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