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

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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: