market. If the restrictions of the lock-up agreement, or other contractual arrangements, are waived, shares of our common stock will be available for sale into the market, subject only to applicable securities rules and regulations, which may cause our stock price to decline. The lock-up agreements with the underwriters are subject to limited extension under certain circumstances if analysts publish reports about our company or we make announcements about our business within 15 days of expiration of the lock-up. In addition, certain of our directors and executive officers may choose to establish programmed selling plans under Rule 10b5-1 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, for the purpose of effecting sales of common stock after the expiration of the lock-up period.

Promptly following this offering, we intend to register approximately 5.7 million shares of common stock that underlie outstanding stock options or are authorized for issuance under our employee benefit plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to vesting provisions, restrictions under the securities laws and the lock-up agreements, or other contractual arrangements, described above. If any of our stockholders cause a large number of securities to be sold in the public market, the sales could reduce the trading price of our common stock. These sales also could impede our ability to raise capital in the future.

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

As of September 30, 2006, we had reserved approximately 4.9 million shares of our common stock for potential issuance upon the exercise of warrants and options (including outstanding warrants to purchase preferred stock and 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 30.8% of our common stock on a fully diluted basis (assuming the conversion into common stock of all outstanding preferred stock and the exercise of all outstanding warrants and options). Of the 4.9 million shares of common stock reserved at September 30, 2006, 1.9 million shares of common stock are reserved for outstanding stock options at a weighted average exercise price of $5.85 per share; 2.5 million shares of common stock are reserved for outstanding warrants to purchase preferred stock and 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 $6.98 per share (on an as-converted to common stock basis); and 0.5 million shares of common stock are reserved for future stock option grants under our 2001 Plan. In addition, we have reserved 3,640,843 shares of our common stock for future grant under our 2006 Equity Incentive Plan, which will become effective upon the closing of this offering. 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 that we intend to adopt prior to the completion of this offering 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;

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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.

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business, contains forward-looking statements. The words may, continue, estimate, intend, plan, will, believe, project, expect, could, would, anti expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. These forward-looking statements include, among other things, statements about:

- our ability to establish and maintain the sales and marketing organization required for successful commercialization of ArteFill;
- the timing of our commercial shipments of ArteFill, including our shipments of the skin tests required before treatment with ArteFill;
- our ability to achieve and maintain market acceptance of ArteFill among physicians and patients;
- our projected expenditures on sales and marketing, manufacturing, physician training and support, and research and development activities;
- the comparative advantages of ArteFill over temporary muscle paralytics, temporary dermal fillers and other competing products or treatments;
- our ability to successfully complete our five-year post-market safety study of ArteFill and a post-market study regarding the incidence of allergic reactions to the bovine collagen used in ArteFill;
- our ability to expand our supply of calf hides for purposes of producing our bovine collagen;
- our existing stockholders willingness to purchase up to approximately 800,000 shares of our common stock in this offering at the initial public offering price;
- our ability to establish, maintain and protect our intellectual property rights in ArteFill and our other proprietary technologies; and
- our anticipated use of the proceeds from this offering and our estimates regarding anticipated operating expenses, future revenues from the commercialization of ArteFill and our capital requirements.

Any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. We have based these forward-looking statements on our current assumptions and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. They may be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions described in Risk Factors. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur as contemplated, and our actual results could differ materially from those anticipated or implied by the forward-looking statements.

These forward-looking statements speak only as of the date of this prospectus. Unless required by law, we do not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See Where You Can Find More Information.

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USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the 4,600,000 shares of common stock we are offering will be approximately $21.9 million, based on the initial public offering price of $6.00 per share, after deducting underwriting discounts and commissions and the estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate the net proceeds to us from this offering will be approximately $25.7 million, based on the same assumptions.

Of the net proceeds we will receive in this offering, we expect to use approximately:

- $12.0 million to build our sales and marketing organization and implement promotional and advertising campaigns related to the commercial launch of ArteFill;
- $5.0 million to conduct our long-term, post-market safety study of approximately 1,000 patients treated with ArteFill, as a condition of regulatory approval;
- $2.5 million to further automate and expand capacity at our manufacturing facilities; and
- $2.0 million to conduct further studies 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 intend to use the remainder of our net proceeds for working capital and general corporate purposes. We may also use a portion of our net proceeds to acquire or to invest in businesses, products or technologies that we believe are complementary to our own, or to obtain the right to use such complementary technologies. We currently have no commitments with respect to any acquisition or investment.

The amounts and timing of our actual expenditures may vary significantly depending upon numerous factors, including the timing of our initial commercial shipments of ArteFill, the progress of our commercialization efforts, and our operating costs and capital expenditures. We will retain broad discretion in the allocation of the net proceeds of this offering, and we reserve the right to change the specific allocation of use of these proceeds. Pending use of the net proceeds from this offering, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade securities. We cannot predict whether the proceeds invested will yield favorable returns. We believe that our available cash, together with the net proceeds of this offering and the funds available under our credit facility, will be sufficient to meet our capital requirements for at least the next 12 months.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock and we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the operation and expansion of our business. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that our board of directors may deem relevant.

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CAPITALIZATION

The following table summarizes our capitalization as of September 30, 2006:

- on an actual basis; and
- on a pro forma as adjusted basis to give effect to the conversion of all outstanding shares of convertible preferred stock as of September 30, 2006 into shares of common stock; the issuance of 107,754 shares of our common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, at a weighted average exercise price of $5.58 per share, which the warrant holders have elected to exercise in cash, contingent and effective upon the completion of this offering; the issuance of 168,148 shares of our common stock upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, which the warrant holders have elected to exercise through a cashless exercise provision of the warrants, contingent and effective upon the completion of this offering, based on the initial public offering price of $6.00 per share; and the sale of the shares of our common stock we are offering in this offering at the initial public offering price of $6.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the following table in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations, Description of Capital Stock and our financial statements and related notes appearing elsewhere in this prospectus.

	As of September 30, 2006	
	Actual	Pro forma as adjusted
	(in thousands, except share and par value data)	
Long-term obligations, less current portion(1)	$ 31	$ 31
Stockholders equity:		
Convertible preferred stock, $0.001 par value: 50,000,000 shares authorized, actual; 10,000,000 shares authorized pro forma as adjusted; 37,891,897 shares issued and outstanding, actual; no shares issued and outstanding, pro forma as adjusted	38	
Common stock, $0.001 par value: 150,000,000 shares authorized, actual; 200,000,000 shares authorized pro forma as adjusted; 1,390,930 shares issued and outstanding, actual; and 15,634,343 shares issued and outstanding pro forma as adjusted	1	16
Additional paid-in capital	94,144	116,061
Deficit accumulated during the development stage	(71,648)	(71,648)
Total stockholders equity	22,535	44,429
Total capitalization	$ 22,566	$ 44,460

(1) The pro forma as adjusted amount does not include the draw down of $5 million under the Company s term loan credit facility, which occurred in November 2006. See Note 11 of Notes to the Consolidated Financial Statements.

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The above table is based upon shares outstanding as of September 30, 2006 and excludes:

1,869,676 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2006, at a weighted average exercise price of $5.85 per share;

335,246 shares of our common stock issuable upon the exercise of outstanding stock options granted after September 30, 2006, at a weighted average exercise price of $10.63 per share;

3,640,843 shares of our common stock available for future grant under our 2006 Equity Incentive Plan, which will become effective upon the closing of this offering, and the annual increases in the number of shares authorized under this plan beginning January 1, 2007;

2,490,189 shares of our common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, at a weighted average exercise price of $6.98 per share; and

28,235 shares of common stock issuable upon the exercise of a preferred stock warrant granted after September 30, 2006 at an exercise price of $10.63 per share.

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DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share you will pay in this offering and the pro forma net tangible book value per share of our common stock immediately after this offering.

Our pro forma net tangible book value as of September 30, 2006 was approximately $18.7 million, or $1.73 per share. Pro forma net tangible book value per share is determined by dividing the amount of our total tangible assets less our total liabilities of $18.7 million by the pro forma number of shares of common stock totaling 10,758,441 shares after giving effect to the conversion of all outstanding shares of our preferred stock as of September 30, 2006 into shares of our common stock, which will become effective at the closing of this offering.

After giving effect to the sale of the 4,600,000 shares of common stock we are offering at the initial public offering price of $6.00 per share, and after deducting underwriting discounts and commissions and our estimated offering expenses payable by us, and giving effect to the issuance of 275,902 shares of common stock from the exercise of certain warrants in connection with this offering, our pro forma as adjusted net tangible book value as of September 30, 2006 would have been approximately $40.6 million, or $2.59 per share.

This amount represents an immediate increase in pro forma net tangible book value of $0.86 per share to our existing stockholders and an immediate dilution of $3.41 per share to new investors. The following table illustrates this calculation on a per share basis:

Initial public offering price per share		$ 6.00
Pro forma net tangible book value per share of common stock as of September 30, 2006	$ 1.73	
Pro forma increase per share attributable to the offering	.86	
Pro forma as adjusted net tangible book value per share of common stock after this offering		2.59
Dilution per share to new investors		$ 3.41

If the underwriters exercise their over-allotment option in full, our pro forma as adjusted net tangible book value will increase to $2.72 per share, representing an increase to our existing stockholders of $1.03 per share, and there will be an immediate dilution of $3.28 per share to new investors.

The following table summarizes, on a pro forma as adjusted basis as of September 30, 2006, after giving effect to this offering, and the pro forma adjustments referred to above, the total number of shares of our common stock purchased from us and the total consideration and average price per share paid by existing stockholders and by new investors:

	Total shares		Total consideration		
	Number	Percent	Amount	Percent	Average price per share
Existing stockholders	11,034,343	70.6%	$ 81,556,051	74.7%	$ 7.39
New investors	4,600,000	29.4	27,600,000	25.3	6.00
Total	15,634,343	100%	$ 109,156,051	100%	$ 6.98

If the underwriters exercise their over-allotment option in full, the following will occur:

the pro forma as adjusted percentage of shares of our common stock held by existing stockholders will decrease to approximately 67.6% of the total number of pro forma as adjusted shares of our common stock outstanding after this offering; and

the pro forma as adjusted number of shares of our common stock held by new public investors will increase to 5,290,000, or approximately 32.4% of the total pro forma as adjusted number of shares of our common stock outstanding after this offering.

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The tables and calculations above are based on 11,034,343 shares of our common stock outstanding as of September 30, 2006 after giving effect to:

- the conversion of all outstanding shares of preferred stock into 9,367,511 shares of common stock;
- the issuance of 107,754 shares of our common stock upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, at a weighted average exercise price of $5.58 per share, which the warrant holders have elected to exercise in cash, contingent and effective upon the closing of this offering; and
- the issuance of 168,148 shares of our common stock upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, which the warrant holders have elected to exercise through a cashless exercise provision of the warrants, based on the initial public offering price of $6.00 per share.

The tables and calculations above exclude:

- 1,869,676 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2006, at a weighted average exercise price of $5.85 per share;
- 335,246 shares of our common stock issuable upon the exercise of outstanding stock options granted after September 30, 2006, at a weighted average exercise price of $10.63 per share;
- 3,640,843 shares of our common stock available for future grant under our 2006 Equity Incentive Plan, which number excludes the cancellation of 121,355 outstanding stock options cancelled after September 30, 2006, at a weighted average exercise price of $6.30 per share, which will become effective upon the closing of this offering, and the annual increases in the number of shares authorized under this plan beginning January 1, 2007;
- 2,490,189 shares of our common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, at a weighted average exercise price of $6.98 per share;
- 28,235 shares of common stock issuable upon the exercise of a preferred stock warrant granted after September 30, 2006 at an exercise price of $10.63 per share; and
- the impact of approximately $2.7 million of estimated offering costs payable by us that we have previously paid in cash as of September 30, 2006.

The preceding discussion and tables assume no exercise of any options and warrants outstanding as of September 30, 2006, except as specifically described above.

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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 prospectus. We derived the consolidated statement of operations data for the years ended December 31, 2001 and 2002, as well as the consolidated balance sheet data as of December 31, 2001, 2002 and 2003, from our audited consolidated statements not included in this prospectus. We derived the consolidated statements of operations data for the years ended December 31, 2003, 2004 and 2005, as well as the consolidated balance sheet data as of December 31, 2004 and 2005, from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statement of operations data for the nine months ended September 30, 2005 and 2006, and the consolidated balance sheet data as of September 30, 2006, are derived from our unaudited consolidated financial statements, which are included elsewhere in this prospectus. Our historical results are not necessarily indicative of operating results to be expected in future periods.

	Years Ended December 31,					Nine Months Ended September 30,	
	2001	2002	2003	2004	2005	2005	2006
						(unaudited)	
	(in thousands, except share and per share amounts)						
Consolidated Statements of Operations Data:							
Expenses:							
Research and development	$ 2,811	$ 1,457	$ 974	$ 3,634	$ 10,189	$ 6,754	$ 5,698
Selling, general and administrative	2,096	1,975	2,976	5,155	10,137	6,723	11,463
Total expenses	4,907	3,432	3,950	8,789	20,326	13,477	17,161
Loss from operations	(4,907)	(3,432)	(3,950)	(8,789)	(20,326)	(13,477)	(17,161)
Interest expense, net	(134)	(914)	(2,170)	(4,028)	(4,416)	(3,518)	(1,907)
Other income (expense), net	99			(22)	2,041	(11)	351
Loss before benefit for income taxes	(4,942)	(4,346)	(6,120)	(12,839)	(22,701)	(17,006)	(18,717)
Benefit for income taxes				454	458	141	148
Net loss	$ (4,942)	$ (4,346)	$ (6,120)	$ (12,385)	$ (22,243)	$ (16,865)	$ (18,569)
Historical net loss per common share:							
Basic and diluted	$ (4.66)	$ (4.10)	$ (5.76)	$ (11.20)	$ (18.76)	$ (14.38)	$ (13.81)
	1,060,117	1,060,117	1,062,825	1,106,188	1,185,387	1,172,419	1,344,503

Weighted average shares - basic and diluted								
Pro forma net loss per common share (unaudited):								
Basic and diluted					$ (5.15)		$ (1.88)	
Weighted average shares - pro forma basic and diluted (unaudited)					4,319,411		9,885,002	
Stock-based compensation is included in the following categories:								
Capitalized to inventory	$	$	$	$	$	$	$	214
Research and development				91	256	113		267
Selling, general and administrative			159	1,042	1,038	389		1,324
	$	$	$ 159	$ 1,133	$ 1,294	$ 502	$	1,805

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

	As of December 31,					As of September 30,
	2001	2002	2003	2004	2005	2006
						(unaudited)
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$ 625	$ 55	$ 36	$ 2,269	$ 6,930	$ 12,789
Working capital (deficit)	(27)	(2,036)	(2,659)	(3,792)	(2,974)	12,403
Total assets	1,122	220	450	10,296	20,320	29,745
Long-term debt and capital lease obligations, less current portion	1,511	2,255	371	5,323	66	31
Stockholders equity (deficit)	(1,347)	(4,139)	(2,628)	(4,594)	5,537	22,535

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MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and accompanying notes included elsewhere in this prospectus. In addition to the historical information, this discussion and other parts of the prospectus contain forward-looking statements based upon current expectations that involve risks and uncertainties. As a result of several factors, including those set forth under Risk Factors and elsewhere in this prospectus, our actual results and the timing of selected events may differ materially from those anticipated in these forward-looking statements.

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 intend to commence 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 September 30, 2006, our deficit accumulated during the development stage was approximately $71.6 million.

We have financed our operations through private placements of preferred stock and convertible debt. As of December 31, 2005, we have raised $34.0 million through private placements of preferred stock, $6.9 million in subscriptions for the purchase of Series E convertible preferred stock and $6.0 million through the issuance of convertible debt that remained outstanding as of December 31, 2005. In addition, as of September 30, 2006, we raised an additional $36.1 million in a private placement of Series E convertible preferred stock. Since inception, we have raised $77.0 million through private equity financings. As of September 30, 2006, our cash and cash equivalents were $12.8 million.

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Financial Operations Overview

Sales

Since inception in 1999, we have not generated any product sales. We intend to commence commercial shipments and begin generating product sales from ArteFill during the first quarter of 2007.

Cost of Sales

Cost of sales will 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 September 30, 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 will be 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 September 30, 2006, we spent an aggregate of approximately $29.7 million on selling, general and administrative expenses, which represented approximately 59% of total operating expenses. After this offering, 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 as we add personnel to meet the anticipated expansion of our product commercialization efforts and become subject 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 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

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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 September 30, 2006, we spent an aggregate of approximately $20.5 million on research and development expenses, which represented approximately 41% of total operating expenses, excluding the impact of stock-based compensation charges. 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 prospectus, 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

Since inception, we have not had any sales of our product. We intend to commence 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. Shipping and handling charges are invoiced to customers based on the amount of products sold. Shipping and handling fees are recorded as revenue and the related expense is recorded as cost of sales.

We expect a substantial amount of our business to be transacted using credit cards. We may offer an early payment discount to certain customers. We also may provide customers with certain product return rights in the case of damaged or defective product. Once we have experience with actual product sales and customer product returns, we will determine the appropriate reserve for product returns. Our inability to accurately estimate product returns in the future may cause us to defer recognition of revenue.

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Allowance for Doubtful Accounts

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

Valuation of Inventory

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

Impairment of Long-Lived Assets

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

Intangible Assets

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

Deferred Taxes

Asset Valuation Allowance

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

Deferred Tax Liability

A deferred tax liability was created on the date of purchase of our wholly-owned German-based manufacturing subsidiary as there was no allocation of the purchase price to the intangible asset for tax purposes, and the foreign subsidiary s tax basis in the intangible asset remained zero. Emerging Issues Task Force, or EITF, Issue No. 98-11, *Accounting for Acquired Temporary Differences in Certain Purchase Transactions That Are Not Accounted for as Business Combinations*, requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability.

Stock-Based Compensation Expense

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-Based Payment* (SFAS No. 123(R)), which revises SFAS No. 123, *Accounting for Stock-Based*

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Compensation and (SFAS No. 123), supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). SFAS No. 123(R) requires that share-based payment transactions with employees and directors be recognized in the financial statements based on their grant-date fair value and recognized as compensation expense over the requisite service period. Prior to January 1, 2006, we accounted for our stock-based employee and director compensation plans using the intrinsic value method under the recognition and measurement provisions of Accounting Principles Board Opinion (APB) 25, *Accounting for Stock Issued to Employees*, and related guidance. We adopted SFAS No. 123(R) effective January 1, 2006, prospectively for new equity awards issued subsequent to January 1, 2006, therefore prior period results have not been restated. The adoption of SFAS No. 123(R) in the first quarter of 2006 resulted in the recognition of additional stock-based compensation expense for the nine months ended September 30, 2006 of $749,000. Of this amount, $89,000 has been capitalized to inventory, $76,000 is included in research and development expenses and $584,000 is included in selling, general and administrative expenses.

Under SFAS No. 123(R), we calculated the fair value of the stock option grants using the Black-Scholes option-pricing model. For the nine months ended September 30, 2006, the fair value was based on the following weighted average assumptions: the expected term of 6.0 years; the expected volatility of 60%, the risk free interest rate of 4.55% and 0% for the dividend yield. Future expense amounts for any particular quarterly or annual period could be affected by changes in our assumptions or changes in market conditions.

The weighted average expected term for the nine months ended September 30, 2006 reflects the application of the simplified method set out in SEC Staff Accounting Bulletin No. 107 (SAB 107), which was issued in March 2005. The simplified method defines the expected term as the average of the contractual term of the options and the weighted average vesting period for all option tranches.

Estimated volatility for the nine months ended September 30, 2006 also reflects the application of SAB 107 interpretive guidance and, accordingly incorporates historical volatility of similar public entities.

Total unrecognized stock-based compensation costs related to unvested stock option and warrant awards at September 30, 2006 is $7,751,000, all of which arose from the adoption of SFAS No. 123(R). The unrecognized cost is expected to be recognized on a straight-line basis over a weighted average period of four years.

Equity instruments issued to non-employees are recorded at their fair values as determined in accordance with SFAS 123, *Accounting for Stock-Based Compensation*, and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the options vest and are recognized as expense over the related service period. During the years ended December 31, 2003, 2004, 2005, and for the nine months ended September 30, 2005 and 2006, and for the period from August 24, 1999 (inception) through September 30, 2006, we recognized $159,000, $1,024,000, $959,000, $303,000, $495,000 and $2,691,000, respectively, for stock options and warrants issued to non-employees.

Deferred Stock-Based Compensation

Deferred stock-based compensation, which is a non-cash charge, results from employee stock option grants at exercise prices that, for financial reporting purposes, are deemed to be below the estimated fair value of the underlying common stock on the date of grant. Given the absence of an active market for our common stock through 2005, our board of directors considered, among other factors, the liquidation preferences, anti-dilution protection and voting preferences of the preferred stock over the common stock in determining the estimated fair value of the common stock for purposes of establishing the exercise prices for stock option grants.

As a result of initiating this offering process, and based on discussions with our investment bankers, we have revised our estimate of the fair value of our common stock for periods beginning on and after July 1, 2004 for financial reporting purposes. Our management, all of whom qualify as related parties, determined that the stock options granted on and after July 1, 2004 were granted at exercise prices that were below the

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

The deferred stock-based compensation is being amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. The expected future amortization expense for deferred stock-based compensation for stock options granted through December 31, 2005, is $789,000, $789,000, $703,000 and $458,000 for the years ending December 31, 2006, 2007, 2008 and 2009, respectively.

During the years ended December 31, 2003, 2004, 2005, and for the nine months ended September 30, 2005 and 2006, and for the period from August 24, 1999 (inception) through September 30, 2006, we recognized $0, $109,000, $335,000, $199,000, $561,000 and $1,005,000, respectively, in expense related to deferred stock-based compensation.

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

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

Results of Operations

Comparison of Nine Months Ended September 30, 2005 to September 30, 2006

Research and development. Research and development expense decreased by $1.1 million from $6.8 million for the nine months ended September 30, 2005 to $5.7 million for the nine months ended September 30, 2006. The decrease was primarily attributable to our transition from the process development stage to the manufacturing of our product. Included in our research and development expenses is $0.9 million of amortization of core technology and patents for each of the nine months ended September 30, 2005 and September 30, 2006. Also included in research and development expenses for the nine months ended September 30, 2006 is a one-time warrant modification charge of $0.1 million.

Selling, general and administrative. The following table sets forth our selling, general and administrative expense for the nine months ended September 30, 2005 and September 30, 2006 (in thousands):

	2005	2006	Amount of Change
Sales and marketing	$ 1,957	$ 4,157	$ 2,200
General and administrative	4,766	7,306	2,540
Total selling, general and administrative	$ 6,723	$ 11,463	$ 4,740

Sales and marketing expense increased by $2.2 million from $2.0 million for the nine months ended September 30, 2005 to $4.2 million for the nine months ended September 30, 2006. The increase was primarily attributable to (i) $1.0 million in payroll and travel expenses for additional personnel and (ii) $0.3 million for the development of marketing and promotion programs and (iii) $0.9 million in non-cash compensation expense,

including a one-time warrant modification charge of $0.6 million.

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General and administrative expense increased by $2.5 million from $4.8 million for the nine months ended September 30, 2005 to $7.3 million for the nine months ended September 30, 2006. The increase was primarily attributable to (i) a $1.6 million increase due to additional executive and administrative personnel and related travel expenses; (ii) $0.6 million in facilities occupancy costs; (iii) a $0.7 million decrease in professional service fees primarily related to lower legal costs; (iv) $0.9 million in non-cash compensation expense, which included a one-time warrant modification charge of $0.2 million and (v) $0.1 million in office related expenses.

Interest expense, net. Net interest expense decreased by $1.6 million from $3.5 million for the nine months ended September 30, 2005 to $1.9 million for the nine months ended September 30, 2006. The net decrease was primarily attributable to non-cash interest expense associated with common stock warrants issued with a convertible promissory note offset by an increase in interest income earned on our cash balances. Included in interest expense for the nine months ended September 30, 2006 is a one-time warrant modification charge of $0.5 million.

Income tax benefit. We recognized an income tax benefit of $141,000 and $148,000 for the nine months ended September 30, 2005 and 2006, respectively. The income tax benefit arose from the amortization of the deferred tax liability attributable to the intangible asset acquired in the purchase of our wholly-owned German-based manufacturing subsidiary. A deferred tax liability was created on the date of purchase as there was no allocation of the purchase price to the intangible asset for tax purposes, and the foreign subsidiary s tax basis in the intangible asset remained zero. EITF 98-11 requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability.

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

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

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

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

Sales and marketing expense increased by $2.4 million from $339,000 for the year ended December 31, 2004 to $2.8 million for the year ended December 31, 2005. The increase was primarily attributable to (i) $1.4 million in payroll and travel expenses for additional personnel; (ii) $847,000 for the development of marketing and promotion programs and (iii) $121,000 for marketing consultants.

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

(ii) $1.0 million in legal expenses and (iii) $100,000 in other expenses.

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Interest expense, net. We recognized net interest expense of $4.4 million for the year ended December 31, 2005, an increase of $400,000 from $4.0 million for the year ended December 31, 2004. The increase was primarily attributable to non-cash interest expense associated with common stock warrants issued with a convertible promissory note.

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

Income tax benefit. We recognized an income tax benefit of $454,000 and $458,000 for the years ended December 31, 2004 and 2005, respectively. The income tax benefit arose from the amortization of the deferred tax liability attributable to the intangible asset acquired in the purchase of our wholly-owned German-based manufacturing subsidiary. A deferred tax liability was created on the date of purchase as there was no allocation of the purchase price to the intangible asset for tax purposes, and the foreign subsidiary s tax basis in the intangible asset remained zero. EITF 98-11 requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability.

Comparison of Year Ended December 31, 2003 to December 31, 2004

Research and development. Research and development expense increased by $2.6 million from $974,000 for the year ended December 31, 2003 to $3.6 million for the year ended December 31, 2004. The increase was primarily attributable to (i) $1.2 million of amortization expense related to our core technology and patents; (ii) an increase of $637,000 in expenses related to process development, contract service, materials and process validation; (iii) payroll and travel costs of approximately $389,000 for additional personnel and (iv) facilities occupancy costs of $404,000, all of which were directly attributable to the scale-up of commercial operations to manufacture our product to meet FDA cGMP and other regulatory agencies requirements.

Selling, general and administrative. The following table sets forth our selling, general and administrative expense for the years ended December 31, 2003 and 2004 (in thousands):

	2003	2004	Amount of Change
Sales and marketing	$ 314	$ 339	$ 25
General and administrative	2,662	4,816	2,154
Total selling, general and administrative	$ 2,976	$ 5,155	$ 2,179

Sales and marketing expense increased by $25,000 from $314,000 for the year ended December 31, 2003 to $339,000 for the year ended December 31, 2004. The increase was primarily attributable to payroll and travel expenses for additional personnel, for the development of marketing and promotion programs and for marketing consultants.

General and administrative expense increased by $2.1 million from $2.7 million for the year ended December 31, 2003 to $4.8 million for the year ended December 31, 2004. The increase was primarily attributable to (i) a $411,000 increase due to additional executive and administrative personnel costs and (ii) $1.7 million in legal and other expenses.

Interest and other expense, net. We recognized net interest expense of $4.0 million for the year ended December 31, 2004, an increase of $1.8 million from $2.2 million for the year ended December 31, 2003. The increase was attributable to non-cash interest expense associated with common stock warrants issued with a convertible promissory note.

Income tax benefit. We recognized an income tax benefit of $0 and $454,000 for the years ended December 31, 2003 and 2004, respectively. The income tax benefit for fiscal 2004 arose from the amortization of the deferred tax liability attributable to the intangible asset acquired in the purchase of our wholly-owned

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German-based manufacturing subsidiary. A deferred tax liability was created on the date of purchase as there was no allocation of the purchase price to the intangible asset for tax purposes, and the foreign subsidiary s tax basis in the intangible asset remained zero. EITF 98-11 requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability.

Income Taxes

Due to uncertainty surrounding the realization of the U.S. deferred tax assets through future taxable income, we have provided a full valuation allowance on those assets and no benefit has been recognized for the U.S. net operating loss and other U.S. deferred tax assets. Accordingly, deferred tax valuation allowances have been established as of December 31, 2003, 2004 and 2005 to reflect these uncertainties.

As of December 31, 2005, we had net operating loss carryforwards of approximately $43.0 million and $43.0 million available to reduce future taxable income, if any, for federal and California income taxes, respectively. The net operating loss carryforwards begin to expire in 2019 and 2009 for federal and California income tax purposes, respectively. Utilization of the net operating loss carryforwards may be subject to an annual limitations due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the net operating loss carryforwards before utilization.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 1999, our operations have never been profitable and we have an accumulated deficit of approximately $71.6 million. Our operations have been financed through private placements of convertible preferred stock and convertible debt, as well as operating and capital leases. As of December 31, 2005, we had raised $34.1 million through private placements of preferred stock, $6.9 million through subscriptions received for the purchase of Series E convertible preferred stock and $6.0 million through the issuance of convertible promissory notes. As of December 31, 2005, our cash and cash equivalents were $6.9 million. In addition, from January to September 2006, we raised an additional $36.1 million in proceeds from the sale of Series E convertible preferred stock. Since inception, we have raised $77.0 million in private equity. As of September 30, 2006, our cash and cash equivalents were $12.8 million. All of our cash equivalents have original maturities of three months or less.

Cash Flow

Net cash used in operating activities. During the nine months ended September 30, 2006, our operating activities used cash of approximately $16.5 million, compared to approximately $9.8 million for the nine months ended September 30, 2005, an increase of $6.7 million. The increase in cash used was due primarily to an increase in the net loss of approximately $1.7 million, primarily attributable to an increase in operating expenses, offset by $1.5 million in adjustments for non-cash expenses and a $6.5 million net decrease in operating assets and liabilities primarily due to payments on accounts payable and accrued expenses and an increase in inventory.

During the year ended December 31, 2005, our operating activities used cash of approximately $13.1 million, compared to approximately $4.8 million for the year ended December 31, 2004, an increase of $8.3 million. The increase in cash used was due primarily to an increase in the net loss of approximately $9.9 million, primarily attributable to an increase in research and development expenses, offset by $1.4 million in adjustments for non-cash expenses and a $200,000 net decrease in operating assets and liabilities.

During the year ended December 31, 2004, our operating activities used cash of approximately $4.8 million, compared to approximately $2.8 million for the year ended December 31, 2003, an increase of $2.0 million. The increase in cash used was due primarily to an increase in the net loss of approximately

$6.3 million, primarily attributable to an increase in research and development expenses, offset by $4.6 million in adjustments for non-cash expenses and a $321,000 net increase in operating assets and liabilities.

Net cash used in investing activities. Our investing activities used cash of approximately $3.3 during the nine months ended September 30, 2006, compared to $5.5 million for the nine months ended September 30, 2005. Investing activities during the nine months ended September 30, 2006 and 2005 were comprised of $1.4 and $3.9 million, respectively, of purchases of plant and production equipment and tenant improvements related to the expansion of our offices and the build-out of our production and manufacturing facilities. During the nine months ended September 30, 2005, we used $1.5 million of cash to purchase our German-based manufacturing subsidiary, Artes Medical Germany GmbH (formerly Mediplant GmbH Biomaterials & Medical Devices). During the nine months ended September 30, 2006, we used cash of $1.9 million for long-term deposits and other assets, primarily capitalized as initial public offering costs. During the nine months ended September 30, 2005, we generated cash of $110,000 due to changes in our long-term deposits and other assets.

Our investing activities used cash of approximately $7.8 million during the year ended December 31, 2005, compared to $2.5 million for the year ended December 31, 2004. Investing activities in 2005 and 2004 were comprised of $4.6 million and $816,000, respectively, of purchases of plant and production equipment and tenant improvements related to the expansion of our offices and the build-out of our production and manufacturing facilities. We also used $2.3 million and $1.7 million in 2005 and 2004, respectively, of cash to purchase our German-based manufacturing subsidiary, Artes Medical Germany GmbH, and in 2005 we used cash of $950,000 for long-term deposits and other assets.

Our investing activities used cash of approximately $2.5 million during the year ended December 31, 2004 compared to $250,000 for the year ended December 31, 2003. Investing activities in 2004 were comprised of $1.7 million in cash used to purchase our German-based manufacturing subsidiary and $816,000 in equipment and tenant improvement investments in our San Diego manufacturing facility. During the same period in 2003, we used cash of $250,000 for long-term deposits and other assets.

Net cash provided by financing activities. Cash provided by financing activities was approximately $25.7 million for the nine months ended September 30, 2006, compared to approximately $15.1 million for the nine months ended September 30, 2005. Financing activities during the nine months ended September 30, 2006 resulted in $31.8 million in proceeds from the issuance of preferred stock, $431,000 in proceeds from the exercise of stock options, repayments of $6.5 million on convertible notes payable and $40,000 in repayments on capital lease obligations. During the nine months ended September 30, 2005, our financing activities resulted in $7.0 million in proceeds from the issuance of convertible promissory notes, $4.5 million in proceeds from the issuance of preferred stock, $3.4 million in proceeds from subscriptions for preferred stock, $130,000 in equipment financing obligations, net of repayments and $25,000 in proceeds from the exercise of stock options.

Cash provided by financing activities was approximately $25.5 million for the year ended December 31, 2005, compared to approximately $9.6 million for the year ended December 31, 2004. Financing activities in 2005 resulted in $7.0 million in proceeds from the issuance of convertible promissory notes, $11.5 million in proceeds from the issuance of preferred stock, $6.9 million in proceeds from subscriptions for preferred stock and $116,000 in equipment financing obligations, net of repayments during the year ended December 31, 2005. During the same period in 2004, our financing activities resulted in $6.1 million in proceeds from the issuance of convertible promissory notes and $3.5 million in proceeds from the issuance of preferred stock. For the same period in 2003, we raised proceeds of $1.5 million from the issuance of convertible promissory notes and $1.6 million from the issuance of preferred stock.

In November 2006, we entered into a loan and security agreement with Comerica Bank, pursuant to which we obtained a credit facility consisting of a revolving line of credit in the amount of up to $5.0 million and a term loan in the amount of up to $5.0 million. Interest on the revolving line of credit and the term loan will be at prime plus 2%. The revolving line and term loan mature in November 2007 and 2010, respectively. We are required to maintain a cash balance equal to 1.25 times our indebtedness to Comerica Bank. In addition, the loan and security agreement includes several restrictive covenants, including requirements that we obtain the consent of Comerica Bank prior to entering into any change of control event, incurring other indebtedness or making distributions to our stockholders. To

secure the credit facility, we granted Comerica

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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. We also granted Comerica Bank a warrant to purchase 28,235 shares of common stock, at an exercise price of $10.63 per share.

Funding Requirements

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of offerings of our equity securities, including the proceeds of this offering. 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 internal sales force and sales management to market ArteFill. We believe that the net proceeds from this offering, together with the interest thereon, our cash and cash equivalents at September 30, 2006 and the funds available under our credit facility, will be sufficient to meet our anticipated cash requirements with respect to the commercial launch of ArteFill, the automation and scale-up of our manufacturing capabilities and our research and development activities and to meet our other anticipated cash needs through the first quarter of 2008. In addition, we may finance future cash needs through the sale of additional equity securities, debt financing and other strategic transactions. However, we may not be successful in obtaining strategic transactions to commercialize our core technology in other medical applications with third parties. In addition, our existing cash and cash equivalents may not be adequate and additional equity or debt financing may not be available when needed on acceptable terms, or at all. Insufficient funds may require us to delay, reduce the scope of or eliminate one or more of our product launch programs, or to relinquish distribution rights to a third party on less favorable terms than we would otherwise choose. Failure to obtain adequate financing may also adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Our cash as of September 30, 2006, is expected to last through the first quarter of 2007. Our future capital requirements are difficult to forecast and will depend on many factors, including, among others:

- the costs of establishing and maintaining the sales and marketing organization required for successful commercialization of ArteFill;
- the success of our product launch and growth in sales and related collections;
- the costs and effectiveness of our sales, marketing, advertising and promotion activities related to ArteFill, including physician training and education;
- the costs related to maintaining and expanding our manufacturing and distribution capabilities;
- the costs relating to changes in regulatory policies or laws that affect our operations;
- the level of investment in research and development to maintain and improve our competitive position, as well as to maintain and expand our technology platform;
- the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the costs of, and our ability to enter into, foreign distribution agreements in certain concentrated international markets; and
- our need or determination to acquire or license complementary products, technologies or businesses.

If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, reduce the scope of, eliminate or divest one or more of our sales and marketing programs, manufacturing capabilities, research and development programs, or our entire business. We may raise additional funds through public or private offerings, debt financings, capital

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leases, corporate collaborations or other means. Due to the uncertainty of financial markets, financing may not be available to us when we need it on acceptable terms or at all. Therefore, we may raise additional capital from time to time when market conditions are favorable, or if strategic considerations require us to do so, even if we have sufficient funds for planned operations.

Contractual Obligations

The following summarizes our long-term contractual obligations as of December 31, 2005:

	Payments Due by Period				
Contractual Obligations	**Total**	**2006**	**2007**	**2008**	**After 2008**
			(in thousands)		
Equipment lease obligations	$ 115	$ 49	$ 45	$ 21	$
Operating lease obligations	5,921	867	956	985	3,113
Total	$ 6,036	$ 916	$ 1,001	$ 1,006	$ 3,113

Our long-term obligations consist primarily of our facilities leases that expire in March and December 2011 and our equipment financing obligations that expire in April and July 2008.

In addition, pursuant to a separation agreement with Dr. Gottfried Lemperle, we have paid Dr. Gottfried Lemperle an aggregate of $400,000 through May 2006. We also paid $500,000 to Stifel, Nicolaus & Company, Incorporated in May 2006 in connection with a settlement agreement.

In November 2006, we entered into a separation agreement and mutual general release with Dr. Stefan Lemperle in connection with his resignation as a director and employee. Pursuant to the agreement, we have paid Dr. Stefan Lemperle a severance payment of $250,000, plus an additional $81,250 in lieu of any bonus payments related to fiscal years 2005 and 2006. We also agreed to make severance payments to Dr. Stefan Lemperle in an aggregate amount of $300,000, payable in 12 monthly installments of $25,000 per month, commencing in December 2006. Dr. Stefan Lemperle is eligible to receive an additional severance payment of $400,000, contingent upon the closing of this offering or another qualifying transaction before March 31, 2007.

In November 2006, we entered into a loan and security agreement with Comerica Bank, pursuant to which we obtained a credit facility consisting of a revolving line of credit in the amount of up to $5 million and a term loan in the amount of up to $5 million. Interest on the revolving line of credit and the term loan will be at prime plus 2%. On November 30, 2006, we drew down the $5.0 million term loan under the credit facility.

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

Related Party Transactions

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

Off-Balance Sheet Arrangements

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

Quantitative and Qualitative Disclosures about Market Risk

The primary objective of our cash management activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. As of December 31, 2005, we had cash and cash equivalents in a bank operating

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account that provides daily liquidity and through an overnight sweep account that is a money market mutual fund and invests primarily in money market investments and corporate and U.S. government debt securities. Due to the liquidity of our cash, cash equivalents and investment securities, a 1% movement in market interest rates would not have a significant impact on the total value of our cash, cash equivalents and investment securities. We do not have any holdings of derivative financial or commodity instruments, or any foreign currency denominated transactions.

Inflation

The impact of inflation on our business has not been material to date.

Recent Accounting Pronouncements

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

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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. 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 intend to commence commercial shipments of ArteFill during the first quarter of 2007. We plan to sell ArteFill to dermatologists, plastic surgeons and cosmetic surgeons in the United States primarily through a direct sales force initially comprised of up to 25 sales professionals. We initially intend to 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. In connection with our product launch, we will train physicians in the technique of injecting ArteFill with the goal of optimizing patient and physician satisfaction with our product. After establishing ArteFill in the United States, we plan to explore opportunities to register and sell ArteFill in selected international markets.

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 9.3 million non-surgical aesthetic procedures performed in the United States in 2005, representing a total consumer market of more than $4.1 billion. The leading non-surgical aesthetic procedure in 2005 was the administration of injectable aesthetic products, followed by laser hair removal, microdermabrasion, chemical peel and the treatment of varicose veins. Women represented 91.7% of the

patients who underwent non-surgical aesthetic procedures in 2005. 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 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 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 2005, approximately 4.9 million injectable aesthetic procedures were performed in the United States, and U.S. consumers spent approximately $2.2 billion on injectable aesthetic treatments. Based on market research conducted by Medical Insight, Inc., we believe that physicians purchased approximately $600 million of injectable aesthetic products for these 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 2005
Temporary Muscle Paralytics	Botox® Cosmetic	Botulinum toxin type A	3,300,000
Temporary Dermal Fillers	Captique™ Hylaform® Hylaform® Plus Restylane®	Hyaluronic acid (HA)	1,200,000
	CosmoDerm® CosmoPlast® Zyderm® Zyplast®	Human or bovine collagen	200,000

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 Radiesse™, a calcium hydroxylapatite, or CaHA, based gel approved by the FDA for vocal cord augmentation, radiographic tissue marking, and oral and maxillofacial defects, or the loss of facial structure and skin tissue, in approximately 40,000 aesthetic procedures in 2005. In addition, 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 35,000 aesthetic procedures in 2005. Similar to the FDA-approved temporary dermal fillers listed above, the substances contained in Radiesse and 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 3.3 million Botox treatments for aesthetic use were performed in the United States in 2005. Since 1997, Botox treatments have experienced a compound annual growth rate of 63%, including a 16% procedure growth rate from 2004 to 2005.

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 two years, from approximately 120,000 procedures in 2003, to 900,000 procedures in 2004 and to 1.2 million procedures in 2005. We believe this increase was mainly

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attributable to the market launch of Restylane, which provides patients with a moderately longer lasting 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	No(1)	Vocal cord augmentation, radiographic tissue marking, and oral maxillofacial defects	Smile lines; frown lines; crow s feet; and lip augmentation
Poly-L lactic acid (PLLA)	Sculptra	No	Facial fat loss associated with HIV	Smile lines; marionette lines; and facial contours

(1) Radiesse is currently under review by the FDA for additional applications, which we believe may include the treatment of facial wrinkles.

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 augmentation or 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 Radiesse and 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

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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.

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. 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 intend to commence commercial shipments of ArteFill during the first quarter of 2007.

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.

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.

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.

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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 differentiate ArteFill from other injectable aesthetic products and position ArteFill as the premier enduring injectable aesthetic product for the treatment of nasolabial folds. We plan 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 intend to implement a comprehensive physician education and training program to foster consistent and high-quality injection procedures and results. Our education and training program will include 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 recently begun to build our direct sales team and initially intend to launch ArteFill with up to 30 full-time sales professionals. We initially intend to 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 intend to provide physicians with training, marketing programs and practice support services with respect to the use of ArteFill. We also plan to 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 intend to sell ArteFill in kits containing five sterile pre-filled syringes. We also will 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 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 bovine collagen 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 intend to 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 (4° to 8° C) for the duration of the product shelf life. We ship each kit inside a container designed to maintain

the 4° to 8° 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 will be administered primarily in an out-patient clinical setting, such as a physician s office. Treatment with ArteFill is expected to require 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. In the first quarter of 2007, we intend to commence 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 will initially 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 will offer physicians a 30 minute web-based interactive tutorial on ArteFill s scientific background, clinical trial information, injection technique and treatment guidelines.

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Training Seminars.

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

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

Physician-to-Physician Training. We will establish 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 intend to commence commercial shipments of ArteFill during the first quarter of 2007. We are currently building a direct sales force in the United States to sell ArteFill into the dermatology and plastic surgery markets. We initially intend to target dermatologists, plastic surgeons and cosmetic surgeons whom we have identified as having performed a large number of procedures involving injectable aesthetic products. We will initially market ArteFill through our sales and marketing organization, which will include up to 25 full-time sales representatives. We anticipate that as demand for ArteFill increases, we may expand our sales force to between 60 and 80 sales representatives.

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 will target these highly experienced physicians and we expect that the size of our direct sales organization will be 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. We plan to 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 will be willing to pay a premium price for ArteFill because 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 also intend to market ArteFill to physicians through scientific presentations at medical conferences and symposia, advertising in scientific journals, industry trade publications and our website. Following our

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product launch, we will continue to publish scientific articles to expand physician awareness of our product, and we intend to offer clinical forums with recognized expert panelists to discuss their experience with ArteFill. We plan to build consumer awareness of ArteFill through physician office marketing programs, health and lifestyle magazine advertisements and our website.

After establishing ArteFill in the United States, we also plan to explore opportunities to register and sell ArteFill in selected countries outside the United States.

Manufacturing

We have established our 43,000 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 1,750 square foot dedicated manufacturing 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. 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.

In March 2006, the FDA completed inspections of our manufacturing facility and our contract sterilizer in Frankfurt, Germany, with no observations noted. In addition, in April 2006, the FDA completed a comprehensive pre-approval inspection of our primary manufacturing facility in San Diego, California. 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 issued final certification of our facilities in connection with its approval of ArteFill for sale in the United States.

We have manufactured ArteFill, including the PMMA microspheres contained in the product, in limited quantities sufficient only to meet the needs for our clinical studies. We currently have limited resources, facilities and experience in commercially manufacturing sufficient quantities to meet expected demand for ArteFill. While we believe that our current facilities will be sufficient to manufacture an adequate supply to meet initial demand for ArteFill, in order to produce ArteFill in the quantities we anticipate will be necessary to meet market demand, we will need to increase our manufacturing capacity significantly over the current level.

Material Agreements

In July 2004, we acquired assets and intellectual property from FormMed BioMedicals AG, or FormMed, related to the development and manufacture of PMMA microspheres used in the production of ArteFill. This transaction had an effective date of January 1, 2004. The assets acquired included rights to all of FormMed s rights to any U.S. and international patents, patent applications and trademarks related to the ArteFill platform technology and Artes Medical Germany GmbH (formerly MediPlant GmbH Biomaterials & Medical Devices), or MediPlant, a facility for the manufacture of the PMMA microspheres. The aggregate purchase price for these assets was $4.3 million, which was paid in installments through December 2005. We pledged certain of the acquired patents to FormMed to secure our obligations with respect to the purchase of the assets. This pledge was released in October 2005 in connection with our settlement agreement with FormMed and Dr. Martin Lemperle, the brother of Dr. Stefan M. Lemperle, our former Chief Executive Officer and a former director, as described below. We currently have no continuing financial obligations under the acquisition agreement with FormMed.

We have in place an intercompany manufacturing and supply agreement with our wholly-owned subsidiary, MediPlant, pursuant to which MediPlant 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 MediPlant s actual documented production costs, 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 MediPlant 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 MediPlant.

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 is a highly purified and partly denatured bovine collagen solution from which we manufacture the 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.

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 October 2005, we also entered into a settlement agreement with FormMed and Dr. Martin Lemperle, pursuant to which we paid to FormMed an aggregate cash fee of 427,500 Euro and issued 7,214 shares of common stock to FormMed in full satisfaction of certain production costs disputed under the FormMed asset acquisition agreement described above. We also paid to Dr. Martin Lemperle an aggregate cash fee of 150,000 Euro and issued 2,549 shares of common stock to Dr. Martin Lemperle in full satisfaction of his claims for reimbursement of certain legal expenses. In addition, our pledge of certain patents to FormMed under our asset acquisition agreement with FormMed was released in connection with these payments. We have no continuing financial obligations under the settlement agreement with FormMed and Dr. Martin Lemperle.

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. 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 will compete against other medical technology and pharmaceutical companies who market aesthetic products. In the United States, we will 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 and Allergan, Inc. In addition, we will compete with companies that offer products that physicians currently use off-label for the correction of facial wrinkles, including BioForm Medical, Inc. and 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 involve a non-resorbable injectable aesthetic implant. We also will 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 will 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

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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 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

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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.

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 as 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 applied for a manufacturing license from the California Department of Health Services, or CDHS. 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

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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 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.

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 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.

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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.

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.

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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.

Five-Year Data

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.

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We currently lack published long-term clinical data for completed trials supporting the aesthetic benefits of ArteFill beyond six months. However, we are currently conducting ongoing, five-year follow-up evaluations of patients who received ArteFill in the U.S. clinical trial and who qualify for long-term follow-up. When completed, we intend to submit the results of these five-year follow-up evaluations to the FDA and to a peer-reviewed scientific journal for publication. The evaluation of the first 69 patients indicates that these patients have experienced sustained aesthetic improvements five years after initial treatment with ArteFill and express high levels of satisfaction with ArteFill treatment. Dr. Steven Cohen, the lead investigator in our U.S. clinical trial, 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.

Research and Development

We incurred research and development expenses of $1.0 million, $3.6 million and $10.2 million in fiscal 2003, 2004 and 2005, respectively, and $5.7 million in the first nine months of 2006, 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.

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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 November 27, 2006, we had 109 full-time employees, including six full-time employees located in Frankfurt, Germany. In the United States, we have 23 manufacturing employees, 17 quality assurance and regulatory employees, 34 sales and marketing employees, including 19 direct sales professionals, nine employees in research and development and 20 general and administrative employees. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

Our management team has recently undergone several changes. At a board meeting held on October 26, 2006, our board of directors determined that it was in the best interests of our company and our stockholders to remove Dr. Stefan M. Lemperle from his position as our Chief Executive Officer. This decision by our board of directors was based on the unanimous recommendations of our audit and nominating and corporate governance committees, which are comprised of our independent non-employee directors, presented to the board on October 2, 2006. On November 17, 2006, we entered into a separation agreement and general release with Dr. Stefan Lemperle, pursuant to which he resigned as a member of our board of directors and as an employee.

Following discussions at a series of weekly board meetings in October 2006, our board approved a plan on October 26, 2006 to reduce our operating costs and to reorganize our business operations, including our sales and marketing organization, to focus our efforts on the U.S. market and on physician-based training and sales programs. In connection with this cost reduction plan and reorganization, we terminated the employment of William von Brendel, our former Vice President of Worldwide Sales and International Markets, Harald T. Schreiber, our former Chief Creative Officer, and a manager in our sales and marketing organization on October 27, 2006.

In connection with their termination, we believe we have paid all amounts owed to Messrs. von Brendel and Schreiber under the terms of their employment agreements. On the date of their termination, we also offered to pay Messrs. von Brendel and Schreiber three months severance and to extend the expiration date of their respective stock options from 90 days to one year after the date of termination of their employment, in exchange for their execution of a general release. As discussed below under Legal Proceedings, Mr. Schreiber filed a demand for arbitration against us on November 2, 2006 and Mr. von Brendel filed a demand for arbitration against us on November 16, 2006.

Facilities

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 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 the 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 an adjacent building under a six-year sublease that expires in March 2011. In addition, we lease a 1,750 square foot manufacturing facility in Frankfurt, Germany, where we manufacture the PMMA microspheres used exclusively in ArteFill. The lease for our Frankfurt facility had an initial term of three years and is 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.

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Legal Proceedings

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 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 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 case was dismissed on June 5, 2006, and the plaintiff is allowed to refile the case at any time within 18 months from that date.

During our recent negotiations with the parties involved in the Sandor litigation, Dr. Gottfried Lemperle informed us that his counsel had contacted an investigator in the FDA s Office of Criminal Investigations to determine whether any investigation of Dr. Gottfried Lemperle was ongoing. In March 2006, Dr. Gottfried Lemperle s counsel informed us that an investigator at the FDA 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, neither Dr. Gottfried Lemperle, Dr. Stefan Lemperle nor any of our current officers or directors has 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 following correspondence from and to 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. In addition, we 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.

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. Artecoll has been manufactured and sold by third parties outside the United States under a CE mark since 1996. In 2004, we acquired all worldwide intellectual property rights related to Artecoll. Following this acquisition, we requested these third parties to cease manufacturing their product named Artecoll. We currently do not manufacture, and we have never manufactured, distributed or received any revenues from Artecoll. We initially named the product used in our clinical trials as Artecoll, but later changed the name of our product candidate to ArteFill to reflect refinements that we have made to the PMMA microsphere manufacturing process following our acquisition of the rights to Artecoll.

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We stated in our correspondence to the FDA that we found no evidence that any of the Artecoll used in the U.S. clinical study was used improperly before or after receipt of the approvable letter from the FDA in January 2004. We also informed the FDA that we could not conclusively determine the source of the Artecoll used on these individuals, that Dr. Gottfried Lemperle s use of Artecoll was not part of a study or any activity sponsored by us and that Dr. Gottfried Lemperle had resigned from his position as Chief Scientific Officer and as a member of our board of directors. In addition to our correspondence to the FDA, we also informed the FDA of these matters during its inspection of our manufacturing facilities in San Diego, California in April 2006. 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. In May 2006, we terminated Dr. Gottfried Lemperle s consulting relationship with us. Dr. Gottfried Lemperle no longer provides services to us in any capacity. In October 2006, our board of directors removed Dr. Stefan Lemperle from the position of Chief Executive Officer, and in November 2006, Dr. Stefan Lemperle resigned as a director and employee. Dr. Stefan Lemperle no longer provides services to us in any capacity.

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. The FDA requested our periodic update to include, among other things, all information available to us regarding individuals who had been treated with Artecoll outside our clinical trials and any adverse events these individuals had experienced. 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, our then serving Chief Executive Officer and director, had been injected with Artecoll in the United States in 2004 by his father, Dr. Gottfried Lemperle. Prior to the time we conducted the additional inquiries to prepare our periodic update for the FDA, Dr. Stefan M. Lemperle had failed to disclose to us, and to the FDA, that he had been injected with Artecoll in contravention of FDA rules and regulations. In October 2006, our board of directors removed Dr. Stefan Lemperle from the position of Chief Executive Officer, and in November 2006, Dr. Stefan Lemperle resigned as a director and employee. Dr. Stefan Lemperle no longer provides services to us in any capacity. We received FDA approval to market ArteFill on October 27, 2006.

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 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 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

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of the warrant, and plan to vigorously pursue our request for declaratory relief and to defend against any claims Mr. Ehrlich asserts. The hearing is expected to be held in San Diego, California.

In October 2006, we made a number of changes in our management team. On October 27, 2006, we terminated the employment of Harald T. Schreiber, our former Chief Creative Officer, and William von Brendel, our former Vice President Worldwide Sales and International Markets, in accordance with the terms of their written employment agreements with us and in connection with a cost reduction plan and a reorganization of our business operations, including our sales and marketing organization, to focus on the U.S. market and physician-based training and sales programs. On November 2, 2006, we were served with a demand for arbitration with the American Arbitration Association by Mr. Schreiber pursuant to the dispute resolution provisions in his employment agreement. Mr. Schreiber seeks compensatory damages of an unspecified amount and alleges several causes of action, including wrongful termination, fraud, breach of contract and the implied covenant of good faith and fair dealing, and hostile work environment. We believe that many of Mr. Schreiber s claims contradict the terms of his employment agreement, and we deny his allegations. To avoid the cost of arbitration, we have issued a settlement offer to Mr. Schreiber. There can be no assurance that our offer will be acceptable to Mr. Schreiber, or that we will reach a settlement with Mr. Schreiber. If we do not reach an agreement with Mr. Schreiber, we will continue to defend the case vigorously.

On November 16, 2006, we were served with a demand for arbitration with the American Arbitration Association by Mr. von Brendel pursuant to the dispute resolution mechanism provided in his employment agreement. Mr. von Brendel seeks compensatory damages of an unspecified amount and alleges various causes of action, including wrongful termination and breach of contract, fraud and the implied covenant of good faith and fair dealing. We deny Mr. von Brendel s allegations and believe that many of his claims contradict the terms of his employment agreement. To avoid the costs of arbitration, we have issued a settlement offer to Mr. von Brendel. There can be no assurance that our offer will be acceptable to Mr. von Brendel, or that we will reach an agreement with Mr. von Brendel. If we do not reach an agreement with Mr. von Brendel, we will defend the case vigorously.

We maintain employment practices liability insurance in an amount of up to $2.0 million in the aggregate for claims made during any one year insurance period. Our insurance carrier has agreed to provide coverage and defense for these actions, subject to a customary reservation of rights. We cannot assure you that our insurance carrier will provide coverage for all outstanding claims, or any employment related claims asserted in the future based on our recent management changes, or that any coverage will be adequate to cover these claims. In addition, regardless of merit or eventual outcome, our existing actions, and any potential actions resulting from our recent management changes, may result in the expenditure of a significant amount of cash on legal fees, expenses, payment of settlements or damages. Further, these actions may divert our management team s time and attention from our business and operations.

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MANAGEMENT

Executive Officers and Directors

Set forth below are the name, age and position and a brief account of the business experience of each of our executive officers and directors as of November 27, 2006.

Name	Age	Position(s)
Christopher J. Reinhard	52	Executive Chairman of the Board of Directors
Diane S. Goostree	50	President and Chief Executive Officer and Director
Peter C. Wulff	47	Chief Financial Officer
Karla R. Kelly, J.D.	52	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	50	Vice President Product Development & Engineering
Larry J. Braga	45	Vice President Manufacturing
Susan A. Brodsky-Thalken	53	Vice President U.S. Sales and Training
Frank M. Fazio	37	Vice President Marketing
Daren J. Barone(1)	42	Director
John R. Costantino(1)	60	Director
Lon E. Otremba(1)	49	Director

(1) Member of the audit committee, compensation committee, and nominating and corporate governance committee.

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 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 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, 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.

Daren J. Barone has been a director since December 2004. Mr. Barone is Chief Executive Officer of The Barone Group, a capital management firm specializing in real estate development and investments. From June 1989 to April 2003, Mr. Barone was Chief Executive Officer at Watkins Contracting, Inc., an environmental remediation company. Mr. Barone is actively involved with the Juvenile Diabetes Research Foundation and on the board of directors for the USO in San Diego.

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John R. Costantino has been a director since June 2006. Since January 2006, Mr. Costantino has also served as Managing General Partner of NGN Capital LLC, a venture capital advisory firm focusing on the healthcare and biotechnology industries. He has served as Vice President of Walden Capital Partners L.P., a Small Business Investment Company (SBIC), since 1994, and has been a Managing Director at Walden Partners Ltd., a merchant bank providing consulting and investing services, since 1992. Mr. Costantino currently also serves on the board of directors of GE Funds, GE Investment Funds, Inc., GE Institutional Funds and GE LifeStyle Funds, each management investment companies. Mr. Costantino holds a B.S. from Fordham University and a J.D. from Fordham Law School. He is also a Certified Public Accountant.

Lon E. Otremba has been a director since March 2006. He is the Principal Managing Partner of Lon E. Otremba, Strategic and Operational Management Advisory, a management advisory firm. Mr. Otremba most recently served as Chief Executive Officer and a director of Muzak, LLC, a leading provider of commercial music services, from September 2003 to July 2005. Prior to joining Muzak, Mr. Otremba served as Executive Vice President, Strategic Planning and Operations of the AOL Interactive Marketing Group of Time Warner, from May 2002 to August 2003, and as Executive Vice President, Strategic Planning, of the AOL Time Warner Local Partnership Group from February 2001 to April 2002. From November 2000 to January 2002, Mr. Otremba served as Chief Executive Officer and a director of a privately held technology company. Mr. Otremba currently also serves on the board of directors of Cardium Therapeutics, Inc., a publicly traded medical technology company, and on the board of a non-profit, independent school in Roslyn, New York. Mr. Otremba holds a B.A. in marketing and economics from Michigan State University.

Medical/Scientific Advisory Board

We have established a medical/scientific advisory board consisting of individuals whom we have selected for their particular expertise in the fields of dermatology, plastic surgery and cosmetic surgery. We anticipate that our medical/scientific advisory board members will consult with us regularly on matters relating to:

our sales and marketing strategy;

our research and development programs;

opportunities for strategic collaborations;

new technologies relevant to our research and development programs; and

scientific and technical issues relevant to our business.

Several members of our medical/scientific advisory board are employed by academic institutions and may have commitments to, or agreements with, other entities that may limit their availability to us. Members of our medical/scientific advisory board may also serve as consultants to other pharmaceutical and/or

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medical device companies, including those that may be our competitors. The following persons are members of our medical/scientific advisory board:

Name	Specialty
Harvey Abrams, M.D.	Dermatology
Jeffrey Adelglass, M.D.	Facial Plastic Surgery
Sassan Alavi, M.D.	Facial Plastic Surgery
Fredric Brandt, M.D.	Dermatology
Alastair Carruthers, M.D.	Dermatology
Jean Carruthers, M.D.	Cosmetic Surgery
Paul Chasan, M.D.	Plastic Surgery
Steve Fagien, M.D.	Aesthetic Surgery
Richard Fitzpatrick, M.D.	Dermatology
Miles Graivier, M.D.	Plastic Surgery
John Joseph, M.D.	Cosmetic Surgery
Rhoda Narins, M.D.	Dermatology
Dennis Nigro, M.D.	Plastic Surgery
Merrel Olesen, M.D.	Plastic Surgery
Marta Rendon, M.D.	Dermatology
Mark Rubin, M.D.	Dermatology
Thomas L. Tzikas, M.D.	Facial Plastic Surgery
Luitgard Wiest, M.D.	Dermatology

Upon joining our medical/scientific advisory board, each member receives a warrant to purchase 5,882 shares of our common stock at an exercise price equal to the then-current fair market value, as determined by our board of directors. These warrants generally have a five-year term and vest in equal monthly installments over 48 months. In addition to their initial warrants, we granted an option to purchase 5,882 shares of common stock to Dr. Alastair Carruthers at an exercise price of $1.49 per share under our 2001 Stock Option Plan in November 2001, we granted to Dr. Rhoda Narins a warrant to purchase 5,882 shares of our common stock in March 2006, and we issued 2,352 shares of common stock to Dr. Mark Rubin in May 2006 in consideration for extraordinary services as members of our medical/scientific advisory board. Dr. Narins additional warrant vests in equal monthly installments over 48 months and has a five-year term.

Board Composition

Our board of directors currently has five members Christopher Reinhard (Executive Chairman), Daren Barone, John Costantino, Diane Goostree and Lon Otremba. Messrs. Barone, Costantino and Otremba are not, and have never been, employed by our company or our subsidiary. Our board of directors has determined that Messrs. Barone, Costantino and Otremba are independent directors within the meaning of Rule 4200(a)(15) of the National Association of Securities Dealers listing standards. Upon the completion of this offering, our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes, each with staggered three-year terms. At each annual meeting of stockholders, or special meeting in lieu thereof, after the initial classification of the board of directors, the successors to directors whose terms will then expire will be elected to serve from the time of election and qualification until the third annual meeting following the election or special meeting in lieu thereof. This classification of the board of directors may have the effect of delaying or preventing changes of control or management. See Description of Capital Stock Anti-Takeover Provisions of Our Amended and Restated Certificate of Incorporation and Bylaws and Delaware Law. Our Class I directors, whose terms will expire at the 2007 annual meeting of stockholders, will be Daren Barone and Lon Otremba. Our Class II directors, whose terms will expire at the 2008 annual meeting of stockholders, will be Christopher Reinhard and John

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Costantino. Our Class III director, whose term will expire at the 2009 annual meeting of stockholders, will be Diane Goostree.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Pursuant to our bylaws, our board of directors may from time to time establish other committees to facilitate the management of our business and operations.

Audit Committee

Our audit committee consists of Messrs. Barone, Costantino and Otremba, with Mr. Barone serving as its chair. The audit committee is responsible for assuring the integrity of our financial control, audit and reporting functions and reviews with our management and our independent auditors the effectiveness of our financial controls and accounting and reporting practices and procedures. In addition, the audit committee reviews the qualifications of our independent auditors, is responsible for their appointment, compensation, retention and oversight and reviews the scope, fees and results of activities related to audit and non-audit services. We believe that our audit committee members meet the requirements for independence and financial literacy under the current requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq Global Market and SEC rules and regulations. In addition, our board of directors has determined that Mr. Costantino is an audit committee financial expert. We have made these determinations based on information received by our board of directors, including questionnaires provided by the members of our audit committee. We believe that our audit committee complies with the applicable requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq Global Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us. We have adopted an audit committee charter. The meeting schedule for the audit committee has not yet been established, but we expect that the committee will meet no less frequently than quarterly.

Compensation Committee

Our compensation committee consists of Messrs. Barone, Costantino and Otremba, with Mr. Otremba serving as its chair. The compensation committee s principal responsibilities are to administer our stock plans and to set the salary and incentive compensation, including stock option grants, for our Chief Executive Officer and senior management. We believe that our compensation committee members meet the requirements for independence under the current requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq Global Market and SEC rules and regulations. We have made this determination based on information received by our board of directors, including questionnaires provided by the members of our compensation committee. We believe that our compensation committee complies with the applicable requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq Global Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us. We have adopted a compensation committee charter. The meeting schedule for the compensation committee has not yet been established, but we expect that the committee will meet at least once a year.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Messrs. Barone, Costantino and Otremba, with Mr. Costantino serving as its chair. The nominating and corporate governance committee is responsible for reviewing and making recommendations on the composition of our board and selection of directors, periodically assessing the functioning of our board of directors and its committees, and making recommendations to our board of directors regarding corporate governance matters and practices. We believe that our nominating and corporate governance committee members meet the requirements for independence under the current requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq Global Market and SEC rules and regulations. We have made this determination based on information received by our board of directors, including questionnaires provided by the members of our nominating and corporate governance committee. We believe that our nominating and corporate governance committee complies with the applicable

requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq Global Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us. We have adopted a nominating and corporate governance committee charter. The meeting schedule for the nominating and corporate governance committee has not yet been established, but we expect that the committee will meet at least once a year.

We strive to operate within a comprehensive plan of corporate governance for the purpose of defining responsibilities, setting high standards of professional and personal conduct and assuring compliance with these responsibilities and standards. We have implemented changes to our corporate governance structure and procedures in response to the Sarbanes-Oxley Act of 2002 and the adopted changes in the Nasdaq Global Market s listing standards regarding corporate governance. We believe that our current corporate governance structure and procedures comply with existing corporate governance requirements. We will strive to maintain our board of directors and committees in full compliance with these corporate governance requirements on an ongoing basis. We will also continue to regularly monitor developments in the area of corporate governance.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee is an officer, former officer or employee of our company. No interlocking relationship exists between any of our executive officers or compensation committee members, on the one hand, and the executive officers or compensation committee members of any other entity, on the other hand, nor has any such interlocking relationship existed in the past.

Director Compensation

In March 2006, our board of directors approved a compensation program pursuant to which we will pay each of our non-employee directors an annual retainer of up to $24,000, payable in amounts of $5,000 on a quarterly basis, plus an additional $1,000 for each quarterly board meeting attended. We also will pay an additional $12,000 per year to each member of the audit committee, payable on a quarterly basis. We reimburse each non-employee director for out-of-pocket expenses incurred in connection with attending our board and committee meetings. The cash compensation paid to our directors may be adjusted from time to time as our board of directors may determine.

We have in the past granted to our directors options to purchase shares of common stock under our 2001 Stock Option Plan, or the 2001 Plan, or issued them warrants to purchase shares of our common stock. In March 2006, our board of directors approved the issuance of an option to purchase 23,529 shares of common stock to each of our non-employee directors under the 2001 Plan. These options vest at a rate of 1/48th per month over a period of four years from the date of grant, subject to full acceleration upon a change of control. Our board of directors or the compensation committee of our board of directors may, at its discretion, implement a policy regarding the issuance of stock options or other equity-based awards to our non-employee directors under our 2006 Equity Incentive Plan, or the 2006 Plan, after the completion of this offering. All options subject to automatic grants to our non-employee directors under the 2006 Plan will be non-statutory stock options.

During fiscal 2005, upon initial election or appointment to the board of directors, each non-employee director was issued a warrant to purchase 17,647 shares of our common stock. Mr. Barone received a warrant to purchase 17,647 shares of our common stock upon his election to the board of directors in April 2005. This warrant has a ten-year term, and has an exercise price equal to the fair market value of our common stock, as determined by our board of directors on the date of grant. This warrant vests in equal monthly installments over a period of four years from the date of grant. In December 2005, Mr. Barone received an additional warrant to purchase 11,764 shares of common stock in consideration for his services as a director. This warrant has a five-year term, and has an exercise price equal to the fair market value of our common stock, as determined by our board of directors on the date of grant. This warrant also vests in equal monthly installments over a period four years from the date of grant.

We are party to a director s agreement with Mr. Reinhard, pursuant to which, among other things, we issued him a warrant to purchase 152,941 shares of our common stock. In January 2006, we issued

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Mr. Reinhard an additional warrant to purchase 35,294 shares of our common stock, in consideration for services performed during fiscal 2005. See Certain Relationships and Related Party Transactions Director s Agreement and Warrants Issued to Christopher Reinhard.

In November 2006, our board of directors granted NGN Capital LLC an option to purchase up to 31,796 shares of common stock, at an exercise price of $10.63 per share, in connection with Mr. Costantino s service as a director on our board of directors. The options vest in equal monthly installments over a 48-month period commencing in June 2006.

Limitation of Liability and Indemnification of Officers and Directors

Our amended and restated certificate of incorporation, which will become effective upon the completion of this offering, limits the liability of our directors to the maximum extent permitted by Delaware law. Delaware law provides that a corporation may eliminate the personal liability of its directors for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following acts:

breach of their duty of loyalty to us or our stockholders;

acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

unlawful payments of dividends or unlawful stock repurchases or redemptions; and

any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation also provides that we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by the Delaware General Corporation Law.

Our amended and restated bylaws, which will become effective upon the completion of this offering, provide that (i) we are required to indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, subject to certain very limited exceptions, (ii) we are required to advance expenses, as incurred, to our directors and executive officers in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to certain very limited exceptions and (iii) the rights conferred in the amended and restated bylaws are not exclusive.

We have entered into indemnification agreements with each of our directors and executive officers to give these individuals additional contractual assurances regarding the scope of the indemnification set forth in our amended and restated certificate of incorporation and bylaws and to provide additional procedural protections. We intend to enter into indemnification agreements with any new directors and executive officers in the future. We have obtained directors and officers insurance providing coverage for all of our directors and officers for certain liabilities. We believe that these provisions and this insurance are necessary to attract and retain qualified directors and officers.

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 member of our board of directors, administered injections of Artecoll and/or ArteFill to Ms. Sandor 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 experienced adverse reactions as a result of the injections. The complaint also 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. See Business Legal Proceedings. 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 has declined coverage. We disclaim any liability for the actions of any person acting in his individual capacity and not as our agent.

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As reported in Business Legal Proceedings, the FDA s Office of Criminal Investigations is conducting an investigation which we believe may concern improper uses of our product prior to FDA approval by us, Dr. Gottfried Lemperle, a former officer and director, and Dr. Stefan M. Lemperle, a former officer and director. Although we have confirmed than this investigation is ongoing, we have received no confirmation of the subject matter of this investigation. We have not been, and to our knowledge, neither Drs. Gottfried Lemperle nor Stefan M. Lemperle nor any of our other former or current officers and directors have been contacted by the FDA regarding this investigation. If any proceeding or action is instituted by the FDA or another government agency against any of our former or current officers and directors regarding improper uses of our product prior to FDA approval, the officers and directors named in these proceedings or actions may request indemnification by the Company. Similarly, if any of our officers and directors are named as parties in the pending legal actions by Messrs. Schreiber and von Brendel described in Business Legal Proceedings, these officers may request indemnification by the Company. Other than the matters described above, we are not aware of any pending or threatened litigation or proceeding that might result in a claim for indemnification against us.

Executive Compensation

Summary compensation table

The following table summarizes the compensation paid to, awarded to or earned during the fiscal year ended December 31, 2005 by our former Chief Executive Officer and our four other most highly compensated executive officers whose annual compensation during fiscal 2005 exceeded $100,000. We refer to our former Chief Executive Officer and the executive officers listed in the table below as our named executive officers in this prospectus.

				Long term compensation	
	Annual Compensation ($)			Securities underlying	
Name and principal position(s)	Salary (1)	Bonus (2)	Other annual compensation(3)	options (# of shares)	All other compensation ($)
Christopher J. Reinhard(4) Executive Chairman of the Board of Directors	$ 112,608(5)	$	$	35,294(6)	
Peter C. Wulff Chief Financial Officer	148,519			70,588	
Stefan M. Lemperle, M.D.(7) Former Chief Executive Officer and former President	253,172				$
Gottfried Lemperle, M.D., Ph.D.(8) Former Vice President of Research and Development and former Chief Scientific Officer	187,882	70,000			
William von Brendel(9) Former Vice President of Worldwide Sales and International Markets	162,346			29,411	

(1) Includes amounts deferred at the election of each named executive officer under our 401(k) plan.

(2) In March 2006, our board of directors approved a bonus pool of $950,000 to be allocated among our employees in consideration for their performance during fiscal 2005. We anticipate that the compensation committee will approve individual bonus allocations to our executive officers from this pool after completion of this offering.

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(3) In accordance with Item 402(b)(2)(iii)(C)(1) of Regulation S-K promulgated under the Securities Act of 1933, the other annual compensation in this table does not include various perquisites and other personal benefits received by a named executive officer that does not exceed the lesser of $50,000 or 10% of such officer s salary and bonus disclosed in this table.

(4) Christopher J. Reinhard is employed with us on a part-time basis as our Executive Chairman of the Board of Directors. As a result, he is deemed to be an executive officer of our company.

(5) Represents $21,168 paid in cash and $91,440 paid in the form of shares of our common stock at the fair market value for our common stock, as determined by our board of directors, as of each payment date in accordance with our standard payroll schedule.

(6) Represents 35,294 shares of common stock issuable upon the exercise of a warrant granted to Mr. Reinhard in January 2006 in consideration for services in his capacity as our Executive Chairman of the Board of Directors during fiscal 2005. See Related Party Transactions Director s Agreement and Warrants Issued to Christopher Reinhard.

(7) Dr. Stefan M. Lemperle served as our Chief Executive Officer from August 1999 to October 2006.

(8) Dr. Gottfried Lemperle resigned from his positions as Vice President of Research and Development and Chief Scientific Officer in March 2006. Pursuant to a separation agreement entered into with Dr. Lemperle in connection with his resignation, we paid Dr. Lemperle a cash bonus of $70,000 in March 2006, in consideration for his performance during fiscal 2005.

(9) Mr. William von Brendel served as our Vice President of Worldwide Sales and International Markets from July 2004 to October 2006.

Option grants in fiscal year 2005

In April 2001, our board of directors adopted, and our stockholders approved, our 2001 Stock Option Plan, or the 2001 Plan. All options granted prior to the closing of this offering are governed by the terms of the 2001 Plan, except for 58,117 options that were granted from November 1999 to April 2001 under our 2000 Stock Option Plan or pursuant to individual option agreements (net of cancellations).

During the fiscal year ended December 31, 2005, we granted options to purchase a total of 610,588 shares of our common stock at an average exercise price of $5.31 per share to our employees, including certain of our named executive officers. Generally, options granted under the 2001 Plan vest in 48 successive equal monthly installments after the date of grant or the vesting start date determined by our board of directors. The options granted to Mr. von Brendel and Mr. Wulff during the fiscal year ended December 31, 2005 vest in 48 successive equal monthly installments after the date of grant. Under the terms of our 2001 Plan, any options to purchase shares of our common stock that expire or are otherwise terminated are returned to the option pool and become available for future grant under the plan. Options expire ten years from the date of grant.

The exercise price per share of each option granted to our named executive officers was equal to the fair market value of our common stock, as determined by our board of directors on the date of the grant. The exercise price is payable in cash, by promissory note or in shares of our common stock previously owned by the optionee. In determining the fair market value of the stock granted on the grant date, our board of directors considered many factors, including:

the illiquid nature of our securities as a nonpublic company;

the prices of preferred stock issued by us to outside investors in arm s-length transactions;

the rights, preferences and privileges of our preferred stock over our common stock; and

the likelihood that our common stock would become liquid through an initial public offering, a sale of our company or another event.

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The following table provides information concerning grants of options to purchase shares of our common stock under the 2001 Plan to our named executive officers during the fiscal year ended December 31, 2005. We did not grant any stock appreciation rights covering our common stock to our named executive officers during the fiscal year ended December 31, 2005.

Name	Number of securities underlying options granted	Percentage of total options granted to employees in fiscal year(1)	Exercise price per share	Expiration date	Potential realizable value at assumed annual rates of stock price appreciation for option term(2)	
					5%	10%
Christopher J. Reinhard			$		$	$
Peter C. Wulff	47,058	7.7%	5.31	4/22/2015	49,172	73,082
	23,529	3.9%	5.31	12/15/2015	25,186	38,281
Stefan M. Lemperle, M.D.						
Gottfried Lemperle, M.D., Ph.D.						
William von Brendel	29,411	4.8%	5.31	12/15/2015	31,482	47,851

(1) Based on 610,588 options granted during the fiscal year ended December 31, 2005 under the 2001 Plan, including grants to our named executive officers.

(2) Potential realizable values are computed by (a) multiplying the number of shares of common stock subject to a given option by the initial public offering price of $6.00 per share, (b) assuming that the aggregate stock value derived from that calculation compounds at the annual 5% or 10% rate shown in the table for the entire term of the option and (c) subtracting from that result the aggregate option exercise price. The 5% and 10% assumed annual rates of stock price appreciation are mandated by the rules of the SEC and do not represent our estimate or projection of future common stock prices.

Aggregated option exercises in last fiscal year and fiscal year-end option values

There were no option exercises by our named executive officers during the fiscal year ended December 31, 2005. The following table summarizes the value of options held by them as of December 31, 2005. There was no public trading market for our common stock as of December 31, 2005. Accordingly, the value of unexercised in-the-money options listed below has been calculated on the basis of the initial public offering price of $6.00 per share, less the applicable exercise price per share multiplied by the number of shares underlying the options.

	Shares acquired upon	Value	Number of securities underlying unexercised options at December 31, 2005	Value of unexercised in-the-money options at December 31, 2005

Name	exercise	realized	Exercisable	Unexercisable	Exercisable	Unexercisable
Christopher J. Reinhard			130,882(1)	22,058(1)	$ 90,309	$ 15,220
Peter C. Wulff			10,784	59,804	7,441	41,265
Stefan M. Lemperle, M.D.			70,588		318,528	
Gottfried Lemperle, M.D., Ph.D.			38,235	55,882	141,728	131,801
William von Brendel			11,909	49,266	20,841	55,040

(1) Represents shares issuable upon the exercise of warrants to purchase common stock at an exercise price of $5.31 per share granted to Mr. Reinhard. See Management Director Compensation.

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Employment, Severance and Change of Control Agreements

We have entered into employment agreements with Russell Anderson, our Vice President Product Development and Engineering and Lawrence Braga, our Vice President Manufacturing.

Pursuant to the employment agreements, each of Messrs. Anderson and Braga is required to devote his full business time to his services to us. The annual base salaries of Messrs. Anderson and Braga are set forth in their respective employment agreements. The employment agreements do not provide for automatic annual increases in salary, but our board of directors may, in its discretion, review the annual base salaries and approve increases to the base salaries. Pursuant to their employment agreements, Messrs. Anderson and Braga received options to purchase common stock at the then-current fair market value under our 2001 Stock Option Plan. We may terminate our relationship with Messrs. Anderson and Braga at any time, with or without cause. Their employment agreements provide each executive with certain severance benefits in the event his employment is terminated other than for good cause, as defined in the agreements. Specifically, in the event of such a termination, the executive will receive three months of salary continuation payments at his then-current base salary and up to three months of medical, dental, long-term disability and retirement benefits as then available to full-time employees (except in the event the executive voluntarily resigns, in which case he will not be entitled to the continuation of medical, dental, long-term disability and retirement benefits). Pursuant to their employment agreements, each of Messrs. Anderson and Braga are also entitled to receive his respective severance benefits described above in the event that we effect a change of control, and the executive resigns as a result of the change of control and the failure of the acquiring or surviving company to agree to his existing employment terms with us.

We have also entered into an employment offer letter agreement with Diane Goostree, our President and Chief Executive Officer and a director on our board of directors. This agreement, as amended, provides for an initial annual base salary of $300,000. In addition, Ms. Goostree received a bonus of $75,000 as an incentive for accepting our offer of employment and a bonus of $50,000 as compensation for a bonus that Ms. Goostree became ineligible to receive from her previous employer as a result of her acceptance of our offer. If Ms. Goostree voluntarily resigns other than for good reason, as defined in the agreement, within the first 24 months of her employment, a prorated portion of the $75,000 incentive bonus will be due to us. Ms. Goostree is also eligible to receive an annual performance-based bonus of up to 50% of her annual base salary, which will be based on both company and individual objectives and is subject to board approval. Pursuant to the offer letter agreement, Ms. Goostree received an option to purchase 117,647 shares of common stock under our 2001 Stock Option Plan at the then-current fair market value. Ms. Goostree is an at-will employee. Her employment offer letter provides her with certain severance benefits in the event her employment is terminated other than for good cause, as defined in the agreement, if she resigns for good reason or if her termination results from a change of control, as defined in the agreement. Specifically, in the event of such a termination, Ms. Goostree will receive a lump-sum payment equal to nine months of her then-current annual base salary and nine months of continued health insurance coverage under COBRA, as well as any unpaid salary, earned bonus amounts, unused paid time off and reimbursable business expenses through the date of termination. In the event of a termination in connection with a change of control, any unvested stock options held by Ms. Goostree that would otherwise lapse upon the change of control will be subject to accelerated vesting in the amount that would have vested over the nine months after her termination, subject to board approval. Ms. Goostree has agreed to resign as a director on our board of directors effective immediately upon the date she resigns or is removed from her office as Chief Executive Officer.

Following our internal investigation in March 2006, we entered into a separation agreement with Dr. Gottfried Lemperle in connection with his retirement and resignation as our Vice President of Research and Development, Chief Scientific Officer and a director. Under the terms of the agreement, we agreed to pay Dr. Gottfried Lemperle a cash bonus of $70,000 for his performance during fiscal year 2005 and to retain Dr. Gottfried Lemperle as a consultant to us for an initial term of up to 24 months beginning March 15, 2006, subject to an extension for an additional 12 months under certain circumstances. In connection with the separation agreement, Dr. Gottfried Lemperle also entered into a voting agreement with us, pursuant to which he has agreed to vote all shares of voting capital stock owned by him as directed by a majority of our board of directors on all matters presented for a vote of our stockholders. In May 2006, we terminated the

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consulting arrangement as permitted under the terms of the separation agreement, and we paid Dr. Gottfried Lemperle a lump sum payment of $366,667, the amount to which he would have been entitled had he completed the initial term of the separation agreement.

On November 17, 2006, we entered into a separation agreement and mutual general release with Dr. Stefan M. Lemperle in connection with his resignation as a director and as an employee. Pursuant to the agreement, we have paid Dr. Stefan Lemperle a severance payment of $250,000, plus an additional $81,250 in lieu of any bonus payments related to fiscal years 2005 and 2006. We also agreed to make severance payments to Dr. Stefan M. Lemperle in an aggregate amount of $300,000, payable in 12 monthly installments of $25,000 per month, commencing in December 2006, and to provide COBRA coverage to Dr. Stefan M. Lemperle for a period of 12 months from the date of his resignation. Dr. Stefan M. Lemperle is eligible to receive an additional severance payment of $400,000, contingent upon our completion of this offering or another qualifying transaction, as defined in the agreement, before March 31, 2007. In connection with the agreement, we also amended the terms of the outstanding stock options held by Dr. Stefan M. Lemperle to provide for the full acceleration of all unvested shares under his stock options, and we have agreed to issue to Dr. Stefan M. Lemperle a warrant to purchase up to 117,647 shares of common stock, subject to certain conditions and in an amount determined in accordance with the terms of the agreement. In consideration for these payments and benefits, Dr. Stefan M. Lemperle has provided a general release of claims against us and has agreed to cooperate with us in various matters, including assisting us in responding to questions raised by the FDA or other regulatory bodies, facilitating the completion of our initial public offering and assisting us with the resolution of outstanding claims against us by certain former employees.

In July 2004 and July 2005, respectively, we also entered into employment agreements with William von Brendel, our former Vice President Worldwide Sales and International Markets, and Harald T. Schreiber, our former Chief Creative Officer, on terms substantially similar to those under our employment agreements with Messrs. Anderson and Braga. Mr. von Brendel was additionally entitled to whole life insurance under his employment agreement, and Mr. Schreiber also received, in addition to his option grant, (i) a warrant to purchase 10,000 shares of common stock at an exercise price of $4.25 per share in consideration for consulting services provided to us prior to his employment, (ii) a warrant to purchase 5,882 shares of common stock at an exercise price of $5.31 in consideration for the assignment of certain intellectual property rights to us in connection with his employment and (iii) a warrant to purchase 11,764 shares of common stock at an exercise price of $5.31 in consideration for certain promotional services performed by Mr. Schreiber for us. In connection with a reduction in costs and the reorganization of our sales and marketing organization, we terminated the employment of Messrs. von Brendel and Schreiber on October 27, 2006. Mr. Schreiber filed a demand for arbitration against us on November 2, 2006. Mr. von Brendel filed a demand for arbitration against us on November 16, 2006. We are currently in settlement discussions with both Messrs. Schreiber and von Brendel. See Business Legal Proceedings.

Equity Compensation Plan Information

2006 Equity Incentive Plan

Our 2006 Equity Incentive Plan, which we refer to as the 2006 Plan, is intended to serve as the successor equity incentive program to our 2001 Stock Option Plan, or the 2001 Plan. We expect that our 2006 Plan will be adopted by our board of directors and stockholders prior to the completion of this offering, and that our 2006 Plan will become effective upon completion of this offering. Upon completion of this offering, all shares of stock remaining available for issuance and not subject to outstanding options under the 2001 Plan will become part of the available pool of shares under our 2006 Plan, and no further option grants will be made under the 2001 Plan. The options granted under the 2001 Plan will continue to be governed by their existing terms, unless our compensation committee elects to extend one or more features of our 2006 Plan to those options. The 2006 Plan will terminate on the earlier of (i) ten years after its adoption by our board of directors or by our stockholders, whichever adoption is earlier, or (ii) when the board of directors terminates the 2006 Plan.

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Stock options, stock appreciation rights, or SARs, stock awards and cash awards may be granted under the 2006 Plan. Each is referred to as an award in the 2006 Plan. Options granted under the 2006 Plan may be either incentive stock options, as defined under Section 422 of the Internal Revenue Code of 1986, as amended, or nonstatutory stock options.

Share Reserve. We have reserved an aggregate 5,882,352 shares of our common stock, including the shares from our 2001 Plan and our 2000 Plan described below, for issuance under the 2006 Plan. Awards generally shall not reduce the share reserve until the earlier of vesting or the delivery of the shares pursuant to an award. Shares reserved under the plan also include (i) shares of common stock available for issuance as of the effective date of this offering under the 2001 Plan and 2000 Plan plus (ii) shares of common stock issued under the 2001 Plan, 2000 Plan or the 2006 Plan that are forfeited or repurchased by us at or below the original purchase price or that are issuable upon exercise of awards granted pursuant to the 2001 Plan, 2000 Plan or the 2006 Plan that expire or become unexercisable for any reason without having been exercised after the effective date of this offering, plus (iii) shares of common stock that are restored by our board of directors or its compensation committee pursuant to provisions in the 2006 Plan that permit options to be settled in shares on a net appreciation basis at our election.

Automatic Annual Increase of Share Reserve. The 2006 Plan provides that the share reserve will be cumulatively increased on January 1 of each year, beginning January 1, 2007 and for nine years thereafter, by a number of shares that is equal to the lesser of (a) 5% of the number of our company s shares issued and outstanding prior to the preceding December 31, (b) 2,352,941 shares and (c) a number of shares set by our board of directors.

Administration. The 2006 Plan will be administered by the Compensation Committee of our board of directors or a delegated officer in certain instances. The Compensation Committee or officer is referred to in the 2006 Plan as the administrator.

Eligibility. Awards under the 2006 Plan may be granted to our employees, directors and consultants. Incentive stock options may be granted only to our employees. The administrator, in its discretion, approves awards granted under the 2006 Plan.

Termination of Awards. Generally, if an awardee s service to us terminates other than by reason of death, disability, retirement or for cause, vested options and SARs will remain exercisable for a period of three months following the termination of the awardee s service. Unless otherwise provided for by the administrator in the award agreement, if an awardee dies or becomes totally and permanently disabled while an employee or consultant or director, the awardee s vested options and SARs will be exercisable for one year following the awardee s death or disability, or if earlier, the expiration of the term of such award.

Nontransferability of Awards. Unless otherwise determined by the administrator, awards granted under the 2006 Plan are not transferable other than by will, a domestic relations order, or the laws of descent and distribution and may be exercised during the awardee s lifetime only by the awardee.

Exercise Price of Options. The administrator determines the exercise price of options at the time the options are granted. The exercise price of an incentive stock option may not be less than 100% of the fair market value of the our common stock on the date of grant. The exercise price of a nonstatutory stock option may not be less than par value of our common stock. The fair market value of our common stock will generally be the closing sales price as quoted on the Nasdaq Global Market.

Exercise of Option; Form of Consideration. The administrator determines the vesting schedule (if any) applicable to options. The administrator may grant options that are exercisable for unvested shares of common stock. To the extent that an optionee exercises an unvested option, we generally have the right to repurchase any or all of such unvested shares for either the exercise price paid by the optionee for such shares or the lower of the (i) exercise price paid by the optionee for such shares or (ii) current fair market value of such shares, as determined in accordance with the 2006 Plan, upon termination of optionee s employment or other relationship with us. This repurchase right lapses at the same rate as the vesting schedule applicable to the shares underlying the option. The means of payment for shares issued on exercise of an option are specified in each award agreement. The 2006 Plan permits payment to be made by any lawful

means including cash, check, wire transfer, other shares of our common stock (with some restrictions), broker-assisted same day sales or cancellation of any debt owed by us or any of our affiliates to the optionholder or in certain instances a delivery of cash or stock for any net appreciation.

Term of Options. The term of an option may be no more than ten years from the date of grant. No option may be exercised after the expiration of its term. Any incentive stock option granted to a ten percent stockholder may not have a term of more than five years.

Stock Appreciation Rights. The administrator may grant SARs alone, in addition to, or in tandem with, any other awards under this plan. An SAR entitles the participant to receive the amount by which the fair market value of a specified number of shares on the exercise date exceeds an exercise price established by the administrator. The excess amount will be payable in ordinary shares, in cash or in a combination thereof, as determined by the administrator. The terms and conditions of an SAR will be contained in an award agreement. The grant of an SAR may be made contingent upon the achievement of objective performance conditions.

Stock Awards. The administrator may grant stock awards such as bonus stock, restricted stock or restricted stock units. Generally such awards will contain vesting features such that awards will either not be delivered, or may be repurchased by us at cost, if the vesting requirements are not met. The administrator will determine the vesting and share delivery terms. In the case of restricted stock units the administrator may in its discretion offer the awardee the right to defer delivery. Stock awards may be settled in cash or stock as determined by the administrator.

Amended and Restated 2001 Stock Option Plan

In April 2001, we adopted our 2001 Stock Option Plan, or the 2001 Plan, which was approved by our stockholders in April 2001. Our board of directors most recently amended and restated the plan in August 2005 and our stockholders approved the amended and restated plan in August 2005. The 2001 Plan provides for the grant of incentive stock options, as defined under Section 422 of the Internal Revenue Code, to employees and for the grant of non-statutory stock options to employees, consultants, and non-employee directors. A total of 2,352,941 shares of our common stock have been authorized and reserved for issuance under the 2001 Plan. As of September 30, 2006, options to purchase a total of 1,813,916 shares of common stock, with a weighted average exercise price of $5.98 per share, were outstanding under the 2001 Plan.

Upon the effectiveness of our initial public offering, we will no longer issue any additional options under the 2001 Plan. Although no future options will be granted under this plan, all options previously granted under the 2001 Plan will continue to be outstanding and will be administered under the terms and conditions of the 2001 Plan.

Our board of directors, or a committee thereof, will continue to administer the 2001 Plan. The exercise price of all incentive stock options granted under the 2001 Plan must be at least equal to the fair market value of the common stock on the date of grant. The exercise price of all non-statutory stock options granted under the 2001 Plan shall be determined by our board of directors or a committee thereof, but in no event may be less than 85% of the fair market value on the date of grant. With respect to any optionee who owns stock possessing more than 10% of the voting power of all our classes of stock, the exercise price of any incentive stock option or non-statutory stock option granted must equal at least 110% of the fair market value on the grant date. The 2001 Plan provides for an option term of up to 10 years, but not to exceed five years for incentive stock options granted to 10% stockholders. Generally, options granted under the 2001 Plan vest in 48 successive equal monthly installments after the date of grant.

If an optionee s service terminates for any reason other than death, disability or cause, the optionee may exercise his or her vested options prior to the earlier of their expiration date or three months following the date of termination. In the event the optionee s service terminates as a result of the optionee s death, the options vested as of the date of death may be exercised prior to the earlier of their expiration date or 6 months from the date of the optionee s death. In the event the optionee s service terminates as a result of the optionee s disability, the options vested as of the date of disability may be exercised prior to the earlier of their

expiration date or one year from the date of the optionee s disability. If an optionee s service is terminated by the company for cause, all outstanding options shall terminate upon the earlier of their expiration date or the date of the occurrence giving rise to termination for cause.

All stock options granted under the 2001 Plan are non-transferable other than by will or the laws of descent and distribution following the optionee s death.

In the event of a corporate transaction where the acquiror assumes or replaces options granted under the 2001 Plan, options issued under the 2001 Plan will not be subject to accelerated vesting unless provided otherwise by agreement with the optionee or unless our board of directors or a committee thereof accelerates such vesting. In the event of a corporate transaction where the acquiror does not assume or replace options granted under the 2001 Plan, such outstanding options will become fully vested and exercisable 30 days prior to the consummation of the corporate transaction. In the event of a corporate transaction where the acquiror does not assume options granted under the 2001 Plan, such outstanding options will terminate upon the consummation of the corporate transaction.

2000 Stock Option Plan

In May 2000, we adopted our 2000 Stock Option Plan, or the 2000 Plan, which was approved by our stockholders in May 2000. The 2000 Plan provides for the grant of incentive stock options, as defined under Section 422 of the Internal Revenue Code, to employees and for the grant of non-statutory stock options to employees, consultants, and non-employee directors. A total of 235,294 shares of our common stock have been authorized and reserved for issuance under the 2000 Plan. As of September 30, 2006, options to purchase a total of 25,880 shares of common stock, with a weighted average exercise price of $2.34 per share, were outstanding under the 2000 Plan.

The 2000 Plan was terminated and superceded by adoption and approval of the 2001 Plan, effective April 2001. No additional options have been issued under the 2000 Plan since April 2001. Upon the effectiveness of our initial public offering, all options previously granted under the 2000 Plan will continue to be outstanding and will be administered under the terms and conditions of the 2000 Plan.

Our board of directors, or a committee thereof, will continue to administer the 2000 Plan. The exercise price of all incentive stock options granted under the 2000 Plan must be at least equal to the fair market value of the common stock on the date of grant. The exercise price of all non-statutory stock options granted under the 2000 Plan shall be determined by our board of directors or a committee thereof, but in no event may be less than 85% of the fair market value on the date of grant. With respect to any optionee who owns stock possessing more than 10% of the voting power of all our classes of stock, the exercise price of any incentive stock option or non-statutory stock option granted must equal at least 110% of the fair market value on the grant date. The 2000 Plan provides for an option term of up to 10 years, but not to exceed five years for incentive stock options granted to 10% stockholders. Generally, options granted under the 2000 Plan vest in 48 successive equal monthly installments after the date of grant.

If an optionee s service terminates for any reason other than death, disability or cause, the optionee may exercise his or her vested options prior to the earlier of their expiration date or three months following the date of termination. In the event the optionee s service terminates as a result of the optionee s death, the options vested as of the date of death may be exercised prior to the earlier of their expiration date or 6 months from the date of the optionee s death. In the event the optionee s service terminates as a result of the optionee s disability, the options vested as of the date of disability may be exercised prior to the earlier of their expiration date or one year from the date of the optionee s disability. If an optionee s service is terminated by the company for cause, all outstanding options shall terminate upon the earlier of their expiration date or the date of the occurrence giving rise to termination for cause.

All stock options granted under the 2000 Plan are non-transferable other than by will or the laws of descent and distribution following the optionee s death.

In the event of a corporate transaction where the acquiror assumes or replaces options granted under the 2000 Plan, options issued under the 2000 Plan will not be subject to accelerated vesting unless provided

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otherwise by agreement with the optionee or unless our board of directors or a committee thereof accelerates such vesting. In the event of a corporate transaction where the acquiror does not assume or replace options granted under the 2000 Plan, such outstanding options will become fully vested and exercisable 30 days prior to the consummation of the corporate transaction. In the event of a corporate transaction where the acquiror does not assume options granted under the 2000 Plan, such outstanding options will terminate upon the consummation of the corporate transaction.

Individual Option Grants

Prior to the establishment of the 2000 Plan, from November 1999 to May 2000, we granted options to purchase shares of common stock pursuant to individual option agreements. These options either were fully vested upon grant, or vested in equal monthly installments over a period of three or four years. As of September 30, 2006, options to purchase a total of 29,880 shares of common stock, with a weighted average exercise price of $0.51 per share, were outstanding under these individual option agreements.

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RELATED PARTY TRANSACTIONS

The following is a description of each transaction or series of transactions during the past three fiscal years, to which we have been a party, and in which the amount involved exceeds $60,000 and in which any of our directors, named executive officers or other executive officers, any holder of more than 5% of our common stock or any member of the immediate family of any of these persons had or will have a direct or indirect material interest, other than the compensation arrangements (including with respect to equity compensation) described in Management. We believe that we have executed all of the transactions described below on terms no less favorable to us than we could have obtained from unaffiliated third parties. All future transactions between us and our officers, directors and principal stockholders and their affiliates will be approved by the Audit Committee of our board of directors or a majority of our board of directors, including a majority of the independent and disinterested members of our board of directors, and will be on terms no less favorable to us than those that we could obtain from unaffiliated third parties. All of the share and per share numbers in this Section assume the completion of a one-for-4.25 reverse stock split of our outstanding common stock and the conversion of all outstanding shares of preferred stock into common stock, which events will occur in connection with the closing of this offering.

Indications of Interest in Purchasing Shares in this Offering by our Existing Stockholders

Certain of our existing stockholders have indicated an interest in purchasing up to approximately 800,000 shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, our underwriters may determine not to sell shares in this offering to our existing stockholders, or our stockholders may decide not to purchase shares in this offering.

Securities Issuances

From May 2002 to March 2003, we issued and sold convertible promissory notes in the aggregate principal amount of $2,615,000 and warrants to purchase an aggregate of 615,294 shares of Series C-1 preferred stock at an exercise price of $4.25 per share to investors in a bridge loan financing transaction. The securities issued in the bridge loan financing included a convertible promissory note in the principal amount of $743,005 and a warrant to purchase 174,824 shares of our Series C-1 preferred stock issued to Creative Microspheres, Inc., a private company beneficially owned by our former Chief Executive Officer and a former director, Dr. Stefan Lemperle. All outstanding principal and interest under the promissory note issued to Creative Microspheres, representing an aggregate amount of $809,614, were converted into 109,497 shares of our Series C-1 preferred stock in July 2003.

In June 2004, we issued and sold convertible promissory notes in the aggregate principal amount of $6,736,427 and warrants to purchase an aggregate of 634,016 shares of common stock at an exercise price of $5.31 per share to investors in a bridge loan financing transaction. Christopher J. Reinhard, our Executive Chairman of the Board of Directors, acquired a promissory note in the principal amount of $100,000 and a warrant to purchase 9,411 shares of common stock. All outstanding principal and interest under the promissory note, representing an aggregate amount of $106,992, were converted into 20,139 shares of Series D preferred stock in May 2005.

From December 2005 to March 2006, we issued shares of Series E preferred stock and warrants to purchase shares of Series E preferred stock at an exercise price of $10.62 per share to investors in a private placement transaction completed in a series of closings, for aggregate gross proceeds of approximately $50.7 million. The securities purchased by investors in this private placement transactions included:

- 9,411 shares of Series E preferred stock and warrants to purchase 1,882 shares of Series E preferred stock, issued for an aggregate purchase price of $100,000 to Lon E. Otremba, a member of our board of directors; and

- an aggregate of 470,588 shares of Series E preferred stock and warrants to purchase 141,176 shares of Series E preferred stock, issued for an aggregate purchase price of $5.0 million to NGN Biomed

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Opportunity I, L.P. and NGN Biomed Opportunity I GmbH & Co. Beteiligungs KG, affiliated funds of NGN Capital LLC. John R. Costantino, a member of our board of directors, is Managing General Partner of NGN Capital LLC.

Amendments to Outstanding Warrants

In June 2006, certain holders of warrants to purchase common stock issued by us to various individuals and entities in consideration for services provided to us, and certain holders of warrants to purchase common stock and warrants to purchase preferred stock issued by us to various individuals and entities in connection with their investments in our securities, elected to amend their warrants. Before their amendment, these warrants had terms ranging from five to 10 years from their issuance date, but would terminate upon the completion of this offering if not exercised before the completion of this offering. As amended, the warrants will not terminate upon the completion of this offering but instead, will continue in effect under their existing terms until (i) March 15, 2007, in the case of warrants issued in consideration for services provided, or (ii) the natural expiration date under the terms of the warrants, in the case of warrants issued in connection with investments in our prior financings. The amended warrants include the following warrants held by related parties:

warrants to purchase 7,058 shares of common stock at an exercise price of $5.31 per share held by Christopher J. Reinhard, our Executive Chairman of the Board of Directors;

warrants to purchase 4,705 shares of common stock at an exercise price of $5.31 per share held by Dr. Stefan M. Lemperle, our former Chief Executive Officer and a former director and employee;

warrants to purchase 174,824 shares of Series C-1 preferred stock at an exercise price of $4.25 per share held by Creative Microspheres, Inc., a private company beneficially owned by Dr. Stefan M. Lemperle;

warrants to purchase 17,647 shares of common stock at an exercise price of $5.31 per share held by Daren J. Barone, a member of our board of directors;

warrants to purchase 18,823 shares of common stock at an exercise price of $5.31 per share held by DJB Holdings, LLC, of which Mr. Barone is the managing member;

warrants to purchase 4,352 shares of common stock at an exercise price of $8.50 per share held by WB Partners, LP, of which Mr. Barone is a general partner; and

warrants to purchase 2,470 shares of common stock at an exercise price of $5.31 per share held by Lisa Bea Alton Anderson, the wife of Russell J. Anderson, our Vice President, Product Development and Engineering.

Indemnification Agreements

We intend to enter into indemnification agreements with our directors and executive officers for the indemnification of and advancement of expenses to these persons to the fullest extent permitted by law. We also intend to enter into these agreements with our future directors and executive officers.

Director s Agreement and Warrants Issued to Christopher Reinhard

In June 2004, we entered into a director s agreement with Christopher Reinhard, our Executive Chairman of the Board of Directors. Pursuant to this agreement, we issued a warrant to purchase 117,647 shares of common stock to Mr. Reinhard in consideration for his services as our Executive Chairman. The warrant is exercisable for up to an additional 35,294 shares of common stock, which became fully vested and exercisable upon our receipt of FDA approval for ArteFill on October 27, 2006. The warrant has an exercise price of $5.31 per share, subject to adjustment, and may be exercised at any time until the earlier of June 7, 2009, or the completion of a merger or sale of our company or the sale of all or substantially all of our assets. Pursuant to the director s agreement, we also agreed to reimburse Mr. Reinhard for expenses incurred in connection with his services as a director.

In January 2006, we granted Mr. Reinhard an additional warrant to purchase 35,294 shares of common stock at an exercise price of $5.31 per share, in consideration for services in his capacity as Executive Chairman of the Board of Directors during fiscal 2005. The warrant may be exercised at any time before January 3, 2011.

Acquisition of Assets from FormMed BioMedicals AG

In July 2004, we acquired assets and intellectual property from FormMed BioMedicals AG, or FormMed, related to the development and manufacture of PMMA microspheres used in the production of ArteFill. This transaction had an effective date of January 1, 2004. The assets acquired included rights to all of FormMed s U.S. and international patents, patent applications and trademarks related to the ArteFill platform technology and Artes Medical Germany GmbH (formerly MediPlant GmbH Biomaterials & Medical Devices), a facility for the manufacture of the PMMA microspheres. The aggregate purchase price for these assets was approximately $4.3 million, which was paid in installments through December 2005. We pledged certain of the acquired patents to FormMed to secure our obligations with respect to the purchase of the assets. At the time of the acquisition, Dr. Martin Lemperle was the controlling shareholder of FormMed. Dr. Martin Lemperle is the brother of Stefan Lemperle, our former Chief Executive Officer and a former director. Dr. Martin Lemperle is also a former director of our company.

Settlement Agreement with FormMed BioMedicals AG and Martin Lemperle

In October 2005, we entered into a settlement agreement with FormMed and Dr. Martin Lemperle, pursuant to which we paid to FormMed an aggregate cash fee of 427,500 Euro in installments through June 2006, and issued 7,214 shares of common stock to FormMed in full satisfaction of certain production costs disputed under the FormMed asset purchase agreement. We also paid to Dr. Martin Lemperle an aggregate cash fee of 150,000 Euro and issued 2,549 shares of common stock to Dr. Martin Lemperle in full satisfaction of his claims for reimbursement of certain legal expenses. In connection with these transactions, FormMed and Dr. Martin Lemperle entered into a voting agreement with us, pursuant to which they have agreed to vote all shares of voting capital stock held by them as directed by a majority of our board of directors on all matters presented to a vote of our stockholders.

Issuance of Common Stock to Directors in Consideration for Personal Guarantees

In December 30, 2005, we amended the terms of certain convertible promissory notes issued by us in connection with a bridge financing transaction to, among other things, extend the maturity date of the notes until February 2006. In connection with the amendment, three members of our board of directors, Stefan M. Lemperle, M.D., Christopher J. Reinhard and Daren J. Barone, agreed to provide personal guarantees on the debt under the notes. In consideration for the issuance of these personal guarantees, we agreed to issue to each of these directors 23,529 shares of common stock, which had a fair market value $10.41 per share on the date of issuance of the personal guarantees. We repaid all of the remaining debt under the notes in February 2006.

Separation and Termination Agreements with Gottfried Lemperle

In March 2006, we entered into a separation agreement with Dr. Gottfried Lemperle in connection with his retirement and resignation as our Vice President of Research and Development, Chief Scientific Officer and a director. Under the separation agreement, we agreed to retain Dr. Gottfried Lemperle as a consultant for an initial term of up to 24 months. In May 2006, we entered into a termination agreement with Dr. Gottfried Lemperle pursuant to which we terminated this consulting arrangement. See Management Employment, Severance and Change of Control Agreements.

Separation Agreement with Stefan Lemperle

In November 2006, we entered into a separation agreement with Dr. Stefan M. Lemperle in connection with his resignation as a director and employee of our company. See Management Employment, Severance and Change of Control Agreements.

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PRINCIPAL STOCKHOLDERS

The following table shows information with respect to the beneficial ownership of our common stock as of October 31, 2006 by:

- each of our current directors;
- each of our named executive officers as of December 31, 2005;
- all of our current directors and executive officers as a group; and
- each person or group of affiliated persons or entities known by us to beneficially own 5% or more of the outstanding shares of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options and warrants held by that person that are currently exercisable or exercisable within 60 days of October 31, 2006 are deemed outstanding, but are not deemed outstanding for computing the percentage ownership of any other person. Percentage of beneficial ownership is based on (i) 11,034,343 shares of common stock outstanding as of October 31, 2006, after giving effect to the conversion of all shares of our preferred stock into an aggregate of 9,367,511 shares of our common stock that will become effective at the closing of this offering and the issuance of 275,902 shares of common stock upon the exercise of outstanding warrants contingent and effective upon the closing of this offering, and (ii) 15,634,343 shares outstanding immediately after this offering. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person s name. Except as otherwise indicated, the address of each stockholder is c/o Artes Medical, Inc., 5870 Pacific Center Boulevard, San Diego, California 92121.

Certain of our existing stockholders have indicated an interest in purchasing up to approximately 800,000 shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, our underwriters may determine not to sell shares in this offering to our existing stockholders, or our stockholders may decide not to purchase shares in this offering. The following table does not reflect potential purchases by any of our existing stockholders.

		Percentage of shares beneficially owned	
Name and address of beneficial owner	**Number of shares beneficially owned**	**Before this offering**	**After this offering**
Directors and named executive officers			
Christopher J. Reinhard(1)	272,533	2.4%	1.7%
Diane S. Goostree(2)	27,941	*	*
Peter C. Wulff(3)	37,009	*	*
Stefan M. Lemperle, M.D.(4)	891,229	7.8%	5.6%
Gottfried H. Lemperle, M.D., Ph.D.(5)	403,026	3.6%	2.6%
William von Brendel(6)	33,867	*	*
Daren J. Barone(7)	149,759	1.4%	1.0%
Lon E. Otremba(8)	34,822	*	*
John R. Costantino(9)	611,762	5.5%	3.9%

All directors and executive officers as a group (12 persons)(10)	1,265,196	10.9%	7.8%

* Represents beneficial ownership of less than one percent of our outstanding common stock.

(1) Includes (i) 46,807 shares held by Christopher J. Reinhard, (ii) 20,139 shares issuable upon conversion of preferred stock held by Mr. Reinhard, (iii) 195,293 shares issuable to Mr. Reinhard upon

the exercise of warrants vested as of 60 days following October 31, 2006 and (iv) 10,294 shares issuable to Mr. Reinhard upon exercise of options vested as of 60 days following October 31, 2006.

(2) Includes 27,941 shares issuable to Diane S. Goostree upon the exercise of options vested as of 60 days following October 31, 2006.

(3) Includes 37,009 shares issuable to Peter C. Wulff upon the exercise of options vested as of 60 days following October 31, 2006.

(4) Includes (i) 23,529 shares held by Dr. Stefan M. Lemperle, (ii) 4,705 shares issuable to Dr. Stefan Lemperle upon the exercise of warrants vested as of 60 days following October 31, 2006, (iii) 117,646 shares issuable to Dr. Stefan Lemperle upon the exercise of options vested as of 60 days following October 31, 2006, (iv) 245,294 shares held by Creative Microspheres, Inc., (v) 259,672 shares issuable upon conversion of preferred stock held by Creative Microspheres, Inc. and (vi) 240,383 shares issuable to Creative Microspheres, Inc. upon the exercise of warrants vested as of 60 days following October 31, 2006. Dr. Stefan Lemperle, our former Chief Executive Officer and a former director, is the beneficial owner of the shares held by Creative Microspheres, Inc. Seyed Hadi Sadr, the director and President of Creative Microspheres, Inc., has sole voting and investment power with respect to the shares held by Creative Microspheres, Inc. Dr. Stefan Lemperle disclaims beneficial ownership of the shares held by Creative Microspheres, Inc., except to the extent of his pecuniary interest therein. The address for Creative Microspheres, Inc. is c/o Sadr & Barrera, APLC, 401 West A Street, Suite 1815, San Diego, CA 92101.

(5) Includes (i) 56,058 shares issuable to Dr. Gottfried Lemperle upon the exercise of warrants vested as of 60 days following October 31, 2006, (ii) 280,217 shares held by Opal Investments Management, Inc. and (iii) 66,751 shares issuable upon conversion of preferred stock held by Opal Investments Management, Inc. Dr. Gottfried Lemperle, our former Vice President of Research and Development and Chief Scientific Officer and a former director, is the beneficial owner of the shares held by Opal Investments Management, Inc., Seyed Hadi Sadr, the director and President of Opal Investments Management, Inc., has sole voting and investment power with respect to the shares held by Opal Investments Management, Inc. Dr. Gottfried Lemperle disclaims beneficial ownership of the shares held by Opal Investments Management, Inc., except to the extent of his pecuniary interest therein. The address for Opal Investments Management, Inc. is c/o Sadr & Barrera, APLC, 401 West A Street, Suite 1815, San Diego, CA 92101.

(6) Includes (i) 2,352 shares issuable upon conversion of preferred stock held by Kristine Jacques and (ii) 31,515 shares issuable to William von Brendel upon the exercise of options vested as of 60 days following October 31, 2006. Kristine Jacques is the wife of Mr. von Brendel. Mr. von Brendel served as our Vice President-Worldwide Sales and International Markets until October 2006.

(7) Includes (i) 11,765 shares issuable to Daren J. Barone upon the exercise of warrants vested as of 60 days following October 31, 2006, (ii) 23,529 shares issuable to Mr. Barone upon the exercise of options vested as of 60 days following October 31, 2006, (iii) 25,925 shares held by DJB Holdings, LLC, (iv) 43,601 shares issuable upon conversion of preferred stock held by DJB Holdings, LLC (v) 18,823 shares issuable to DJB Holdings, LLC upon the exercise of warrants vested as of 60 days following October 31, 2006; (vi) 21,764 shares issuable upon conversion of preferred stock held by WB Partners, LP. and (vii) 4,352 shares issuable to WB Partners, LP upon the exercise of warrants vested as of 60 days following October 31, 2006. Mr. Barone, a member of our board of directors, is the managing member of DJB Holdings, LLC and has sole voting and investment power with respect to the shares held by DJB Holdings, LLC. Mr. Barone and Greg Watkins are general partners of WB Partners, LP and share voting and investment power with respect to the shares held by WB Partners, LP. The address for DJB Holdings, LLC is 5776 Ruffin Road, San Diego,

California 92123.

(8) Includes (i) 9,411 shares issuable upon conversion of preferred stock held by Lon E. Otremba, (ii) 1,882 shares issuable to Mr. Otremba upon the exercise of warrants vested as of 60 days following October 31, 2006 and (iii) 23,529 shares issuable to Mr. Otremba upon the exercise of options vested as of 60 days following October 31, 2006.

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(9) Includes (i) 273,129 shares issuable upon conversion of preferred stock held by NGN BioMed Opportunity I, L.P., (ii) 81,938 shares issuable to NGN BioMed Opportunity I, L.P. upon the exercise of warrants vested as of 60 days following October 31, 2006, (iii) 197,458 shares issuable upon conversion of preferred stock held by NGN BioMed Opportunity I GmbH & Co. Beteiligungs KG and (iv) 59,237 shares issuable to NGN BioMed Opportunity I GmbH & Co. Beteiligungs KG upon exercise of warrants vested as of 60 days following October 31, 2006. NGN BioMed I, GP, L.P., which is the sole general partner of NGN BioMed Opportunity I, L.P., and NGN Capital LLC, which is the sole general partner of NGN BioMed I, GP, L.P. and the managing limited partner of NGN BioMed Opportunity I, GmbH & Co. Beteiligungs KG, each may be deemed to share voting and investment power with respect to all shares held by those entities. Mr. Costantino is Managing General Partner of NGN Capital LLC. Mr. Costantino disclaims beneficial ownership of the shares held by NGN Capital LLC, NGN BioMed Opportunity I, L.P., NGN BioMed Opportunity I GmbH & Co. Beteiligungs KG and NGN BioMed I, GP, L.P., except to the extent of his pecuniary interest therein.

(10) Excludes shares held by Dr. Stefan Lemperle, who was removed from his position as an executive officer in October 2006 and resigned as a director in November 2006, shares held by Dr. Gottfried Lemperle, who resigned as an executive officer and a director in March 2006, and shares held by William von Brendel, who was removed from his position as an executive officer in October 2006. Includes 27,941 shares issuable to Diane S. Goostree upon the exercise of options vested as of 60 days following October 31, 2006.

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DESCRIPTION OF CAPITAL STOCK

The description below of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will become effective upon closing of this offering. These documents will be filed as exhibits to the registration statement of which this prospectus is a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur upon the completion of this offering.

General

Our amended and restated certificate of incorporation authorizes the issuance of up to 200,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share. The rights and preferences of any authorized but undesignated preferred stock may be established from time to time by our board of directors.

As of September 30, 2006, there were issued and outstanding 1,390,930 shares of common stock and 8,915,740 shares of preferred stock convertible into 9,367,511 shares of common stock. As of September 30, 2006, we had 61 common stockholders of record and 845 preferred stockholders of record.

We will have a total of 15,634,343 shares of common stock outstanding immediately following this offering, assuming:

- 4,600,000 shares of common stock offered by us in this offering;
- 10,758,441 shares of common stock outstanding as of September 30, 2006 after giving effect to the conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering;
- 107,754 shares of common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, which the warrant holders have elected to exercise in cash, contingent and effective upon the closing of this offering; and
- 168,148 shares of common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, which the warrant holders have elected to exercise through the cashless exercise provisions of the warrants, based on the initial public offering price of $6.00 per share.

Common Stock

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, except matters that relate only to one or more of the series of preferred stock and each holder does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose.

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Holders of common stock have no preemptive or conversion rights or other subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock currently existing or which we may designate in the future.

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Preferred Stock

Upon the completion of this offering, all outstanding shares of preferred stock will be converted into an aggregate of 9,367,511 shares of common stock. Under our amended and restated certificate of incorporation, our board of directors will be authorized, subject to any limitations prescribed by law, without stockholder approval, to issue up to an aggregate of 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions granted to or imposed upon the preferred stock, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that may be issued in the future. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of delaying, deferring or preventing a change in control of our company. We have no present plans to issue any shares of preferred stock.

Warrants

As of September 30, 2006, we had outstanding warrants to purchase 2,490,189 shares of common stock, at a weighted average exercise price of $6.98 per share. Of these warrants:

- warrants to purchase 78,817 shares of common stock must be exercised in cash at any time prior to March 15, 2007;
- warrants to purchase 1,189,432 shares of common stock must be exercised in cash at any time prior to the expiration date of the warrant, which is typically five years from the date of issuance; and
- warrants to purchase 1,221,940 shares of common stock that may be exercised in cash or through cashless exercise provisions of the warrants at any time prior to the expiration date of the warrant, which is typically five years from the date of issuance.

In addition, in November 2006, we granted Comerica Bank a warrant to purchase 28,235 shares of common stock at an exercise price of $10.63 per share. This warrant may be exercised any time prior to November 2016.

These warrant numbers do not include the following shares of common stock issuable upon the closing of this offering:

- 107,754 shares of common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, which the warrant holders have elected to exercise in cash, contingent and effective upon the closing of this offering; and
- 168,148 shares of common stock issuable upon the exercise of preferred stock and common stock warrants outstanding as of September 30, 2006, which the warrant holders have elected to exercise through the cashless exercise provisions of the warrants, based on the initial public offering price of $6.00 per share.

Stock Options

As of September 30, 2006, there were outstanding options to purchase 1,869,676 shares of common stock, at a weighted average exercise price of $5.85 per share, including options to purchase 1,813,916 shares of common stock issued under our 2001 Stock Option Plan and 55,760 shares of common stock issued under our 2000 Stock Option Plan and pursuant to individual stock option agreements. In addition, in November 2006, we issued options to purchase up to 335,246 shares of common stock, at a weighted average exercise price of $10.63 per share, under our 2001 Stock Option Plan. We have also reserved an additional 3,640,843 shares of common stock for future grant under our 2006 Equity Incentive Plan, which will become effective upon the closing of this offering.

Registration Rights

After the offering, the holders of an aggregate of 11,606,882 shares of our outstanding common stock and shares of common stock issuable upon exercise of outstanding warrants are entitled to certain registration

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rights under an amended and restated investor rights agreement we entered into with these holders. The amended and restated investor rights agreement provides these stockholders with customary demand, piggyback and Form S-3 registration rights with respect to the shares of our common stock that will be issued to them upon conversion of our preferred stock upon the effectiveness of this registration statement.

Demand registration

Under the terms of the amended and restated investor rights agreement, holders of at least a majority of (i) the shares of common stock issued upon conversion of our preferred stock, including shares of preferred stock issuable upon the exercise of warrants to purchase preferred stock issued in our prior financing transactions and (ii) shares of common stock issuable upon the exercise of warrants to purchase common stock issued in our prior financing transactions, which we refer to as registrable securities, will have the right to require us to register their shares with the SEC for resale to the public. The holders of our preferred stock will be entitled to exercise this right at any time beginning on the earlier of January 1, 2008 or 180 days after the effective date of this registration statement. In both cases, however, the registered offering must be fully underwritten and the aggregate gross proceeds, prior to deduction for underwriters discounts and expenses, must exceed $25,000,000. Under the investor rights agreement, we will not be required to effect more than two demand registrations. We currently have not effected, or received a request to effect, any demand registrations under our existing investor rights agreements.

Piggyback registration

Under the terms of the amended and restated investor rights agreement, if we file a registration statement for a public offering of any of our securities (either for our own account or upon exercise of demand registration rights) on a form that would be suitable for a registration involving registrable common stock, holders of registrable securities will have the right to include their shares in the registration statement, subject to certain limitations. These piggyback registration rights will be exercisable beginning on the earlier of January 1, 2008 or 180 days after the effective date of this registration statement.

Form S-3 registration

Under the terms of the amended and restated investor rights agreement, at any time after we become eligible to file a registration statement on Form S-3, holders of 30% of the registrable securities will be entitled to require us to file a registration statement on Form S-3; provided that the aggregate gross proceeds of an offering pursuant to a Form S-3 registration must be at least $1,000,000.

Conditions and limitations; delay

The registration rights described above will be subject to certain conditions and limitations, including the right of the underwriters of an offering to limit the number of shares to be included in the registration. In the event any registered offering involves an underwriting, each stockholder s right to participate in the offering is conditioned upon that stockholder s participation in the underwriting. In addition, we will have the right to delay a demand registration or request for registration on Form S-3 during certain periods before and after the filing of registration statements by us, other than registrations of securities in Rule 145 transactions or with respect to employee benefit plans. We may also delay such registrations for one period not to exceed 120 days in any 12-month period if our board of directors believes it would be seriously detrimental to us or our stockholders to file a registration statement.

Expenses; indemnification

We are generally required to bear the expenses of all registrations, including reasonable fees and expenses of a single counsel acting on behalf of all selling stockholders, except underwriting discounts and selling commissions. The amended and restated investor rights agreement also will contain our commitment to indemnify the holders of registration rights for losses attributable to statements or omissions by us incurred with registrations under the agreement.

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Termination

The registration rights granted under the amended and restated investor rights agreement will terminate, with respect to each holder of such registration rights, upon the earlier of (i) five years following the closing of our initial public offering and (ii) the date on which any holder of such rights is eligible to sell such holder s registrable common stock under Rule 144 of the Securities Act within any ninety-day period.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation and Bylaws and Delaware Law

Amended and restated certificate of incorporation and bylaws

Some provisions of Delaware law and our amended and restated certificate of incorporation and bylaws contain provisions that could make the following transactions more difficult:

acquisition of us by means of a tender offer;

acquisition of us by means of a proxy contest or otherwise; or

removal of our incumbent officers and directors.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids and to promote stability in our management.

Stockholder meetings. Our charter documents provide that a special meeting of stockholders may be called only by a resolution adopted by a majority of our board of directors.

Elimination of stockholder action by written consent. Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Undesignated preferred stock. The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue one or more series of preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Requirements for advance notification of stockholder nominations and proposals. Our bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Amendment of bylaws. Any amendment of our bylaws by our stockholders requires approval by holders of at least 66 2/3% of our then outstanding common stock, voting together as a single class.

Staggered board. Our amended and restated certificate of incorporation provides for the division of our board of directors into three classes, as nearly equal in size as possible, with staggered three-year terms. Under our amended and restated certificate of incorporation and amended and restated bylaws, any vacancy on the board of directors resulting from death, resignation, removal, or other causes, other than a vacancy with respect to a director who must be elected by the holders of any class or series of stock (either in general or under specified circumstances), may only be filled by either (i) the affirmative vote of the holders of a majority of the voting power of the then-outstanding shares of voting stock of the Company entitled to vote generally in the election of directors, voting together as a single class; or (ii) the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors. Subject to the rights of any class or series of stock then outstanding, newly created directorships resulting from any increase in the number of directors shall, unless the Board of Directors determines by resolution that any such newly created directorship shall be filled by the stockholders, be filled only by the affirmative vote of the directors then in office, even though less than a quorum of the Board of Directors, or by a sole remaining director. The classification of the

board of directors and the limitations on the removal of directors and

filling of vacancies would have the effect of making it more difficult for a third party to acquire control of us or of discouraging a third party from acquiring control of us.

Amendment of amended and restated certificate of incorporation. Amendments to certain provisions of our amended and restated certificate of incorporation require approval by holders of at least 66 2/3% of our then outstanding common stock, voting together as a single class.

These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Delaware anti-takeover statute

We are subject to Section 203 of the Delaware General Corporation Law. This law prohibits a publicly held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless:

prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon completion of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines business combination to include:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, transfer, pledge or other disposition of 10% or more of our assets involving the interested stockholder;

in general, any transaction that results in the issuance or transfer by us of any of our stock to the interested stockholder;

in general, any transaction involving the corporation that has the effect, directly or indirectly, of increasing the proportionate share of our stock owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Limitation Of Liability

Our amended and restated certificate of incorporation provides that no director shall be personally liable to us or to our stockholders for monetary damages for breach of fiduciary duty as a director, except that the limitation shall not eliminate or limit liability to the extent that the elimination or limitation of such liability is not permitted by the Delaware General Corporation Law as the same exists or may hereafter be amended.

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The Nasdaq Global Market

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol ARTE.

Transfer Agent And Registrar

The transfer agent and registrar for our common stock is Mellon Investor Services LLC. Its address is 400 South Hope Street, 4th Floor, Los Angeles, CA 90071, and its telephone number is (213) 553-9700.

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SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and we cannot assure you that a significant public market for our common stock will develop or be sustained after this offering. Future sales of substantial amounts of our common stock, including shares of our outstanding common stock and shares of our common stock issued upon exercise of outstanding options and warrants, in the public market after this offering, or the perception that these sales could occur, could adversely affect the prevailing market price of our common stock and could impair our future ability to raise capital through the sale of equity securities.

Sale of Restricted Shares

Based on the number of shares outstanding as of September 30, 2006, we will have approximately 15,634,343 shares of common stock outstanding after the completion of this offering, and approximately 16,324,343 shares if the underwriters exercise their over-allotment option in full. Of these shares, the 4,600,000 shares of common stock sold in this offering, plus the additional 690,000 shares if the underwriters exercise their over-allotment option in full, will be freely transferable without restriction, unless purchased by our affiliates, as that term is defined under Rule 144 of the Securities Act of 1933, as amended.

The remaining 11,034,343 shares of common stock to be outstanding immediately following the completion of this offering, which are restricted securities, as well as any other shares held by our affiliates, may not be resold except pursuant to an effective registration statement or an applicable exemption from registration, including an exemption under Rule 144, Rule 144(k) or Rule 701 of the Securities Act. As of the date of this prospectus, these outstanding shares will be eligible for sale as follows:

- 321,823 shares of common stock that are not subject to the 180-day lock-up period described below will be immediately eligible for sale in the public market under Rule 144 or Rule 144(k) upon the effective date of the registration statement of which this prospectus is a part; and

- 10,712,520 shares of common stock that are subject to the 180-day lock-up period described below will be eligible for sale in the public market under Rule 144, Rule 144(k) or Rule 701, immediately upon expiration of the 180-day lock-up period described below, subject to the volume, manner of sale and other limitations under those rules.

Lock-Up Agreements

The holders of substantially all of our securities outstanding prior to the closing of this offering, including all of our officers and directors, have entered into lock-up agreements with the underwriters, or are subject to contractual arrangements with us, pursuant to which they have generally agreed, subject to certain exceptions, not to, without the prior written approval of Cowen and Company, LLC and Lazard Capital Markets LLC or us, as applicable, offer, sell, contract to sell or otherwise dispose of, directly or indirectly, or hedge our common stock or securities convertible into or exchangeable or exercisable for our common stock. These restrictions will be in effect for a period of 180 days after the date of this prospectus. This 180-day lock-up period with respect to the lock-up agreements with the underwriters and the contractual lock-up arrangements between us and our securityholders, for all but approximately 375,000 shares of common stock, may be extended under certain circumstances where we release, or pre-announce a release of, our earnings or material news or a material event shortly before or after the termination of the 180-day period. At any time and without public notice, Cowen and Company, LLC and Lazard Capital Markets LLC may, in their discretion, release all or some of the securities from their lock-up agreements. The 180-day lock-up period in the lock-up agreements with the underwriters shall not apply to the shares of common stock purchased by our securityholders, who are not officers and directors, from the underwriters participating in this offering or under the directed share program discussed below. See Underwriting.

Neither Rule 144, Rule 144(k) nor Rule 701 described below supersede the contractual obligations of our security holders set forth in the lock-up agreements described above.

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Registration Rights

After the offering, the holders of an aggregate of 11,606,882 shares of outstanding common stock and shares of common stock issuable upon exercise of outstanding warrants are entitled to certain registration rights. By exercising their registration rights and causing a large number of shares to be registered and sold in the public market, these holders could cause the price of our common stock to fall. In addition, any demand to include their shares in our registration statements could harm our ability to raise needed capital. For more information on these registration rights, see Description of Capital Stock Registration Rights.

Rule 144

In general, under Rule 144, as currently in effect, an affiliate of ours who beneficially owns shares of our common stock that are not restricted securities, or a person who beneficially owns for more than one year shares of our common stock that are restricted securities, may generally sell, within any three month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 156,343 shares immediately after this offering (approximately 163,243 shares if the underwriters exercise their over-allotment option in full); and
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four preceding calendar weeks.

Sales under Rule 144 are also subject to requirements with respect to manner of sale, notice and the availability of current public information about us.

Rule 144(k)

A person who was not our affiliate at any time during the three months before the sale, and who has beneficially owned shares of our common stock that are restricted securities for at least two years, may sell those shares without regard to the volume limitations, manner of sale provisions, notice requirements or the requirements with respect to availability of current public information about us. Affiliates must always sell pursuant to Rule 144, even after the applicable holding periods have expired.

Rule 701

Generally, an employee, officer, director or consultant who purchased shares of our common stock before the effective date of the registration statement of which this prospectus is a part, or who holds options as of that date, pursuant to a written compensatory plan or contract, may rely on the resale provisions of Rule 701 under the Securities Act. Under Rule 701, these persons who are not our affiliates may generally sell their eligible securities, commencing 90 days after the effective date of the registration statement of which this prospectus is a part, without having to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. These persons who are our affiliates may generally sell their eligible securities under Rule 701, commencing 90 days after the effective date of the registration statement of which this prospectus is a part, without having to comply with Rule 144 s one-year holding period restriction.

Warrants

There were outstanding warrants to purchase 2,490,189 shares of our common stock, as of September 30, 2006, after giving effect to the assumed issuance of 275,902 shares of common stock upon the exercise of warrants contingent and effective upon the closing of this offering. In addition, in November 2006, we granted a warrant to purchase 28,235 shares of common stock. Any shares of common stock acquired upon the exercise of these warrants after the completion of this offering will become eligible for sale in accordance with Rule 144 or Rule 144(k) after the date of exercise and subject to the expiration of applicable contractual lock-up or market standoff periods. As of the date of this prospectus, the holders of outstanding warrants to purchase 38,234 shares of common stock are not subject to lock-up agreements or other contractual lock-up provisions.

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Stock Options

There were outstanding options to purchase 1,869,676 shares of our common stock, as of September 30, 2006. In November 2006, we granted options to purchase 335,246 shares of common stock. In addition, we have reserved an additional 3,640,843 shares of our common stock for issuance under our 2006 Equity Incentive Plan, which will become effective on the closing of this offering. We intend to register, under the Securities Act of 1933, the shares of common stock underlying these outstanding stock options and the shares of common stock reserved for issuance under our 2006 Equity Incentive Plan on a registration statement on Form S-8 following this offering. Subject to the lock-up agreements, vesting restrictions and the restrictions imposed under our stock option plans, shares of common stock issued under our stock option plans after the effective date of any registration statement on Form S-8 will be available for sale in the public market without restriction to the extent that they are held by persons who are not our affiliates. As of the date of this prospectus, the holders of outstanding options to purchase 88,952 shares of common stock are not subject to lock-up agreements or other contractual lock-up provisions.

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MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion of certain material United States federal income tax considerations relevant to Non-U.S. Holders (as defined below) of our common stock is for general information only. Accordingly, all prospective Non-U.S. Holders of our common stock are urged to consult their own tax advisors with respect to the U.S. federal, state and local and foreign tax consequences of the acquisition, ownership and disposition of our common stock.

As used in this prospectus, the term Non-U.S. Holder is a person who is an owner of our common stock other than:

- a citizen or resident of the United States;
- a corporation or other entity taxable as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the United States or of any political subdivision of the United States;
- an estate the income of which is includable in gross income for United States federal income tax purposes regardless of its source; or
- a trust subject to the primary supervision of a U.S. court and the control of one or more U.S. persons, or a trust (other than a wholly owned grantor trust) that was treated as a domestic trust despite not meeting the requirements described above.

This discussion does not address:

- U.S. federal income, estate or gift tax consequences other than as expressly set forth below;
- state, local or foreign tax consequences;
- the tax consequences for the stockholders, beneficiaries or holders of other beneficial interests in a Non-U.S. Holder;
- special tax rules that may apply to selected Non-U.S. Holders, including without limitation, non-U.S. holders of interests in domestic or foreign partnerships, partnerships, banks or other financial institutions, insurance companies, dealers in securities, traders in securities, tax-exempt entities and United States expatriates; or
- special tax rules that may apply to a Non-U.S. Holder that holds our common stock as part of a straddle, hedge, conversion, synthetic security, or constructive sale transaction for United States federal income tax purposes, or a Non-U.S. Holder that does not hold our common stock as a capital asset within the meaning of Section 1221 of the United States Internal Revenue Code of 1986, as amended, or the Code.

If a partnership, including any entity treated as a partnership for U.S. federal income tax purposes, is a holder, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partnership. A holder that is a partnership, and partners in such partnership, should consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of our common stock.

The following discussion is based on provisions of the Code, applicable Treasury regulations and administrative and judicial interpretations, all as of the date of this prospectus, and all of which are subject to change, retroactively or prospectively. We have not requested a ruling from the United States Internal Revenue Service or an opinion of counsel with respect to the United States federal income tax consequences of the purchase or ownership of our common stock to a Non-U.S. Holder. There can be no assurance that the U.S. Internal Revenue Service will not take a position contrary to such statements or that any such contrary position taken by the U.S. Internal Revenue Service would not be sustained.

YOU ARE URGED TO CONSULT YOUR TAX ADVISOR WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO YOUR PARTICULAR SITUATION

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AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX RULES OR UNDER THE LAWS OF ANY STATE, LOCAL, FOREIGN OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.

Dividends

We do not anticipate paying cash dividends on our common stock in the foreseeable future. See Dividend Policy. In the event, however, that distributions are made on shares of our common stock, such distributions paid to a Non-U.S. Holder generally will be subject to withholding of U.S. federal income tax at a 30% rate on the gross amount of the distribution or such lower rate as may be provided by an applicable income tax treaty.

Dividends that are effectively connected with a Non-U.S. Holder s conduct of a trade or business in the United States or attributable to a permanent establishment in the United States under an applicable income tax treaty, known as United States trade or business income, are generally not subject to the 30% withholding tax if the Non-U.S. Holder files the appropriate United States Internal Revenue Service form with the payor. However, such U.S. trade or business income, net of specified deductions and credits, is taxed at the same graduated rates applicable to U.S. persons. Any U.S. trade or business income received by a Non-U.S. Holder that is a corporation may also, under certain circumstances, be subject to an additional branch profits tax at a 30% rate or such lower rate as specified by an applicable income tax treaty.

A Non-U.S. Holder of our common stock who claims the benefit of an applicable income tax treaty generally will be required to satisfy applicable certification and other requirements prior to the distribution date. Non-U.S. Holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A Non-U.S. Holder that is eligible for a reduced rate of U.S. withholding tax or other exclusion from withholding under an income tax treaty but that did not timely provide required certifications or other requirements, or that has received a distribution subject to withholding in excess of the amount properly treated as a dividend, may generally obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the United States Internal Revenue Service.

Gain on Disposition of Common Stock

A Non-U.S. Holder generally will not be subject to U.S. federal income tax in respect of gain recognized on a disposition of our common stock unless:

- the gain is U.S. trade or business income, in which case the regular corporate income tax and the branch profits tax described above may apply to a corporate Non-U.S. Holder;
- the Non-U.S. Holder is an individual who is present in the United States for more than 182 days in the taxable year of the disposition and meets other requirements;
- the Non-U.S. Holder is subject to tax pursuant to the provisions of the U.S. tax law applicable to selected U.S. expatriates; or
- we are or have been a United States real property holding corporation for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. Holder held our common stock.

Generally, a corporation is a United States real property holding corporation if the fair market value of its United States real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. The tax imposed on stock in a United States real property holding corporation generally will not apply to a Non-U.S. Holder whose holdings, direct or indirect, have not exceeded 5% of our common stock. We believe we have never been, are not currently, and are not likely to become a U.S. real property holding corporation for U.S. federal income tax purposes.

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Federal Estate Tax

Common stock owned or treated as owned by an individual who is a Non-U.S. Holder at the time of death will be included in the individual s gross estate for U.S. federal estate tax purposes, unless an applicable estate tax or other treaty provides otherwise.

Information Reporting and Backup Withholding Tax

We must report annually to the United States Internal Revenue Service and to each Non-U.S. Holder the amount of dividends paid to such holder and the tax withheld with respect to such dividends. Copies of the information returns reporting dividends and withholding may also be made available to the tax authorities in the country in which the Non-U.S. Holder is a resident under the provisions of an applicable income tax treaty or other agreement.

U.S. federal backup withholding generally will not apply to payments of dividends made by us or our paying agents, in their capacities as such, to a Non-U.S. Holder of our common stock, if the holder has provided the required certification, under penalties of perjury, as to its Non-U.S. Holder status in accordance with applicable United States Treasury Regulations.

The payment of the proceeds of the disposition of our common stock by a holder to or through a U.S. office of a broker, or through a foreign office of a broker who is a U.S. person or a United States related person (as defined below) generally will be subject to information reporting and backup withholding tax unless the holder provides the requisite certification of status as a Non-U.S. Holder, the broker has documentary evidence in its files that the holder is a Non-U.S. Holder and the broker has no actual knowledge, or reason to know, to the contrary or another exemption is established. For this purpose, a United States related person is:

a controlled foreign corporation for U.S. federal income tax purposes;

a foreign partnership if, at any time during the taxable year, (A) U.S. persons own more than 50% of the income or capital interests in the partnership, or (B) the partnership is engaged in a United States trade or business;

a foreign person 50% or more of whose gross income from all sources for the three-year period ending with the close of its taxable year preceding the payment, (or for such part of the period that the person has been in existence), is derived from activities that are effectively connected with the conduct of a United States trade or business; or

some U.S. branches of foreign banks or insurance companies.

Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder that result in an overpayment of taxes will generally be refunded, or credited against the holder s U.S. federal income tax liability, if any, provided that the required information is furnished to the U.S. Internal Revenue Service.

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UNDERWRITING

The underwriters named below, for whom Cowen and Company, LLC and Lazard Capital Markets LLC are acting as representatives, have agreed to purchase, subject to the terms of an underwriting agreement, the number of shares listed opposite their names below. The underwriters are committed to purchase and pay for all of the shares if any are purchased, other than those shares covered by the over-allotment option described below.

Underwriters	Number of Shares
Cowen and Company, LLC	1,812,400
Lazard Capital Markets LLC	1,812,400
Stifel, Nicolaus & Company, Incorporated	906,200
National Securities Corporation	23,000
Maxim Group LLC	23,000
WBB Securities, LLC	23,000
Total	4,600,000

The underwriting agreement provides that the obligations of the several underwriters to purchase shares of our common stock are subject to the satisfaction of the conditions contained in the underwriting agreement, which include that:

- the registration statement of which this prospectus is a part has been declared effective;
- the representations and warranties made by us to the underwriters are true;
- there is no material adverse change in our business;
- the shares of our common stock to be sold in this offering have been approved for listing on the Nasdaq Global Market; and
- we deliver customary closing documents to the underwriters.

The underwriters have advised us that they propose to offer the shares initially to the public at $6.00 per share. The underwriters propose to offer the shares to certain dealers at the same price less a concession of not more than $0.22 per share. The underwriters may allow and the dealers may reallow a concession of not more than $0.10 per share on sales to certain other brokers and dealers. After this offering, these figures may be changed by the underwriters.

Certain of our stockholders have indicated an interest in purchasing up to approximately 800,000 shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine not to sell shares in this offering to our existing stockholders, or our stockholders may decide not to purchase shares in this offering.

We have granted to the underwriters an over-allotment option to purchase up to an additional 690,000 shares of our common stock from us at the same price as to the public, and with the same underwriting discount, as set forth on the front cover of this prospectus. The underwriters may exercise this option any time during the 30-day period after the date of this prospectus, but only to cover over-allotments, if any. To the extent the underwriters exercise the option, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares as it was obligated to purchase under the underwriting agreement.

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The following table shows the underwriting discounts and commissions to be paid to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the over-allotment option.

	No Exercise	Full Exercise
Per share	$ 0.42	$ 0.42
Total to be paid by us	$ 1,932,000	$ 2,221,800

We estimate that the total expenses of this offering payable by us, excluding underwriting discounts and commissions, will be approximately $3,774,000. We have agreed to indemnify the underwriters against certain liabilities that may be based upon an untrue statement of material fact contained in this prospectus, including civil liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have informed us that neither they, nor any other underwriter participating in the distribution of this offering, will make sales of our common stock offered by this prospectus to accounts over which they exercise discretionary authority without the prior specific written approval of the customer.

The offering of our shares of common stock is made for delivery when and if accepted by the underwriters and subject to prior sale and to withdrawal, cancellation, or modification of this offering without notice. The underwriters reserve the right to reject an order for the purchase of shares in whole or part.

We and each of our directors, executive officers, and our security holders collectively beneficially owning substantially all of our outstanding securities, have entered into lock-up agreements with the underwriters or are subject to contractual arrangements with us providing that they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock, whether any transaction is to be settled by delivery of common stock or other securities, in cash or otherwise, without the prior written consent of Cowen and Company, LLC and Lazard Capital Markets LLC or us, as applicable, for a period of 180 days after the date of this prospectus.

Notwithstanding the foregoing, for the purpose of allowing the underwriters to comply with NASD Rule 2711(f)(4), if (1) during the last 17 days of the initial 180-day lock-up period, we release earnings results or material news or a material event relating to us occurs or (2) prior to the expiration of the initial 180-day lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the initial 180-day lock-up period, then in each case the initial 180-day lock-up period with respect to the lock-up agreements between the underwriters and our security holders and the contractual lock-up arrangements between us and our security holders, for all but approximately 375,000 shares of common stock, may be extended until the expiration of the 18-day period beginning on the date of release of the earnings results or the occurrence of the material news or material event, as applicable.

The lock-up agreements and the contractual arrangements do not prevent a security holder from transferring such securities by bona fide gift or by will or intestate succession to his or her immediate family or to a trust, the sole beneficiary of which is one or more of the security holder and his or her immediate family. Cowen and Company, LLC and Lazard Capital Markets LLC may waive their lock-up restrictions without public notice. Our lock-up agreement with the underwriters does not limit our ability to grant options to purchase common stock under our stock option plans.

The 180-day lock-up period in the lock-up agreement with the underwriters shall not apply to the shares of common stock purchased by our security holders, who are not officers or directors, from the underwriters participating in this offering or under the directed share program discussed below.

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Prior to this offering, there has been no established trading market for our common stock. The initial public offering price for the shares of our common stock offered by this prospectus was negotiated between us and the underwriters immediately prior to this offering. Factors considered in determining the initial public offering price included:

the history of, and the prospects for, the industry in which we compete;

our past and present operations;

our historical results of operations;

our prospects for future earnings;

the recent market prices of securities of generally comparable companies; and

the general condition of the securities markets at the time of this offering and other relevant factors.

The initial public offering price of our common stock may not correspond to the price at which our common stock will trade in the public market subsequent to this offering, and an active public market for our common stock may never develop or, if it does develop, continue after this offering.

To facilitate this offering, the underwriters may engage in transactions that stabilize, maintain, or otherwise affect the price of our common stock during and after this offering. Specifically, the underwriters may over-allot or otherwise create a short position in our common stock for their own account by selling more shares of our common stock than have been sold to them by us. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. Covered short sales are sales made in an amount not greater than the underwriters option to purchase additional shares from us in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are sales in excess of this option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

In addition, the underwriters may stabilize or maintain the price of our common stock by bidding for or purchasing shares of our common stock in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions allowed to syndicate members or other broker-dealers participating in this offering are reclaimed if shares of our common stock previously distributed in this offering are repurchased, whether in connection with stabilization transactions or otherwise.

The effect of these transactions may be to stabilize or maintain the market price of our common stock at a level above that which might otherwise prevail in the open market. The imposition of a penalty bid may also affect the price of our common stock to the extent that it discourages resales of our common stock. The magnitude or effect of any stabilization or other transactions is uncertain. These transactions may be effected on the Nasdaq Global Market or otherwise and, if commenced, may be discontinued at any time.

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by the underwriters participating in this offering or by their affiliates. In those cases, prospective investors may view offering terms and this prospectus online and, depending upon the underwriter, prospective investors may be allowed to place orders online or through their financial advisor. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations.

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Other than this prospectus in electronic format, the information on any underwriter s website and any information contained in any other website maintained by the underwriters is not part of this prospectus or the registration statement of which the prospectus forms a part, has not been approved or endorsed by us or the underwriters in its capacity as underwriter and should not be relied upon by investors.

At our request, certain of the underwriters have reserved up to 5% of the shares of common stock being sold in this offering for sale under a directed share program to our employees, directors, officers, stockholders and other persons who are associated with us and certain of their friends and family members. The purchasers of these shares will not be subject to a lock-up except to the extent these purchasers are subject to a lock-up agreement with the underwriters as described above. The number of shares available for sale to the general public in this offering will be reduced to the extent that these reserved shares are purchased by these purchasers. Any reserved shares not purchased by these purchasers will be offered by certain of the underwriters to the general public on the same basis as the other shares in this offering. All sales of shares under the directed share program will be made at the initial public offering price set forth on the cover page of this prospectus.

Certain of the underwriters and their affiliates have performed certain investment banking, advisory and commercial banking services for us from time to time for which they have received customary fees and expenses. From time to time in the ordinary course of their respective businesses, some of the underwriters and their affiliates may in the future engage in commercial banking and/or investment banking transactions with our affiliates and us. We paid Lazard Frères & Co. LLC $392,000 in December 2005 for investment banking and advisory services performed from October 2005 to December 2005. Lazard Frères & Co. LLC referred this transaction to Lazard Capital Markets LLC and will receive a referral fee from Lazard Capital Markets LLC in connection therewith.

In September 2004, we entered into an engagement letter with Legg Mason Wood Walker, Inc., pursuant to which we agreed to engage Legg Mason Wood Walker, Inc. as an exclusive placement agent or underwriter with respect to future securities offerings. We and Legg Mason Wood Walker, Inc. subsequently agreed to amend the engagement letter to require that we engage Legg Mason Wood Walker, Inc. only as a non-exclusive agent with respect to future securities offerings, and in connection with the amendment, we agreed to pay Legg Mason Wood Walker, Inc. $526,213 in cash and to issue to Legg Mason Wood Walker, Inc. a warrant to purchase 47,058 shares of Series E preferred stock at a price per share of $10.63. In December 2005, Stifel, Nicolaus & Company, Incorporated acquired Legg Mason Wood Walker, Inc. s investment banking business. In May 2006, we entered into a settlement agreement with Stifel, Nicolaus & Company, Incorporated. The parties agreed to settle their respective claims and disputes arising from the engagement letter, as amended. Pursuant to this settlement agreement, we agreed to pay Stifel, Nicolaus & Company, Incorporated $500,000 in cash and agreed to the terms of their participation as an underwriter in this offering.

Pursuant to the terms of selected dealer agreements entered into with National Securities Corporation in December 2005 and February 2006, we engaged National Securities Corporation to act as our placement agent with respect to private placements of our Series E preferred stock. We paid cash commissions in an aggregate amount of $3,549,100 and issued warrants to purchase an aggregate of 324,621 shares of Series E preferred 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 placements.

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LEGAL MATTERS

Legal matters with respect to the validity of the common stock offered hereby will be passed upon for us by Heller Ehrman LLP, San Diego, California. Wilson Sonsini Goodrich & Rosati, P.C., San Diego, California is counsel for the underwriters in connection with this offering.

EXPERTS

The consolidated financial statements of Artes Medical, Inc. at December 31, 2004 and 2005, and for each of the three years in the period ended December 31, 2005, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933 with respect to the common stock we are offering. This prospectus, which constitutes a part of the registration statement, does not contain all of the information in the registration statement or the exhibits of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits to the registration statement. Statements contained in this prospectus as to the contents of any contract, agreement or other document to which we make reference are not necessarily complete. In each instance, we refer you to the copy of such contract, agreement or other document filed as an exhibit to the registration statement, each such statement being qualified in all respects by the more complete description of the matter involved.

You may read and copy the registration statement of which this prospectus is a part at the SEC s Public Reference Room, which is located at 100 F Street, N.E., Washington, D.C. 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC s Public Reference Room. In addition, the SEC maintains an Internet web site, which is located at www.sec.gov, which contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC s Internet web site. Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, and we will file reports, proxy statements and other information with the SEC.

We maintain an Internet website at *http://www.artesmedical.com.* We have not incorporated by reference into this prospectus the information on our web site, and you should not consider it to be a part of this prospectus.

This prospectus includes statistical data obtained from industry publications. These industry publications generally indicate that the authors of these publications have obtained information from sources believed to be reliable but do not guarantee the accuracy and completeness of their information. While we believe these industry publications to be reliable, we have not independently verified their data.

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Artes Medical, Inc.
(a development stage company)
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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Artes Medical, Inc.

We have audited the accompanying consolidated balance sheets of Artes Medical, Inc. (a development stage company) as of December 31, 2004 and 2005, and the related consolidated statements of operations, stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2005. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Artes Medical, Inc. (a development stage company) at December 31, 2004 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California
May 4, 2006,
except for the third through the nineteenth paragraphs of Note 11, as to which the date is
November 27, 2006

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Artes Medical, Inc.
(a development stage company)
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,		September 30,	Pro Forma Stockholders Equity at September 30,
	2004	2005	2006	2006
			(unaudited)	(unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$ 2,269	$ 6,930	$ 12,789	
Prepaid expenses	130	204	274	
Inventory, net	250	692	4,019	
Other assets	299	374	78	
Deferred financing costs		1,011		
Total current assets	2,948	9,211	17,160	
Property and equipment, net	921	4,926	5,419	
Intellectual property, net	5,964	4,770	3,876	
Deposits	222	233	239	
Other assets	241	1,180	3,051	
Total assets	$ 10,296	$ 20,320	$ 29,745	
Liabilities and stockholders equity (deficit)				
Current liabilities:				
Accounts payable	$ 3,553	$ 3,317	$ 1,231	
Accrued compensation and benefits	154	1,499	2,304	
Accrued liabilities	740	1,585	1,108	
Income taxes payable	43	70	70	
Mediplant acquisition liability	2,250			
Convertible notes payable (net of discount of $860 at December 31, 2005)		5,665		
Capital lease obligations, current portion		49	44	
Total current liabilities	6,740	12,185	4,757	
Convertible notes payable (net of discount of $1,780 at December 31, 2004)	5,323			
Capital lease obligations, less current portion		66	31	
Deferred rent	486	686	718	
Deferred tax liability	2,341	1,846	1,704	
Commitments and contingencies				
Stockholders equity (deficit):				
	2	2	2	$

Series A convertible preferred stock, $0.001 par value, 2,050,839 shares authorized, issued and outstanding at December 31, 2004 and 2005 and September 30, 2006 (unaudited); liquidation preference of $3,076 at December 31, 2005 and September 30, 2006 (unaudited); no shares issued or outstanding pro forma (unaudited)				
Series B convertible preferred stock, $0.001 par value, 679,239 shares authorized, issued and outstanding at December 31, 2004 and 2005 and September 30, 2006 (unaudited); liquidation preference of $2,262 at December 31, 2005 and September 30, 2006 (unaudited); no shares issued or outstanding pro forma (unaudited)	1	1	1	
Series C-1 convertible preferred stock, $0.001 par value, 7,052,741 shares authorized, 4,437,741 issued and outstanding at December 31, 2004 and 2005 and 4,487,741 issued and outstanding at September 30, 2006 (unaudited); liquidation preference of $12,204 at December 31, 2005 and $12,341 at September 30, 2006 (unaudited); no shares issued or outstanding pro forma (unaudited)	4	4	4	
Series D convertible preferred stock, $0.001 par value, 11,500,000 shares authorized, none and 10,019,857 issued and outstanding at December 31, 2004 and 2005, respectively and 10,019,857 issued and outstanding at September 30, 2006 (unaudited); liquidation preference of $20,040 at December 31, 2005 and September 30, 2006 (unaudited); no shares issued or outstanding pro forma (unaudited)		10	10	
Series E convertible preferred stock, $0.001 par value, 10,000,000 shares authorized, none and 3,463,615 issued and outstanding at December 31, 2004 and 2005, respectively and 25,000,000 authorized, 20,654,221 issued and outstanding at September 30, 2006 (unaudited); liquidation preference of $8,659 at December 31, 2005 and $51,636 at September 30, 2006 (unaudited); no shares issued or outstanding pro forma (unaudited)		3	21	
Convertible preferred stock subscribed	3,543	6,900		
Common stock, $0.001 par value 150,000,000 shares authorized at December 31, 2004 and 2005; 1,138,644 and 1,229,553 shares issued and outstanding at December 31, 2004 and 2005 and 1,390,930 issued and outstanding at September 30, 2006 (unaudited), respectively; 200,000,000 shares authorized pro forma; 10,758,441 shares issued and outstanding pro	5	5	1	11

forma (unaudited)				
Common stock issuable		735		
Additional paid-in capital	23,318	53,635	94,144	94,172
Deferred stock-based compensation	(631)	(2,679)		
Deficit accumulated during the development stage	(30,836)	(53,079)	(71,648)	(71,648)
Total stockholders equity (deficit)	(4,594)	5,537	22,535	$ 22,535
Total liabilities and stockholders equity (deficit)	$ 10,296	$ 20,320	$ 29,745	

See accompanying notes.

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Artes Medical, Inc.
(a development stage company)
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Years Ended December 31,			Nine Months Ended September 30,		Period from August 24, 1999 (Inception) through September 30, 2006
	2003	2004	2005	2005	2006	
				(unaudited)	(unaudited)	(unaudited)
Expenses:						
Research and development	$ 974	$ 3,634	$ 10,189	$ 6,754	$ 5,698	$ 26,603
Selling, general and administrative	2,976	5,155	10,137	6,723	11,463	35,062
Loss from operations	(3,950)	(8,789)	(20,326)	(13,477)	(17,161)	(61,665)
Interest income	1		52	27	503	669
Interest expense	(2,171)	(4,028)	(4,468)	(3,545)	(2,410)	(14,181)
Other income (expense), net		(22)	2,041	(11)	351	2,469
Loss before benefit for income taxes	(6,120)	(12,839)	(22,701)	(17,006)	(18,717)	(72,708)
Benefit for income taxes		454	458	141	148	1,060
Net loss	$ (6,120)	$ (12,385)	$ (22,243)	$ (16,865)	$ (18,569)	$ (71,648)
Historical net loss per common share:						
Basic and diluted	$ (5.76)	$ (11.20)	$ (18.76)	$ (14.38)	$ (13.81)	
Weighted average shares - basic and diluted	1,062,825	1,106,188	1,185,387	1,172,419	1,344,503	
Pro forma net loss per common share (unaudited):						
Basic and diluted			$ (5.15)		$ (1.88)	
Weighted average shares - pro forma basic and diluted (unaudited)			4,319,411		9,885,002	

See accompanying notes.

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Artes Medical, Inc.
(a development stage company)
Consolidated Statements of Stockholders Equity (Deficit)
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Common Stock Issuable	Convertible Preferred Stock Subscribed	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Deferred Stock-Based Compensation	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount							
Issuance of common stock for cash at $0.09 per share		$	735,294	$ 1	$	$	$ 84	$	$	$	$ 85
Issuance of common stock for services			173,529				176				176
Issuance of Series A preferred stock for cash at $1.50 per share	112,266						168				168
Net loss and comprehensive loss										(896)	(896)
Balance at December 31, 1999	112,266		908,823	1			428			(896)	(467)
Issuance of Series A preferred stock for cash at $1.50 per share, net of issuance costs	1,912,902	2					2,811				2,813
Issuance of Series A preferred stock for services	25,671						114				114
Issuance of Series B preferred stock for cash at $3.33 per share	489,187	1					1,417				1,418
Issuance of Series B preferred stock for services	1,141						4				4
Issuance of common stock for cash, in March,			151,294				508				508

May, and September									
Issuance of stock options to consultants						48			48
Unrealized loss on available-for-sale investments							(36)		(36)
Net loss								(2,147)	(2,147)
Comprehensive loss									(2,183)
Balance at December 31, 2000	2,541,167	3	1,060,117	1		5,330	(36)	(3,043)	2,255
Series C preferred stock subscriptions at $7.00 per share for cash					682				682
Stock-based compensation						1			1
Issuance of Series B preferred stock in July for cash at $3.33 per share, net of issuance costs	188,911					620			620
Reclassification adjustment for losses realized in net loss							36		36
Net loss								(4,942)	(4,942)
Comprehensive loss									(4,906)
Balance at December 31, 2001	2,730,078	3	1,060,117	1	682	5,951		(7,985)	(1,348)
Issuance of subscribed Series C preferred stock in March	88,857				(622)	622			
Issuance of Series C preferred stock, in March, for cash at $7.00 per share, net of issuance costs	21,286					99			99

Refund due to cancellation of Series C preferred stock subscribed					(60)		(60)
Stock-based compensation					6		6
Issuance of warrants in connection with convertible notes from May to November					1,489		1,489
Issuance of Series C preferred stock for services in March	2,730				19		19
Net loss and comprehensive loss						(4,346)	(4,346)
Balance at December 31, 2002	2,842,951	3	1,060,117	1	8,186	(12,331)	(4,141)
Issuance of common stock upon exercise of stock options in November			17,647		7		7
Issuance of Series C-1 preferred stock for services in July	25,000				69		69
Issuance of warrants in connection with convertible notes from January through March					1,126		1,126
Issuance of Series C-1 preferred stock for cash, in July, at $2.75 per share, net of issuance costs	637,980	1			1,595		1,596
Stock-based compensation					159		159
Issuance of warrant in June in connection with patent acquisition					34		34

Conversion of Series C preferred stock to Series C-1 preferred stock in July	174,954						
Conversion of principal and interest on promissory notes to Series C-1 preferred stock in July	3,486,934	3			4,639		4,642
Net loss and comprehensive loss						(6,120)	(6,120)
Balance at December 31, 2003	7,167,819	7	1,077,764	1	15,815	(18,451)	(2,628)

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Artes Medical, Inc.
(a development stage company)
Consolidated Statements of Stockholders Equity (Deficit) (continued)
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Common Stock Issuable	Convertible Preferred Stock Subscribed	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Deferred Stock-Based Compensation	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount							
Issuance of common stock upon exercise of stock options, in April and October			14,117				29				29
Issuance of common stock in connection with intellectual property acquisition, in March and September			42,352				270				270
Issuance of common stock for services rendered in September			4,411				37				37
Series D preferred stock subscriptions at $2.00 per share for cash						3,543					3,543
Stock-based compensation							1,096				1,096
Deferred stock compensation							740		(740)		
Issuance of warrants in connection with convertible notes from							5,335				5,335

January though September									
Amortization of deferred compensation							109		109
Net loss and comprehensive loss								(12,385)	(12,385)
Balance at December 31, 2004	7,167,819	7	1,138,644	1	3,543	23,322	(631)	(30,836)	(4,594)
Issuance of common stock upon exercise of stock options in March			5,882			25			25
Issuance of common stock upon exercise of warrants in May through October			23,731			120			120
Issuance of common stock for services rendered in April through December			51,528			386			386
Issuance of common stock in connection with settlement agreement in October			9,768			102			102
Common stock issuable in exchange for guarantee on convertible debt in December					735				735
Issuance of Series D preferred stock in exchange for convertible notes and accrued interest, and cash, in May, at	9,754,761	10			(3,543)	14,245			10,712

$2.00 per share, net of issuance costs				
Issuance of Series D preferred stock at $2.00 in exchange for services in May	265,096		367	367
Issuance of warrants in connection with Series D convertible preferred stock in May			809	809
Issuance of warrants in connection with convertible note payable in January through September			2,007	2,007
Issuance of warrants in connection with amendment of convertible notes in December			276	276
Issuance of Series E preferred stock for cash, in December 2005, at $2.50 per share, net of issuance costs	3,089,615	3	7,703	7,706
Series E preferred stock subscriptions at $2.50 per share for cash in December		6,900		6,900
Issuance of Series E preferred stock	124,000		310	310

at $2.50 per share in exchange for termination agreement in December										
Issuance of Series E preferred stock at $2.50 per share in exchange for amendment of convertible note payable in December	250,000						625			625
Stock-based compensation							959			959
Deferred stock compensation							2,383	(2,383)		
Amortization of deferred compensation								335		335
Net loss and comprehensive loss									(22,243)	(22,243)
Balance at December 31, 2005	20,651,291	20	1,229,553	1	735	6,900	53,639	(2,679)	(53,079)	5,537
Issuance of common stock upon exercise of warrants and stock options in March through September (unaudited)			78,036				381			381
Issuance of common stock for services in January through May (unaudited)			8,048				89			89
Issuance of common stock in connection with intellectual property in January			4,705				49			49

(unaudited)							
Issuance of Series E convertible preferred stock at $2.50 per share for cash, in January, net of issuance costs (unaudited)	3,994,000	4		(6,750)	9,367		2,621
Issuance of Series E convertible preferred stock at $2.50 per share for cash, in February, net of issuance costs (unaudited)	5,484,200	6		(150)	12,444		12,300
Issuance of Series E convertible preferred stock at $2.50 per share for cash, in March, net of issuance costs (unaudited)	7,712,406	8			16,888		16,896
Issuance of Series C-1 convertible preferred stock upon exercise of warrants for cash in May (unaudited)	50,000				50		50
Issuance of common stock in connection with guarantee on convertible debt (unaudited)			70,588	(735)	735		
Stock-based compensation (unaudited)					1,805		1,805
Deferred stock compensation					(2,679)	2,679	

(unaudited)											
Warrant modification expense (unaudited)							1,376				1,376
Net loss and comprehensive loss (unaudited)										(18,569)	(18,569)
Balance at September 30, 2006 (unaudited)	37,891,897	$ 38	1,390,930	$ 1	$	$	$ 94,144	$	$	$ (71,648)	$ 22,535

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Artes Medical, Inc.
(a development stage company)
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,			Nine Months Ended September 30,		Period from August 24, 1999 (Inception) through September 30, 2006
	2003	2004	2005	2005	2006	
				(unaudited)		(unaudited)
Operating activities						
Net loss	$ (6,120)	$ (12,385)	$ (22,243)	$ (16,865)	$ (18,569)	$ (71,648)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization	35	1,148	1,742	1,210	1,786	4,863
Provision for obsolete inventory		117	120		200	437
Benefit for income taxes		(454)	(458)	(142)	(142)	(1,054)
Noncash interest expense associated with issuance of warrants and convertible notes	1,870	4,002	4,308	3,412	2,348	13,273
Warrant modification expense					899	899
Stock-based compensation	159	1,133	1,294	502	1,805	4,445
Issuance of stock for services	69	38	558	419	90	1,066
Issuance of stock for settlement and termination agreements			412			412
Issuance of common stock for intellectual property		270			49	319
Loss on disposal of fixed assets		25			32	57
Deferred rent	(1)	474	200	147	32	718
Deferred taxes		(43)	(27)			
Changes in operating assets and liabilities:						
Inventory		(160)	(562)	(122)	(3,527)	(4,249)
Prepaid expenses and other assets		(776)	(208)	(81)	226	(757)
Accounts payable	709	1,281	(398)	945	(2,085)	1,384
Accrued compensation	188	(20)	1,346	810	804	2,334
Accrued expenses	263	471	834	(53)	(478)	1,287
Income taxes payable		43	27			
Net cash used in operating activities	(2,828)	(4,836)	(13,055)	(9,818)	(16,530)	(46,214)
Investing activities						
Purchase of short-term investments						(3,028)
Sale of short-term investments						3,028
		(1,730)	(2,250)	(1,500)		(3,980)

Acquisition of intellectual property, net of cash acquired						
Purchases of property and equipment		(816)	(4,554)	(3,948)	(1,415)	(7,046)
Deposits and other assets	(250)		(950)	(110)	(1,878)	(3,133)
Net cash used in investing activities	(250)	(2,546)	(7,754)	(5,558)	(3,293)	(14,159)
Financing activities						
Proceeds from issuance of convertible notes payable	1,455	6,093	6,970	6,970		17,519
Proceeds from capital lease obligations			157	157		157
Payments on capital lease obligations			(41)	(28)	(40)	(81)
Proceeds from issuance of note payable						416
Payments on note payable						(416)
Refund on canceled subscribed Series C preferred stock						(60)
Payments on convertible note payable		(50)			(6,525)	(6,575)
Proceeds from subscribed preferred stock		3,543	6,900	3,446		11,125
Proceeds from issuance of preferred stock, net	1,596		11,456	4,528	31,816	49,986
Proceeds from issuance of common stock						595
Proceeds from exercise of stock options and warrants	8	29	28	26	431	496
Net cash provided by financing activities	3,059	9,615	25,470	15,099	25,682	73,162
Net (decrease) increase in cash and cash equivalents	(19)	2,233	4,661	(277)	5,859	12,789
Cash and cash equivalents at beginning of period	55	36	2,269	2,269	6,930	
Cash and cash equivalents at end of period	$ 36	$ 2,269	$ 6,930	$ 1,992	$ 12,789	$ 12,789
Noncash financing activities						
Issuance of subscribed preferred stock	$	$	$ 3,543	$	$ 6,900	$ 11,065
Issuance of warrants and common stock in connection with intellectual property acquisition	$ 34	$ 270	$	$	$ 49	$ 353
Conversion of convertible notes and interest into convertible preferred	$ 4,640	$	$ 8,246	$ 1,008	$	$ 12,886

stock

Issuance of convertible notes payable as commission for financing	$		$	141	$	203	$		$		$	344
Conversion of payables to convertible notes payable	$		$	234	$	95	$		$		$	327
Supplemental activities												
Cash paid for income taxes	$	1	$	2	$	1	$		$	6	$	13
Cash paid for interest	$		$	26	$	160	$		$	60	$	334

See accompanying notes.

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization and Business

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

The Company is a development stage company, and since inception has been engaged in organizational activities, including research and development, recruiting personnel, establishing office and manufacturing facilities, preparing for ArteFill s regulatory market approval and the related commercial scale-up of ArteFill manufacturing, preparing for ArteFill product marketing and distribution activities, and obtaining financing. Since inception, and through December 31, 2005, the Company has an accumulated deficit of $53.1 million.

Principles of Consolidation

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

Unaudited Pro Forma Stockholders Equity

The Company s board of directors has authorized the filing of a registration statement with the Securities and Exchange Commission to register shares of its common stock in an initial public offering. Upon the closing of the initial public offering, all of the shares of convertible preferred stock, including common stock issuable under anti-dilution provisions, will be converted into 9,367,511 shares of common stock. The unaudited pro forma stockholders equity reflects the conversion of all outstanding convertible preferred stock into common stock as if such conversion had occurred at September 30, 2006.

Use of Estimates

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

Interim Financial Information

The consolidated financial statements as of September 30, 2006 and for the nine months ended September 30, 2005 and 2006 and for the period from August 24, 1999 (inception) through September 30, 2006 are unaudited. The unaudited consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements, and, in the opinion of management, include all adjustments, consisting of only normal recurring accruals, necessary to state fairly the financial information set forth therein, in accordance with accounting principles generally accepted in the United States.

The results of operations for the interim period ended September 30, 2006 are not necessarily indicative of the results which may be reported for any other interim period or for the year ending December 31, 2006.

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

1. Organization and Summary of Significant Accounting Policies (continued)

Cash and Cash Equivalents

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

Reclassifications

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

Fair Value of Financial Instruments

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

Concentration of Credit Risk

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

Property and Equipment

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

Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company will record impairment losses on long-lived assets used in operations when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. While the Company s current and historical operating losses and cash flows are indicators of impairment, the Company believes the future cash flows to be received support the carrying value of its long-lived assets and, accordingly, the Company has not recognized any impairment losses through June 30, 2006.

Deferred Rent

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

Patent Costs

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

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

1. Organization and Summary of Significant Accounting Policies (continued)

Research and Development Expenses

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

Income Taxes

The Company uses the liability method of accounting for income taxes as required by SFAS No. 109, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

Foreign Currency Translation and Transactions

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

Comprehensive Income (Loss)

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

Stock-based Compensation

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

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

1. Organization and Summary of Significant Accounting Policies (continued)
Stock-based Compensation (continued)

For purposes of calculating the stock-based compensation under SFAS 123(R), the Company estimates the fair value of stock options using a Black-Scholes option-pricing model which is consistent with the model used for pro forma disclosures under SFAS 123 prior to the adoption of SFAS 123(R). The Black-Scholes option-pricing model was developed for use in estimating the fair value of short lived exchange traded options that have no vesting restrictions and are fully transferable. In addition, the Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. The expected volatility is based on the historical volatility of the Company s common stock over the most recent period commensurate with the estimated expected term of the Company s stock options. The expected term of the Company s stock options is based on historical experience. In addition, in accordance with SFAS 123(R) share-based compensation expense recognized in the statement of operations for the first quarter of 2006 is based on awards ultimately expected to vest and is reduced for estimated forfeitures. Prior to the adoption of SFAS 123(R), the Company used the minimum value method for valuing stock options granted to employees and directors. In the Company s pro forma information required under SFAS 123 for the periods prior to 2006, the Company accounted for forfeitures as they occurred.

The assumptions used to estimate the fair value of stock options granted to employee and directors during the nine-months ended September 30, 2006 and 2005 are as follows:

	Nine Months Ended September 30,	
	2006	2005
	Actual	Pro Forma
Volatility	60%	0%
Expected term (years)	6.0	4.0
Risk free interest rate	4.55%	3.00%
Expected dividend yield	0%	0%

The risk-free interest rate assumption was based on the United States Treasury s rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company s expectation of not paying dividends in the foreseeable future. The weighted average expected life of options was calculated using the simplified method as prescribed by the SEC s SAB No. 107 (SAB No. 107). This decision was based on the lack of relevant historical data due to the Company s limited historical experience. In addition, due to the Company s limited historical data, the estimated volatility also reflects the application of SAB No. 107, incorporating the historical volatility of comparable companies whose share prices are publicly available.

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2006 was $7.10 per share.

During the nine months ended September 30, 2006, the Company recorded approximately $749,000, as a result of the adoption of SFAS No. 123(R). Of this amount, $89,000 has been capitalized to inventory, $76,000 is included in research and development expenses and $584,000 is included in selling, general and administrative expenses.

Total unrecognized stock-based compensation costs related to non-vested stock options granted during the nine months ended September 30, 2006 was approximately $7,751,000 as of September 30, 2006, which

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

1. Organization and Summary of Significant Accounting Policies (continued)

Stock-based Compensation (continued)

related to 897,451 shares. This unrecognized cost is expected to be recognized on a straight-line basis over a weighted average period of approximately four years.

The following table illustrates the effect on net losses as if the Company had applied the fair value recognition provisions of SFAS 123 to determine stock-based compensation for the nine months ending September 30, 2005:

(in thousands, except per share amounts)		**Nine Months Ended September 30, 2005**
		(unaudited)
Net loss as reported	$	(16,865)
Add: Stock-based compensation included in net loss		199
Deduct: Stock-based employee and director compensation determined under fair value method for all awards		(296)
Pro forma net loss	$	(16,962)
Basic and diluted net loss per share as reported	$	(14.38)
Basic and diluted pro forma net loss per share	$	(14.47)

Equity instruments issued to non-employees are recorded at their fair values as determined in accordance with SFAS 123, *Accounting for Stock-Based Compensation*, and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the options vest and are recognized as expense over the related service period. During the years ended December 31, 2003, 2004, 2005, and for the nine months ended September 30, 2005 and 2006, and for the period from August 24, 1999 (inception) through September 30, 2006, we recognized $159,000, $1,024,000, $959,000, $303,000, $495,000 and $2,691,000, respectively, for stock options and warrants issued to non-employees.

Deferred Stock-Based Compensation

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

On September 13, 2005, the Company commenced the initial public offering process, and based on discussions with its investment bankers, reassessed the fair value of its common stock going back to July 1, 2004. The Company s management, all of whom qualify as related parties, determined that the stock options granted from July 1, 2004 forward were granted at exercise prices that were below the reassessed fair value of the common stock on the date of grant. The Company completed the reassessment of its fair value without the use of an unrelated valuation specialist and started with the proposed valuation from its investment bankers, considering a number of accomplishments in 2004 and 2005 that would impact its valuation, including achievement of key clinical milestones, hiring executive officers, and the increased possibility of completing an initial public offering. Accordingly, deferred stock-based

compensation of $740,000 was recorded within Stockholders Equity (deficit) during 2004 which represented the difference between the

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

1. Organization and Summary of Significant Accounting Policies (continued)
Deferred Stock-Based Compensation (continued)

weighted-average exercise price of $4.25 and the weighted-average fair value of $6.38 on 324,705 options granted to employees during 2004. Deferred stock-based compensation of $2,383,000, net of forfeitures, was recorded within Stockholders Equity (deficit) during 2005 which represented the difference between the weighted-average exercise price of $5.31 and the weighted-average fair value of $9.18 on 620,000 options granted to employees during 2005.

The deferred stock-based compensation is being amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. The Company recorded amortization of deferred stock-based compensation expense of $109,000 and $335,000 during 2004 and 2005 and $444,000 for the period from August 24, 1999 (inception) through December 31, 2005.

The expected future amortization expense for deferred stock-based compensation for stock options granted through December 31, 2005, is as follows (in thousands):

2006	$ 789
2007	789
2008	703
2009	458
Total	$ 2,739

During the years ended December 31, 2003, 2004, 2005, and for the nine months ended September 30, 2005 and 2006, and for the period from August 24, 1999 (inception) through September 30, 2006, we recognized $0, $109,000, $335,000, $199,000, $561,000 and $1,005,000, respectively, in amortization of deferred stock-based compensation which was provided for prior to the adoption of SFAS 123(R).

Unrecognized deferred stock-based compensation related to non-vested stock option and warrant awards granted prior to January 1, 2006 was approximately $1,874,509 at September 30, 2006.

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

1. Organization and Summary of Significant Accounting Policies (continued)
Deferred Stock-Based Compensation (continued)

Below is a summary of employee stock option grant activity, net of forfeitures and exercises, and related fair value information for the period from August 24, 1999 (inception) through November 27, 2006:

Grant date	Shares Granted	Exercise Price	Fair Value of Common Stock on Date of Grant	Intrinsic Value Per Share
November 1999	17,647	$ 0.43	$ 0.43	$
November 1999	470	0.64	0.64	
February 2000	5,882	0.64	0.64	
May 2000	5,882	0.64	0.64	
September 2000	5,882	2.34	2.34	
December 2000	20,000	2.34	2.34	
April 2001	2,352	2.34	2.34	
November 2001	91,764	1.49	1.49	
April 2002	11,764	1.49	1.49	
March 2003	9,411	6.38	6.38	
June 2003	27,058	6.38	6.38	
September 2004	356,470	4.25	6.38	2.12
April 2005	183,823	5.31	6.93	1.62
June 2005	8,235	5.31	6.93	1.62
September 2005	9,411	5.31	9.39	4.08
December 2005	392,941	5.31	10.41	5.10
March 2006 (unaudited)	292,941	5.31	11.69	6.38
September 2006 (unaudited)	691,764	7.86	12.75	4.89
November 7, 2006 (unaudited)	691,764	7.86	12.75	4.89
November 27, 2006 (unaudited)	335,246	10.63	13.00	2.37

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

As of September 30, 2006, 1,869,783 options to purchase common stock were outstanding, of this number 484,148 options were vested and 1,385,635 options were unvested. The intrinsic value of the vested and unvested stock options outstanding was $4,151,850 and $8,757,119, respectively.

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

1. Organization and Summary of Significant Accounting Policies (continued)

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

(in thousands, except per share amounts)	Nine Months Ended September 30, 2005	2006
		(unaudited)
Capitalized to inventory	$	$ 214
Research and development expense	$ 113	$ 267
Sales, general and administrative expense	389	1,324
	$ 502	$ 1,591
Net effect on basic and diluted net loss per share	$ 0.43	$ 1.18

Recently Issued Accounting Standards

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

2. Net Loss Per Common Share

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

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

2. Net Loss Per Common Share (continued)

Historical outstanding anti-dilutive securities on an as-if-converted method not included in the diluted net loss per common calculation:

	December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
Convertible preferred stock	1,686,545	1,712,800	5,307,180	4,492,212	9,367,511
Warrants to purchase preferred and common stock	638,431	1,566,653	2,423,758	2,366,486	3,365,534
Options to purchase common stock	375,003	560,470	1,149,000	2,405,176	1,869,676
	2,699,979	3,839,923	8,879,938	9,263,874	14,602,721

Pro Forma Net Loss per Common Share

Management believes that the additional disclosure below is useful to investors because it shows what basic loss per share would have been if the conversions of the Company s preferred stock had occurred at the beginning of the respective periods being reported rather than during the periods.

The calculation of unaudited pro forma basic and diluted net loss per common share assumes the conversion of all shares of Series A, Series B, Series C-1, Series D and Series E convertible preferred stock into shares of common stock using the as-if-converted method, as if such conversion had occurred as of January 1, 2003, or the original issuance date, if later.

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

2. Net Loss Per Common Share (continued)

Pro Forma Net Loss per Common Share (continued)

The Company s pro forma net loss per share is as follows:

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
Numerator:					
Net loss, as reported (in thousands)	$ (6,120)	$ (12,385)	$ (22,243)	$ (16,865)	$ (18,569)
Denominator:					
Shares used to compute basic and diluted net loss per share	1,062,825	1,106,188	1,185,387	1,172,419	1,344,503
Pro forma adjustments to reflect assumed weighted-average effect of conversion of preferred stock on January 1, 2003, 2004 and 2005, respectively	1,163,291	1,712,800	3,134,024	3,447,913	8,540,499
Pro forma shares used in basic and diluted pro forma net loss per share	2,226,116	2,818,988	4,319,411	4,620,332	9,885,002
Pro forma basic and diluted net loss per share attributable to common stockholders	$ (2.75)	$ (4.39)	$ (5.15)	$ (3.65)	$ (1.88)

3. Acquisitions

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

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

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

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

3. Acquisitions (continued)

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

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

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

Based on a third-party valuation, net intangible assets acquired were allocated to patents of $287,000 and core technology of $4,030,000. However, there was no allocation of the purchase price to these intangibles for tax purposes, and Mediplant s tax basis in the intangibles remained zero. EITF 98-11 requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability. Using the prescribed methodology, the Company assigned a value of $6,868,000 to the core technology and $2,838,000 to the related deferred tax liability. The weighted-average useful life of the patents and core technology was estimated to be six years. Accumulated amortization at December 31, 2005 was $96,000 for patents and $2,289,000 for core technology. Accumulated amortization at September 30, 2006 was $132,000 for patents and $3,148,000 for core technology. Amortization expense for patents and core technology is estimated to be $1,192,000 for each year from 2006 to 2009.

MediPlant Acquisition Settlement Agreement

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

The Company agreed to pay FormMed 428,000 Euro for the prior production and development costs on a payment schedule through June 30, 2006. In addition, the Company issued FormMed 7,214 shares of

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Artes Medical, Inc.
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3. Acquisitions (continued)

MediPlant Acquisition Settlement Agreement (continued)

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

All parties agreed that both the cash payments and common stock grant covers in full all prior period production, development and legal costs incurred by FormMed and Dr. Martin Lemperle. In the event that the Company completes an Initial Public Offering (IPO) prior to June 30, 2006, all unpaid amounts are payable within twenty (20) days upon closing of such IPO.

4. Balance Sheet Details

Other Assets

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

Deferred Financing Costs

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

Inventory

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

Inventory consisted of the following at (in thousands):

	December 31,		September 30,
	2004	2005	2006
			(unaudited)
Raw materials	$ 367	$ 929	$ 2,130
Work in process			2,267
Less: reserve for obsolete inventory	(117)	(237)	(378)
Total	$ 250	$ 692	$ 4,019

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Artes Medical, Inc.
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4. Balance Sheet Details (continued)

Property and Equipment

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

	December 31,		September 30,
	2004	2005	2006
			(unaudited)
Furniture and fixtures	$ 97	$ 385	$ 539
Office equipment	123	471	729
Lab equipment	390	1,820	2,273
Leasehold improvements	406	2,894	3,401
	1,016	5,570	6,942
Less accumulated depreciation and amortization	(95)	(644)	(1,523)
Total	$ 921	$ 4,926	$ 5,419

Total depreciation expense for the years ended December 31, 2003, 2004 and 2005 and for the nine months ended September 30, 2005 and 2006, and the period from August 24, 1999 (inception) through September 30, 2006, was $35,000, $42,000, $549,000, $316,000, $892,000 and $1,583,000, respectively.

5. Commitments and Contingencies

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

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

Years ended December 31,	
2006	$ 49
2007	45
2008	21
Total	$ 115

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

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Artes Medical, Inc.
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Notes to Consolidated Financial Statements (continued)

5. Commitments and Contingencies (continued)

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

Years ended December 31,	
2006	$ 867
2007	956
2008	985
2009	1,036
2010	1,087
Thereafter	990
Total minimum lease payments	$ 5,921

Rent expense was $110,000, $435,000, $954,000, $625,000 and $682,000 for the years ended December 31, 2003, 2004 and 2005 and for the nine months ended September 30, 2005 and 2006, respectively, and $2,478,000 for the period from August 24, 1999 (inception) through September 30, 2006.

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

Litigation Settlement Agreement

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

Legal Representation Settlement Agreement

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

6. Convertible Notes Payable

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

The remaining $33,000 of principal that was not converted and $12,000 of accrued interest is included in convertible notes payable on the December 31, 2004 and the $33,000 of principal and $15,000 of accrued

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Artes Medical, Inc.
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Notes to Consolidated Financial Statements (continued)

6. Convertible Notes Payable (continued)

interest is included in convertible notes payable on the December 31, 2005 consolidated balance sheets. For the years ended December 31, 2003, 2004 and 2005, and for the nine months ended September 30, 2005 and 2006, and for the period from August 24, 1999 (inception) to September 30, 2006, the Company recorded $70,000, $4,000, $4,000, $3,000, $1,000 and $353,000 of interest expense associated with the 2000 Notes, respectively.

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

For the years ended December 31, 2003, 2004 and 2005, and for the nine months ended September 30, 2005 and 2006, and for the period from August 24, 1999 (inception) to September 30, 2006, the Company recorded $163,000, $0, $0, $0, $0 and $213,000 of interest expense associated with the 2002 Notes, respectively.

In December 2003 and throughout 2004, the Company received bridge loan financing by issuing unsecured convertible notes payable (2004 Notes) in the amount of $6,736,000. The 2004 Notes bore interest at an annual rate of 8%. In May 2005, $6,736,000 of principal and $501,000 in accrued interest was converted into 5,789,801 shares of Series D preferred stock at a conversion rate of $1.25 per share. For the years ended December 31, 2004 and 2005, and for the nine months ended September 30, 2005 and 2006, and for the period from August 24, 1999 (inception) through September 30, 2006, the Company recorded $322,000, $179,000, $179,000, $0 and $501,000 of interest expense associated with the 2004 Notes, respectively.

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

In accordance with EITF 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments, the Company initially recorded its convertible debt net of a discount for the (i) the estimated fair value of the warrants issued in the amount of $2,667,500 and (ii) the intrinsic value of the related beneficial conversion feature in the same amount for a total of $5,335,000. The estimated fair value of the warrants was determined in accordance with the Black-Scholes valuation model. The discount associated with the warrants and beneficial conversion feature is being amortized to interest expense over the term of the outstanding convertible notes payable. Interest expense related to the warrants and beneficial conversion features was $3,555,000, $1,780,000, $1,780,000, $0 and $5,335,000 for the years ended December 31, 2004 and 2005, and for the nine months ended September 30, 2005 and 2006, and for the period from August 24, 1999 (inception) to September 30, 2006.

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

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Artes Medical, Inc.
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Notes to Consolidated Financial Statements (continued)

6. Convertible Notes Payable (continued)

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

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

Interest expense related to the warrants and beneficial conversion features was $1,772,000, $1,062,000, $235,000 and $2,007,000 for the year ended December 31, 2005, and for the nine months ended September 30, 2005 and 2006, and for the period from August 24, 1999 (inception) to September 30, 2006.

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

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

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

Per the note amendment, the investor waived both its conversion and redemption options under the original note and extended the due date of the remaining outstanding principal of $2,500,000 from February 3, 2006 to February 15, 2006. As additional consideration, the Company granted the investor a stock grant of 250,000 shares of Series E convertible preferred stock in December 2005. In addition, three Company directors personally guaranteed the remaining outstanding principal under the amended note agreement. In exchange for the personal guarantees, the three Company directors were given 23,529 shares of common stock. At December 31, 2005, the common stock had not yet been issued and is included as common stock issuable in the 2005 consolidated balance sheet and the consolidated statement of shareholders equity (deficit).

7. Stockholders Equity (Deficit)

Convertible Preferred Stock

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

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Artes Medical, Inc.
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Notes to Consolidated Financial Statements (continued)

7. Stockholders Equity (Deficit) (continued)

Convertible Preferred Stock (continued)

payable (2004 Notes), including accrued interest of $500,000, converting to 5,789,801 shares of Series D convertible preferred stock.

Certain purchasers of Series D convertible preferred stock received a warrant to purchase one share of common stock for each five shares of Series D convertible preferred stock purchased, or 842,969 warrants to purchase common stock, at an exercise price of $2.00 per share. The warrants may be exercised any time for a period of five years. The purchasers that were issued shares of Series D convertible preferred stock in connection with the conversion of promissory notes previously issued by the Company did not receive such warrants.

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

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

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

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

On January 6, 2006, the Company closed the second round of its Series E Financing. Upon closing, total gross proceeds of $6,750,000 were received resulting in the issuance of 2,700,000 shares of Series E convertible preferred stock and warrants for the future purchase of 702,000 shares of convertible Series E convertible preferred stock at $2.50 per share. The warrants expire January 6, 2011. In addition, the Company issued a warrant for the future purchase of 16,875 shares of common stock at $1.25 per share. This warrant expires January 6, 2011.

On January 13, 2006, the Company closed the third round of Series E Financing. Upon closing, total gross proceeds of $3,235,000 were received resulting in the issuance of 1,294,000 shares of Series E convertible preferred stock and warrants for the future purchase of 536,440 shares of Series E convertible preferred stock at $2.50 per share. The warrants expire January 13, 2011. In addition, the Company issued a warrant for the future purchase of 8,088 shares of common stock at $1.25 per share. This warrant expires January 13, 2011.

On February 14, 2006, the Company closed its fourth round of Series E Financing. Upon closing, total gross proceeds of $13,711,000 were received resulting in the issuance of 5,484,200 shares of Series E convertible

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Artes Medical, Inc.
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Notes to Consolidated Financial Statements (continued)

7. Stockholders Equity (Deficit) (continued)

Convertible Preferred Stock (continued)

preferred stock and warrants for the future purchase of 948,420 shares of convertible Series E convertible preferred stock at $2.50 per share. The warrants expire February 14, 2011. In addition, the Company issued a warrant for the future purchase of 5,727 shares of common stock at $1.25 per share. This warrant expires February 14, 2011.

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

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

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

At December 31, 2004, 2005 and September 30, 2006, the Company was authorized to issue 25,000,000 35,000,000 and 50,000,000 shares of preferred stock, respectively.

	December 31,						September 30,		
	2004			2005			2006 (unaudited)		
	Shares Designated	Shares Issued and Outstanding	Aggregate Liquidation Preference	Shares Designated	Shares Issued and Outstanding	Aggregate Liquidation Preference	Shares Designated	Shares Issued and Outstanding	Aggregate Liquidation Preference
			(in thousands)			(in thousands)			(in thousands)
Series A	2,050,839	2,050,839	$ 3,076	2,050,839	2,050,839	$ 3,076	2,050,839	2,050,839	$ 3,076
Series B	679,239	679,239	2,262	679,239	679,239	2,262	679,239	679,239	2,262
Series C-1	7,052,741	4,437,741	12,204	7,052,741	4,437,741	12,204	7,052,741	4,487,741	12,341
Series D	11,000,000			11,500,000	10,019,857	20,040	11,000,000	10,019,857	20,040
Series E				10,000,000	3,463,615	8,659	25,000,000	20,654,221	51,636
	20,782,819	7,167,819	$ 17,542	31,282,819	20,651,291	$ 46,241	46,282,819	37,891,897	$ 89,355

Conversion

Each share of Series A, B, C-1, D and E convertible preferred stock is convertible into one share of common stock at the option of the holder at an initial conversion price of $6.38, $14.15, $11.69, $8.50 and $10.63 per share, respectively, subject to anti-dilution adjustments.

Each share of preferred stock shall automatically be converted to common stock immediately prior to the closing of a firmly written public offering pursuant to an effective registration statement under the Securities Act of 1933, as

amended, covering the offer and sale of common stock of the Company in which the per share price is at least $10.00 per share and the gross proceeds exceed $25,000,000.

The Company s existing Fifth Amended and Restated Certificate of Incorporation provides that each outstanding share of preferred stock will automatically convert into shares of common stock upon the earlier of: (i) the Company s sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities Act of 1933, as amended, the public offering price of which is not less than $10.00 per share (adjusted to reflect subsequent stock dividends, stock splits or recapitaliza-

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Artes Medical, Inc.
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Notes to Consolidated Financial Statements (continued)

7. Stockholders Equity (Deficit) (continued)

Conversion (continued)

tions) and which results in aggregate cash proceeds of at least $25,000,000 (net of underwriting discounts and commissions); (ii) the date on which the Company first becomes subject to the periodic reporting requirements of Section 12(g) or Section 15(d) of the Securities Exchange Act of 1934, as amended; or (iii) the date specified by written consent or agreement of the holders of a majority of the then outstanding shares of preferred stock, voting together as a single class on an as-converted-to common stock basis. The Company has requested its preferred stockholders to execute a written consent that provides for the automatic conversion of the preferred stock immediately prior to the closing date of the Company s proposed initial public offering. The Company currently believes this written consent will be executed by the holders of more than a majority of the outstanding shares of preferred stock in accordance with item (iii) above.

Dividends

The holders of the Series A, B, C-1, D and E convertible preferred stock are entitled to receive noncumulative dividends at $0.12, $0.26, $0.22, $0.16 and $0.20 per share, respectively, per annum only when and if declared by the Board of Directors. To date, the Board of Directors has not declared any dividends.

Voting Rights

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

Liquidation

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

Anti-Dilution Provisions

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

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

Stock Option Plans

In 2001, the Company adopted the 2001 Stock Option Plan (the 2001 Plan) for eligible employees, officers, directors, advisors, and consultants that provides for the grant of incentive and nonstatutory stock options. The 2001 Plan supersedes the 2000 Stock Option Plan (the 2000 Plan). The Company has 2,352,941 shares of common stock options authorized under the 2001 Plan. Terms of the stock option

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Artes Medical, Inc.
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Notes to Consolidated Financial Statements (continued)

7. Stockholders Equity (Deficit) (continued)

Stock Option Plans (continued)

agreements, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the 2001 Plan. Options granted by the Company generally vest over four years and vested options are exercisable from the date of grant for a period of ten years. The exercise price of the incentive stock options must equal at least the fair market value of the stock on the date of grant.

The exercise price of nonstatutory stock options must equal at least 85% of the fair market value of the stock on the date of grant. The exercise price of any incentive stock option granted to a 10% stockholder may be no less than 110% of the fair value of the Company s common stock on the date of grant. As of December 31, 2005, there were 28,235 and 1,090,882 options outstanding under the 2000 and 2001 Plans, respectively, and 29,880 options granted outside the 2000 and 2001 Plans.

The Company recorded stock-based compensation for options granted to nonemployees of $54,000, $112,000, $107,000, $79,000, $78,000 and $406,000 for the years ended December 31, 2003, 2004 and 2005, and for the nine months ended September 30, 2005 and 2006, and for the period from August 24, 1999 (inception) through September 30, 2006, respectively. The fair value of each option was determined using the Black-Scholes valuation model and periodically re-measured and recognized over the related service period.

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Artes Medical, Inc.
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Notes to Consolidated Financial Statements (continued)

7. Stockholders Equity (Deficit) (continued)

Stock Option Plans (continued)

The following table summarizes stock option activity under the Plans, as well as outside the Plans (shares in thousands):

	Options	Weighted-Average Exercise Price
August 24, 1999 (inception)		
Granted	71	$ 0.43
Outstanding, December 31, 1999	71	0.43
Granted	187	1.36
Canceled	(29)	2.34
Outstanding, December 31, 2000	229	1.15
Granted	94	1.53
Canceled	(6)	0.64
Outstanding, December 31, 2001	317	1.28
Granted	11	1.49
Canceled	(8)	1.40
Outstanding, December 31, 2002	320	1.28
Granted	118	6.38
Exercised	(18)	0.43
Canceled	(46)	6.38
Outstanding, December 31, 2003	374	2.30
Granted	391	4.25
Exercised	(14)	2.04
Canceled	(191)	2.34
Outstanding, December 31, 2004	560	3.57
Granted	611	5.31
Exercised	(6)	4.25
Canceled	(16)	5.31
Outstanding, December 31, 2005	1,149	4.46
Granted (unaudited)	293	5.31
Exercised		
Canceled (unaudited)	(52)	4.55
Outstanding, March 31, 2006 (unaudited)	1,390	4.63
Granted (unaudited)	692	7.86

Exercised (unaudited)	(57)	4.51
Canceled (unaudited)	(20)	5.31
Outstanding, June 30, 2006 (unaudited)	2,005	5.74
Exercised (unaudited)	(6)	5.31
Canceled (unaudited)	(130)	4.46
Outstanding, September 30, 2006 (unaudited)	1,869	5.85
Exercised (unaudited)		
Canceled (unaudited)	(121)	6.30
Outstanding, November 7, 2006 (unaudited)	1,748	5.85
Granted (unaudited)	335	10.63
Outstanding, November 27, 2006	2,083	6.59

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Artes Medical, Inc.
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Notes to Consolidated Financial Statements (continued)

7. Stockholders Equity (Deficit) (continued)

Stock Option Plans (continued)

The following table summarizes information about options outstanding at December 31, 2005 under the 2000 and 2001 Plans and outside the Plans:

	Options Outstanding			Options Exercisable	
Grant Exercise Price	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$0.43 - $0.64	29,880	4.0 years	$ 0.51	27,308	$ 0.51
$1.49 - $2.34	131,764	5.7 years	1.66	116,800	1.62
$4.25 - $6.38	987,352	9.3 years	4.97	199,339	4.76
	1,148,996	8.7 years	4.46	343,447	3.36

Warrants

In February and May 2000, the Company issued in aggregate 16,666 fully vested warrants to purchase common stock at an exercise price of $6.38 per share in connection with services provided to obtain financing. The warrants expire ten years from the date of grant. The value of the warrants was estimated using the Black-Scholes valuation model and was not material to the financial statements. As of September 30, 2006, 12,745 warrants to purchase common stock have been exercised.

In June 2003, the Company issued a warrant to purchase 6,471 fully vested shares of common stock to a member of the Board of Directors at an exercise price of $5.40 per share in connection with services provided to facilitate the acquisition of certain worldwide patents and patent rights. The warrant expires in June 2014. The value of the warrant was estimated using the Black-Scholes valuation model and $34,000 was capitalized as intellectual property in the December 31, 2004 balance sheet and is being amortized over six years. The following assumptions were utilized in the model: expected dividend yield of 0%, expected volatility of 75%, risk-free interest rate of 4%, and contractual life of ten years. As of September 30, 2006, no warrants have been exercised.

In connection with the 2002 Notes, the Company issued 1,125,505 and 1,489,495 warrants to purchase Series C-1 preferred stock to the holders of the 2002 Notes during the years ended December 31, 2002 and 2003, respectively. The warrants are fully vested and have an exercise price of $1.00. The proceeds from the 2002 Notes were allocated to the carrying values of the notes and the warrants on the basis of their relative fair values at the date of issuance. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk-free interest rate of 3%, and contractual life of five years. As the fair value of the warrants exceeded the carrying value of the 2002 Notes, the allocated discount related to the warrants was limited to the amount of the proceeds from the 2002 Notes. As a result, $1,126,000 and $1,489,000 was recorded as a debt discount in 2002 and 2003, respectively. The discount was amortized over the term the 2002 Notes were outstanding, which resulted in interest expense of $745,000 and $1,870,000 in the years ended December 31, 2002 and 2003, respectively. The discount was fully amortized at December 31, 2003, as the 2002 Notes had been converted to Series C-1 preferred stock. As of September 30, 2006,

50,000 warrants have been exercised.

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

7. Stockholders Equity (Deficit) (continued)

Warrants (continued)

In connection with the 2004 Notes, the Company issued warrants to purchase 634,016 shares of common stock to the holders of the 2004 Notes during the year ended December 31, 2004. The warrants are fully vested and have an exercise price of $5.31. The proceeds from the 2004 Notes were allocated to the carrying values of the notes and the warrants on the basis of their relative fair values on the date of issuance. Due to the value ascribed to the warrants, the Company also recorded a beneficial conversion equal to the value ascribed to the warrants. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk free interest of 3%, and contractual life of five years. As a result, $5,335,000 was recorded as a debt discount in 2004. The debt discount is being amortized over the period during which the 2004 Notes are outstanding, which resulted in interest expense of $3,555,000 and $1,780,000 in the years ended December 31, 2004 and 2005, respectively. As of September 30, 2006, warrants to purchase 2,823 shares of common stock have been exercised.

In 2004, the Company issued a warrant to a member of the Board of Directors to purchase 152,941 shares of common stock at an exercise price of $5.31 per share. The warrant expires in 2009. 117,647 of the warrant shares were immediately vested and the remaining 35,294 warrant shares vest at 735 shares per month and the warrant shares vest earlier if the Company receives final marketing approval for ArteFill. The value ascribed to the 117,647 warrant shares was estimated using the Black-Scholes valuation model and resulted in $495,000 expensed to compensation for the year ended December 31, 2004. The 35,294 warrants were deemed to be employee warrants. As these warrants were issued with an exercise price less than the deemed fair market value of the underlying shares at grant date, the Company recorded the intrinsic value of $38,000 as deferred compensation and is amortizing to compensation expense over the term of the vesting period.

In September and November 2004, the Company issued in aggregate 100,000 fully vested warrants to purchase common stock at exercise prices ranging from $4.25 to $8.50 per share in connection with various consulting services provided to the Company. The warrants expire from four to ten years from the date of grant. The value of the warrants was estimated using the Black-Scholes valuation model and resulted in $417,000 expensed to compensation for the year ended December 31, 2004. As of September 30, 2006, no warrants have been exercised.

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

In November 2004, the Company issued 8,235 fully vested warrants to purchase common stock at an exercise price of $8.50 in connection with Series D subscriptions as direct financing related costs. There was no net impact to the consolidated financial statements. The warrants expire November 22, 2009 and as of September 30, 2006, no warrants have been exercised.

In September 2004, the Company issued 23,528 fully paid warrants to purchase common stock in connection with services provided by an employee to the Company. The warrants were to vest monthly in an equal amount over a 12-month period. The Company recorded $100,000 of compensation expense in 2004 based on the fair value of the warrants as the warrants vested. On December 31, 2004, 7,843 warrants were cancelled due to termination of services. On May 17, 2005, the 15,685 vested warrants were exercised.

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

7. Stockholders Equity (Deficit) (continued)

Warrants (continued)

In connection with the 2005 Bridge Loans, in 2005 the Company issued warrants equal to 30% of the principal amount of the Notes divided by the exercise price of $2.00 per share or warrants to purchase 1,045,500 shares of Series D convertible preferred stock. The warrants may be exercised any time for a period of five years. The proceeds from the 2005 Bridge Loan were allocated to the carrying values of the notes and the warrants on the basis of their relative fair values on the date of issuance. Due to the value ascribed to the warrants, the Company also recorded a beneficial conversion equal to the value ascribed to the warrants. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk free interest of 3.0%, and contractual life of five years. As a result, $2,007,360 was recorded as a debt discount in 2005 and $1,772,000 was amortized in 2005. As of September 30, 2006, no warrants have been exercised.

In 2005, certain purchasers of Series D convertible preferred stock received a warrant to purchase one share of common stock for each five shares of Series D convertible preferred stock purchased, or 198,310 warrants to purchase common stock at an exercise price of $8.50 per share. The warrants vest immediately and may be exercised any time for a period of five years. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk free interest of 3.0%, and contractual life of five years. As a result, $809,000 was recorded as equity issuance costs in 2005 with no net impact on the financial statements. As of September 30, 2006, no warrants have been exercised.

On December 22, 2005, the Company issued warrants to purchase up to 200,000 shares of Series E convertible preferred stock at $2.50 per share. These warrants were issued pursuant to a settlement agreement. The warrants vest immediately and may be exercised any time for a period of seven years. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk free interest of 4.5%, and contractual life of seven years. As a result, $364,000 was recorded as stock-based compensation. As of September 30, 2006, no warrants have been exercised.

On December 22, 2005, the Company issued warrants to purchase up to 4,543 shares of common stock at $5.31 per share. These warrants were issued pursuant to a settlement agreement. The warrants vest immediately and may be exercised any time for a period of five years. The fair value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0%, expected volatility of 75%, risk free interest of 4.5%, and contractual life of five years. As a result, $35,000 was recorded as stock-based compensation. As of September 30, 2006, no warrants have been exercised.

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

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

7. Stockholders Equity (Deficit) (continued)

Warrants (continued)

The following table summarizes common and preferred stock warrant activity from August 24, 1999 (inception) through November 27, 2006, on an as-if converted to common stock basis:

	Warrants	Weighted-Average Exercise Price
Outstanding, August 24, 1999 (inception)		
Issued	16,666	$ 6.37
Outstanding, December 31, 2000	16,666	6.37
Outstanding, December 31, 2001	16,666	6.37
Issued	846,029	4.25
Outstanding, December 31, 2002	862,695	3.02
Issued	6,471	5.40
Outstanding, December 31, 2003	869,166	3.02
Issued	928,223	5.31
Exercised	(471)	5.31
Outstanding, December 31, 2004	1,796,918	4.21
Issued	684,111	7.61
Expired	(16,666)	6.37
Cancelled	(17,343)	5.82
Exercised	(23,261)	6.33
Outstanding, December 31, 2005	2,423,759	5.10
Issued (unaudited)	951,145	10.11
Exercised (unaudited)	(12,745)	6.37
Outstanding, March 31, 2006 (unaudited)	3,362,159	6.59
Exercised (unaudited)	(18,529)	3.36
Outstanding, June 30, 2006 (unaudited)	3,343,630	6.59
Issued (unaudited)	26,070	4.25
Cancelled (unaudited)	(4,166)	5.31
Outstanding, September 30, 2006 (unaudited)	3,365,534	6.59
Cancelled (unaudited)	(1,715)	5.31
Outstanding, November 7, 2006 (unaudited)	3,364,037	6.59
Granted (unaudited)	28,235	10.63

Outstanding, November 27, 2006 (unaudited)	3,392,272	6.62

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

7. Stockholders Equity (Deficit) (continued)

Common Shares Reserved for Issuance

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

	December 31, 2005	September 30, 2006 (unaudited)
Convertible preferred stock as adjusted for anti-dilution provisions in conjunction with Series C-1 shares issued	5,307,180	9,367,511
Warrants for common and preferred stock	2,423,758	3,365,534
Common stock options outstanding previous to 2001 Plan	58,117	55,760
Common stock options outstanding under 2001 Plan	1,090,880	1,813,916
Common stock options available for future grant	1,256,176	472,558
Total common shares reserved for issuance	10,136,111	15,075,279

8. Income Taxes

At December 31, 2005, the Company had federal and California tax net operating loss carryforwards of approximately $43,044,000 and $43,034,000, respectively. The federal and state tax loss carryforwards begin to expire in 2019 and 2009, respectively, unless previously utilized.

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

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

	December 31,	
	2004	2005
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 9,977	$ 17,146
Reserves and other	1,182	2,200
Total deferred tax assets	11,159	19,346
Valuation allowance for deferred tax assets	(11,144)	(19,346)
	15	
Deferred tax liabilities:		
Foreign intangible	(2,341)	(1,831)

Other	(15)	(15)
Total deferred tax liabilities	(2,356)	(1,846)
Net deferred tax liabilities	$ (2,341)	$ (1,846)

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

8. Income Taxes (continued)

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

	Years Ended December 31,		
	2003	2004	2005
Current:			
Federal	$	$	$
State			
Foreign		(43)	(37)
		(43)	(37)
Deferred:			
Federal			
State			
Foreign		497	495
		497	495
	$	$ 454	$ 458

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

	December 31,		
	2003	2004	2005
Tax benefit at federal statutory rate	$ 2,081	$ 4,365	$ 7,718
State, net of federal benefit	357	749	1,324
Foreign tax		454	458
Change in valuation allowance excluding change applicable to purchased intangibles	(2,435)	(4,034)	(8,202)
Change in valuation allowance applicable to purchased intangibles		84	5
Other foreign loss		(452)	(457)
Other permanent differences	(3)	(712)	(388)
Benefit for income taxes	$	$ 454	$ 458

9. Employee Benefit Plan

Effective January 1, 2000, the Company adopted a defined contribution 401(k) profit sharing plan (the Plan) covering substantially all employees that meet certain age requirements. Employees may contribute up to 100% of their compensation per year (subject to a maximum limit by federal law). The Plan does allow for employer matching.

To date, no employer match has been made.

10. Related-Party Transactions

The Company receives services from entities affiliated with stockholders of the Company. The Company paid $318,000, $0, $0, $0, $0 and $389,000 during the years ended December 31, 2003, 2004, 2005, and for the nine months ended September 30, 2005 and 2006 and for the period from August 24, 1999 (inception) through September 30, 2006, respectively, for those services.

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

10. Related-Party Transactions (continued)

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

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

11. Subsequent Events

In January 2006, the Company s stockholders approved the filing of two amendments to the Company s Fifth Amended and Restated Certificate of Incorporation that would allow the Company to complete an additional financing transaction (Series E Financing). One amendment provides for an increase in the authorized shares of Series E convertible preferred stock from 10,000,000 shares to 25,000,000 shares, and a corresponding increase in the number of total authorized shares of Preferred Stock for all designations. The second amendment provides for certain changes in voting rights, whereby (a) the holders of Preferred Stock (voting together as a single class on an as-converted to Common Stock basis) shall be entitled to elect one (1) member of the Board of Directors, (b) the holders of Common Stock (voting as a separate class) shall be entitled to elect one (1) member of the Board of Directors and (c) the holders of Common Stock and Preferred Stock (voting together as a single class on an as-converted basis), shall be entitled to elect all remaining members of the Board of Directors. In addition, the shareholders approved the proposed terms and conditions of the Series E Financing for which the first round had closed on December 22, 2005 (see Note 7).

In March 2006, the Company entered into a separation agreement with a founder in connection with his retirement and resignation. Under the terms of the agreement, the Company agreed to pay a cash bonus of $70,000 for his performance during fiscal year 2005 and to retain him as a consultant for an initial term of up to 24 months beginning March 15, 2006, subject to an extension for an additional 12 months under certain circumstances. In connection with the separation agreement, the parties also entered into a voting agreement, pursuant to which the founder agreed to vote all shares of voting capital stock owned by him as directed by a majority of the board of directors on all matters presented for a vote of the stockholders. In May 2006, the Company terminated the consulting arrangement as permitted under the terms of the separation agreement and the Company paid a lump sum payment of $366,667, the amount to which the founder would have been entitled had he completed the initial term of the separation agreement.

In May 2006, the Company paid $500,000 to Stifel, Nicolaus & Company, Incorporated in connection with a settlement agreement.

On June 9, 2006, the Company granted 132,941 options to purchase common stock to employees at a weighted average exercise price of $7.86 per share. These options vest over a four a year term with a six-month cliff. The grant-date fair value of the underlying common stock was $12.75 per share. For purposes of calculating the stock-based compensation expense to be recognized under SFAS No. 123R, the Company valued these employee stock options using the Black-Scholes option pricing model with the following assumptions: an expected term of 5.96 years; expected volatility of 60%; a risk free interest rate of 4.55%; and a dividend yield of 0%. Stock-based compensation related to these stock options was $1,186,500 and will be recognized over a weighted average requisite service period of approximately four years.

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

11. Subsequent Events (continued)

On June 30, 2006, the Company granted 558,823 options to purchase common stock to employees at a weighted-average exercise price of $7.86 per share. These options vest over a four-year term. The grant-date fair value of the underlying common stock was $12.75 per share. For the purposes of calculating the stock-based compensation expense to be recognized under SFAS No. 123R, the Company valued these employee stock options using the Black-Scholes option pricing model with the following assumptions; expected volatility of 60%; a risk free interest rate of 4.55%; and a dividend yield of 0%. Stock-based compensation related to these stock options was $4,987,500 and will be recognized over a weighted average requisite service period of approximately four years.

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

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

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

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

These offers remained open until June 23, 2006. Based on the warrant holder s preferences, the Company recorded a warrant modification expense of $1,376,000 during the nine months ended September 30, 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 Company expects that warrants to purchase 2,490,189 shares of the Company s common stock, at a weighted average exercise price of $6.98, will be outstanding upon completion of the Company s initial public offering.

In October 2006, the Company made a number of changes to its management team. At a board meeting held on October 26, 2006, the Company s board determined that it was in the best interests of the Company and its stockholders to remove Dr. Stefan M. Lemperle from his position as Chief Executive Officer. In addition, on October 26, 2006, the Company s board approved a plan to reduce the Company s operating costs and to reorganize its business operations, including the Company s sales and marketing organization, to focus its efforts on the U.S. market and on physician-based training and sales programs. In connection with this cost reduction plan and reorganization, the Company terminated the employment of William von Brendel, Vice President of Worldwide Sales and International Markets, Harold T. Schreiber, Chief Creative Officer, and a manager in the Company s sales and marketing organization.

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Artes Medical, Inc.
(a development stage company)
Notes to Consolidated Financial Statements (continued)

11. Subsequent Events (continued)

On October 27, 2006, the FDA approved ArteFill, the Company s non-resorbable aesthetic injectable implant for the correction of facial wrinkles known as smile lines, or nasolabial folds.

On November 2, 2006, the Company received a notice of demand for arbitration from Mr. Schreiber in connection with the termination of his employment. While the ultimate outcome cannot be predicted, management does not believe that the final resolution will have a material adverse effect on the Company s financial statements.

On November 6, 2006, the Company filed a demand for arbitration with the American Arbitration Association against Melvin Ehrlich, who served as the Company s President and Chief Operating Officer from January 2004 to April 2004. The Company is seeking declaratory relief regarding the number of shares of common stock Mr. Ehrlich is entitled to purchase under a warrant issued to him in connection with his employment agreement. While the ultimate outcome cannot be predicted, management does not believe that the final resolution will have a material adverse effect on the Company s financial statements.

On November 16, 2006, the Company received a notice of demand for arbitration from Mr. Von Brendel in connection with the termination of his employment. While the ultimate outcome cannot be predicted, management does not believe that the final resolution will have a material adverse effect on the Company s financial statements.

On November 17, 2006, the Company entered into a separation agreement and mutual general release with Dr. Stefan M. Lemperle in connection with his resignation as a director and as an employee. Pursuant to the agreement, the Company has paid Dr. Stefan Lemperle a severance payment of $250,000, plus an additional $81,250 in lieu of any bonus payments related to fiscal years 2005 and 2006. The Company also agreed to make severance payments to Dr. Stefan M. Lemperle in an aggregate amount of $300,000, payable in 12 monthly installments of $25,000 per month, commencing in December 2006, and to provide COBRA coverage to Dr. Stefan M. Lemperle for a period of 12 months from the date of his resignation. Dr. Stefan M. Lemperle is eligible to receive an additional severance payment of $400,000, contingent upon the Company s completion of this offering or another qualifying transaction, as defined in the agreement (including an IPO), before March 31, 2007. In connection with the agreement, the Company also amended the terms of the outstanding stock options held by Dr. Stefan M. Lemperle to provide for the full acceleration of all unvested shares under his stock options, and the Company has agreed to issue to Dr. Stefan M. Lemperle a warrant to purchase up to 117,647 shares of common stock, subject to certain conditions and in an amount determined in accordance with the terms of the agreement. In consideration for these payments and benefits, Dr. Stefan M. Lemperle has provided a general release of claims against the Company and has agreed to cooperate with the Company in various matters, including assisting the Company in responding to questions raised by the FDA or other regulatory bodies, facilitating the completion of the initial public offering and assisting with the resolution of outstanding claims against the Company by certain former employees. The impact on the financial statements of the separation agreement with Dr. Lemperle is estimated to range from $1,800,000 to $2,300,000.

On November 22, 2006, a 1-for-4.25 reverse stock split was approved by the Company s Board of Directors, which was previously approved by the Company s stockholders. The accompanying consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

On November 22, 2006, the Company granted 335,246 options to purchase common stock to employees at a weighted-average exercise price of $10.63 per share. These options vest over a four-year term. The grant-date fair value of the underlying common stock was $13.00 per share. For purposes of calculating the stock-based compensation expense to be recognized under SFAS No. 123R, the Company valued these employee

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Artes Medical, Inc.
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Notes to Consolidated Financial Statements (continued)

11. Subsequent Events (continued)

stock options using the Black-Scholes option pricing model with the following assumptions; expected volatility of 60%; a risk free interest rate of 4.55%; and a dividend yield of 0%. Stock-based compensation related to these stock options was $2,806,847 and will be recognized over a weighted average requisite service period of approximately four years.

On November 27, 2006, the Company entered into a loan and security agreement with Comerica Bank, pursuant to which the Company has obtained a credit facility with Comerica Bank, consisting of a revolving line of credit in the amount of up to $5,000,000 and a term loan in the amount of up to $5,000,000. Interest on the revolving line and the term loan will be at prime plus 2%. The revolving line and term loan mature on November 27, 2007 and 2010, respectively. The agreement requires the Company to meet certain liquidity ratios and there are also limitations on mergers, acquisitions and distributions. In addition the Company granted the bank a warrant to purchase 120,000 shares of Series E preferred stock at $2.50. The fair value of the warrant plus the related beneficial conversion feature of $253,600, will be recorded as debt discount and amortized over the life of the credit lines. The debt is secured by substantially all of the assets of the Company.

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4,600,000 Shares
Common Stock

PROSPECTUS

Cowen and Company
Lazard Capital Markets
Stifel Nicolaus
December 19, 2006

Through and including January 13, 2007 (25 days after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.