ARTES MEDICAL INC
Form 10-Q
November 10, 2008

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2008

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-33205

ARTES MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0870808**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

5870 Pacific Center Boulevard
San Diego, California
(Address of principal executive offices, including zip code)
(858) 550-9999
(Registrant s telephone number, including area code)
N/A
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer: o	Accelerated filer: þ	Non-accelerated filer: o	Smaller reporting company: o

(Do not check if a smaller reporting company)

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

As of November 1, 2008, there were 19,742,285 shares of the registrant s common stock outstanding.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

Artes Medical, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except per share data)
(Unaudited)

	September 30, 2008	December 31, 2007
Assets		
Current Assets:		
Cash and cash equivalents	$ 5,858	$ 20,293
Accounts receivable, net	1,470	792
Inventories, net	6,075	5,528
Other current assets	790	1,044
Total Current Assets	14,193	27,657
Property and equipment, net	5,798	5,034
Intangibles, net	1,255	2,385
Other assets	604	645
Total Assets	$ 21,850	$ 35,721
Liabilities and Stockholders Equity (Deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 6,132	$ 3,074
Accrued compensation and benefits	1,571	1,802
Revenue interest financing, current portion	1,775	
Term note payable, current portion		1,250
Revolving credit line		5,000
Other current liabilities	120	42
Total Current Liabilities	9,598	11,168
Revenue interest financing, less current portion (net of discount of $1,016)	13,391	
Note payable (net of discount of $779)	5,721	
Term note payable (net of discount of $165)		2,231
Deferred tax liability	316	915
Other liabilities	2,051	783
Commitments and Contingencies		
Stockholders Equity (Deficit):		
Series A Participating Preferred Stock, $0.001 par value, 200,000 shares authorized; 0 shares issued and outstanding		
Common stock, $0.001 par value, 200,000,000 shares authorized; 19,742,285 and 16,514,163 shares issued and outstanding at September 30,	20	17

2008 and December 31, 2007, respectively		
Additional paid-in capital	132,501	126,894
Accumulated deficit	(141,748)	(106,287)
Total Stockholders Equity (Deficit)	(9,227)	20,624
Total Liabilities and Stockholders Equity (Deficit)	$ 21,850	$ 35,721

See accompanying notes to condensed consolidated financial statements.

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Artes Medical, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
Product sales	$ 2,261	$ 1,220	$ 7,095	$ 4,716
License fees		5,500		6,232
	2,261	6,720	7,095	10,948
Cost of product sales	2,343	3,002	7,404	6,880
Gross profit (loss)	(82)	3,718	(309)	4,068
Operating expenses:				
Selling and marketing	4,347	2,846	14,673	8,252
General and administrative	2,943	3,022	10,530	9,513
Research and development	3,088	1,541	7,865	3,709
	10,378	7,409	33,068	21,474
Loss from operations	(10,460)	(3,691)	(33,377)	(17,406)
Other income (expense):				
Interest expense	(1,063)	(342)	(2,755)	(873)
Interest income	20	310	219	1,181
Other income (expense), net	227	(10)	235	
Loss before benefit from income taxes	(11,276)	(3,733)	(35,678)	(17,098)
Benefit from income taxes	70	51	217	151
Net loss	$ (11,206)	$ (3,682)	$ (35,461)	$ (16,947)
Basic and diluted net loss per share	$ (0.67)	$ (0.22)	$ (2.14)	$ (1.03)

Basic and diluted weighted average shares	16,654,516	16,493,767	16,561,289	16,444,915

See accompanying notes to condensed consolidated financial statements.

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Artes Medical, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands, except per share data)
(Unaudited)

	Nine Months Ended September 30,	
	2008	**2007**
Cash flows from operating activities:		
Net loss	$ (35,461)	$ (16,947)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	1,810	1,983
Bad debt expense	120	29
Benefit from income taxes	(226)	(142)
Stock-based compensation	2,357	2,772
Financing arrangements and notes payable (non-cash)	1,958	111
Other liabilities	323	(39)
Changes in assets and liabilities:		
Accounts receivable	(798)	(308)
Inventories	(547)	(1,785)
Other current assets	254	(5,852)
Accounts payable and accrued expenses	4,117	(681)
Accrued compensation and benefits	(231)	(776)
Net cash used by operating activities	(26,324)	(21,635)
Cash flows from investing activities:		
Purchases of property and equipment	(1,833)	(783)
Other assets	41	(411)
Net cash used for investing activities	(1,792)	(1,194)
Cash flows from financing activities:		
Proceeds from revenue interest financing, net	14,491	
Proceeds from note payable	6,500	
Proceeds from issuance of common stock, net	2,044	
Payments on term note payable	(8,646)	(938)
Payments on revenue interest financing	(687)	
Miscellaneous payments	(21)	(46)
Proceeds from exercise of stock options and warrants		536
Net cash provided by (used for) financing activities	13,681	(448)

Net decrease in cash and cash equivalents	(14,435)	(23,277)
Cash and cash equivalents beginning of period	20,293	46,258
Cash and cash equivalents end of period	$ 5,858	$ 22,981
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,177	$ 762
Fair value of embedded derivatives	$ 286	$

See accompanying notes to condensed consolidated financial statements.

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

Note 1 Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission. Pursuant to these rules and regulations, the Company has condensed or omitted certain information and footnote disclosures it normally includes in its annual consolidated financial statements prepared in accordance with Generally Accepted Accounting Principles in the United States (GAAP). The condensed consolidated financial statements of the Company include the accounts of its wholly-owned subsidiary Artes Medical Germany GHMB. All significant intercompany transactions and accounts have been eliminated in consolidation.

These financial statements, in the opinion of management, include all adjustments necessary for a fair presentation of the financial position, results of operations and cash flows for all periods presented. The financial statements should be read in conjunction with the financial statements and notes thereto included in the Company s Annual Report on Form 10-K filed for the year ended December 31, 2007. Interim operating results are not necessarily indicative of operating results for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (the FASB) issued Statement of Financial Accounting Standards (SFAS No. 157), *Fair Value Measurements* (SFAS No. 157). This statement provides a definition of fair value, establishes a hierarchy for measuring fair value in generally accepted accounting principles, and requires certain disclosures about fair values used in financial statements. On February 14, 2008, FASB Staff Position (FSP) FAS 157-2, *Effective Date of FASB Statement No. 157*, was issued. This FSP defers application of SFAS No. 157 for non-financial assets and liabilities to years beginning after November 15, 2008 (beginning with the Company s 2009 fiscal year). As a result, the Company is only partially adopting SFAS No. 157 as it relates to the Company s financial assets and liabilities until it is required to apply this pronouncement to its non-financial assets and liabilities beginning with fiscal year 2009.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities (* SFAS No. 159) which permits all entities to choose, at specified election dates, to measure many financial instruments and certain other items at fair value. SFAS No. 159 was effective for the Company on January 1, 2008, and the Company did not intend to elect to re-measure any of its existing financial assets or financial liabilities under the provision of SFAS 159.

Note 2 Financial Resources

The Company has a history of recurring losses from operations and as of September 30, 2008, has an accumulated deficit of $141.7 million; cash and cash equivalents of $5.9 million and working capital of $4.6 million. The Company has an immediate need to raise additional cash funding to support its operations. These factors raise substantial doubt about the Company s ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company s assets and the satisfaction of liabilities in the normal course of business and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

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The Company s successful transition to achieving and maintaining profitable operations is dependent upon a number of factors, including its success in raising additional funds to support its operations, achieving a level of revenues adequate to support its cost structure, and its ability to reduce and control its operating expenses. In April 2008, the Company initiated a plan to significantly reduce certain administrative and operating expenses to realign the Company s overall cost structure to its revised operating plan for fiscal 2008. As part of this cost containment plan, the Company had a reduction in force of approximately 15%. Additionally, in August 2008, the Company decided to outsource its research and development activities, as part of the ongoing transition from a research and development stage company to a sales and marketing based company.

In addition to the capital raised in September 2008 and February 2008 (See Note 4), the Company is seeking additional debt or equity financing to support its operations. There can be no assurances that there will be adequate financing available to the Company on acceptable terms or at all. Further, the cost reduction measures the Company has taken may not be successful and the Company s actual revenues may not meet its expectations. If the Company is unable to obtain additional financing, and achieve its forecasted revenues during the remainder of 2008, the Company will need to begin curtailing or reorienting its operations, which will have a material adverse effect on the Company s ability to achieve its business objectives.

Note 3 Inventories

Inventories consist of the following (in thousands):

	September 30, 2008	December 31, 2007
Raw materials	$ 1,242	$ 1,147
Work in process	4,171	6,017
Finished goods	1,395	602
	6,808	7,766
Less: Reserve for excess and obsolete inventory	(733)	(2,238)
	$ 6,075	$ 5,528

Note 4 2008 Financing Transactions

Equity Financing In September 2008, the Company completed a private financing with accredited investors raising approximately $2.4 million in gross proceeds from a private placement of its common stock and related warrants. Pursuant to the financing, the Company issued 2,735,817 shares of common stock at a purchase price of $0.73 per share. The Company also issued to the investors warrants to purchase an additional 1,367,916 shares of common stock at an exercise price of $0.75 per share. The warrants are exercisable no sooner than six months following the closing of the private placement and will expire on March 26, 2014. In addition, the Company issued 497,228 shares of common stock at a purchase price of $0.8125 per share and warrants to purchase 248,616 shares of common stock, at an exercise price of $0.75 per share, to investors who may be deemed to be affiliated with a member of the Company s board of directors.

In connection with the financing, the Company has agreed, subject to certain terms and conditions, to provide piggyback registration rights with respect to the resale of the shares purchased and the shares issuable upon exercise of the warrants. Also, the Company paid its placement agent a cash fee equal to 8% of the aggregate proceeds raised in the financing. The 8% placement fee and other costs totaling $0.3 million were recorded as issuance costs and netted against the proceeds. The Company also issued warrants to its placement agent to purchase up to 218,865 shares of common stock at an exercise price of $0.73 per share, up to 129,322 shares of common stock at an exercise price of $0.75 and up to 39,778 shares of common stock at an exercise price of $0.8125 per share.

Cowen Healthcare Royalty Partners, L.P. (CHRP) - In January 2008, the Company entered into a financing arrangement with CHRP to raise $21.5 million (the Financing), and the potential for an additional $1.0 million in 2009 contingent upon the Company s satisfaction of a net product sales milestone. The Company is using the proceeds to expand both its dedicated U.S. sales force and consumer outreach programs. In February 2008, the Company repaid the total amount due of $8.6 million to Comerica Bank under a term loan and terminated its line of credit facility. After the Comerica Bank payment and the payment of certain transaction expenses, the Company received net proceeds of $12.3 million from the Financing.

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The Financing comprised two separate agreements. (i) the Revenue Interest Financing and Warrant Purchase Agreement (the Revenue Agreement), and (ii) the Note and Warrant Purchase Agreement (the Note and Warrant Agreement).

Revenue Agreement CHRP acquired the right to receive a revenue interest on the Company s U.S. net product sales from October 2007 through December 2017 (the Term). The Company is required to pay a revenue interest on U.S. net product sales of ArteFill, any improvements to ArteFill, any internally developed, in-licensed or purchased dermal filler products. The Company is also required to make two lump sum payments of $7.5 million to CHRP, the first in January 2012 and the second in January 2013.

In connection with the Revenue Agreement, the Company recorded a liability, referred to as the Revenue interest financing in the accompanying condensed consolidated balance sheet, of $15.0 million, in accordance with EITF 88-18, Sales of Future Revenues, when the funds were received in February 2008. The Company imputes interest expense associated with this liability using the effective interest rate method and is recording a corresponding accrued interest liability, which is offset by payments made to CHRP. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of U.S. ArteFill sales. The Company evaluates the interest rate quarterly based on its current sales forecast. Payments made to CHRP as a result of ArteFill sales levels reduce the amount of the revenue interest financing liability.

Under the Revenue Agreement, the Company issued CHRP a warrant to purchase 375,000 shares of Common Stock, at an exercise price equal to $3.13 per share. The warrant has a 5 year term, and allows for cashless exercise. In accordance with EITF 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments, the Company recorded proceeds from the Revenue Agreement net of a discount for the estimated fair value of the warrant which was valued using the Black-Scholes model totaling $364,000. The discount is amortized to interest expense over the life of the Revenue Agreement. The warrant is being accounted for as an equity instrument under EITF 00-19 Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.

The Revenue Agreement includes two embedded derivatives. The first derivative is a put option, which states that in the event of (i) a change of control, (ii) a bankruptcy, or (iii) subject to a cure period, breach of certain material covenants and representations in the Revenue Agreement, CHRP has the right, but not the obligation, to require the Company to repurchase the royalty interest at a price in cash which equals the greater of (a) a specified multiple of cumulative payments made by CHRP under the Revenue Agreement less the cumulative royalties previously paid to CHRP; or (b) the amount which will provide CHRP, when taken together with the royalties previously paid, a specified rate of return. The second derivative is a step down option, where the Company has the right to prepay the Revenue Agreement in cash at a 200% return less the amount already received by CHRP. Subsequent to the exercise of the step down option, the Company will pay a lower percentage of sales until the end of the term of the Revenue Agreement.

The Company recorded the estimated fair value of the two embedded derivatives as of the date of the Revenue Agreement in accordance with SFAS No. 133, Accounting for Derivatives Instruments and Hedging Activities (SFAS No. 133). The estimated fair value of $286,000 was determined by using a binomial lattice option pricing model. This liability is revalued on a quarterly basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation recorded in earnings. As of September 30, 2008, there was no material change in the estimated fair value of the two embedded derivates.

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	September 30, 2008 (in thousands)
Revenue interest financing	$ 16,182
Less: current portion	(1,775)
	14,407
Less: Debt discount	(1,016)
Revenue interest financing, long term portion	$ 13,391

Note and Warrant Agreement - The Company issued to CHRP a 10% senior secured note in the principal amount of $6,5 million. The note has a term of five (5) years and bears interest at 10% per annum, payable monthly in arrears. The Company has the option to prepay all or a portion of the note at a premium.

If there is an event of default, with event of default defined as (i) a put option event under the Revenue Agreement, (ii) a failure to pay the note when due, (iii) the Company s material breach of its covenants and agreements in the Note and Warrant Agreement, (iv) the Company s failure to perform an existing agreement with a third party that accelerates the majority of any debt in excess of $500,000 or (v) subject to a cure period, material breach of the covenants, representations or warranties in the Financing documents, the outstanding principal and interest in the note , plus the prepayment premium, shall become immediately due and payable.

Under the Note and Warrant Agreement, the Company issued CHRP a warrant to purchase 1,300,000 shares of Common Stock, at an exercise price equal to $5.00 per share. The warrant has a 5 year term, and allows for cashless exercise. In accordance with EITF 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments, the Company recorded proceeds from the Note and Warrant Agreement net of a discount for the estimated fair value of the warrant which was valued using the Black-Scholes model totaling $845,000. The discount is amortized to interest expense over the life of the Note and Warrant Agreement. The warrant is being accounted for as an equity instrument under EITF 00-19 Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.

Note 5 Stock Based Compensation

Stock options and Warrants - For purposes of calculating stock-based compensation under SFAS No. 123(R), the Company estimates the fair value of stock options using a Black-Scholes option-pricing model. The Black-Scholes option-pricing model incorporates various sensitive assumptions including expected volatility, expected term and interest rates.

The assumptions used to estimate the fair value of stock options granted to employees and directors during the three and nine months ended September 30, 2008 and 2007 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Volatility	48%	48%	48%	48%
Risk free interest rate	3.23%	4.75%	3.09%	4.75%
Expected dividend yield	0%	0%	0%	0%
Forfeiture rate	14%	14%	14%	14%
Expected term (years)	6.0	6.0	6.0	6.0

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The risk-free interest rate assumption was based on the United States Treasury s rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company s expectation of not paying dividends in the foreseeable future. The weighted average expected life of options was calculated using the simplified method as prescribed by the SEC s Staff Accounting Bulletin (SAB) No. 110. This decision was based on the lack of relevant historical data due to the Company s limited historical experience. In addition, due to the Company s limited historical data, the estimated volatility incorporates the historical volatility of comparable companies whose share prices are publicly available and the Company s historical volatility. The estimated forfeiture rate is based on historical data for forfeitures and the Company is recognizing compensation expense only for those equity awards expected to vest.

The weighted average grant-date fair value of stock options granted during the three and nine months ended September 30, 2008 and 2007 was $0.74 and $0.94, and $3.29 and $3.73 per share, respectively.

During the three and nine months ended September 30, 2008 and 2007, the Company recorded approximately $503,000 and $2,093,000, and $866,000 and $2,326,000 respectively, of stock compensation expense under SFAS No. 123(R).

Total unrecognized stock-based compensation costs related to non-vested stock options at September 30, 2008 was approximately $4,910,000. This unrecognized cost is expected to be recognized on a straight-line basis over a weighted average period of approximately 2.64 years.

Equity instruments issued to non-employees are recorded at their fair values as determined in accordance with Emerging Issues Task Force (EITF) 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services, and are periodically revalued as the stock options vest and are recognized as expense over the related service period. During the three and nine months ended September 30, 2008 and 2007, the Company recognized $3,000 and $142,000, and $41,000 and $131,000 respectively, for stock options and warrants issued to non-employees.

Deferred stock-based compensation In 2005 deferred stock-based compensation of $2,383,000, net of forfeitures, which represented the difference between the weighted-average exercise price of $5.31 and the weighted-average fair value of $9.18 on stock options to purchase 620,000 shares of common stock granted to employees during 2005, was recorded within Stockholders Equity. The Company is amortizing deferred stock-based compensation on a straight-line basis over the vesting period of the related awards, which is generally four years. Upon the adoption of SFAS No. 123(R) on January 1, 2006, the Company reclassified deferred stock-based compensation against additional paid-in capital.

During the three and nine months ended September 30, 2008 and 2007, the Company recognized $66,000 and $264,000, and $147,000 and $446,000 respectively, in amortization of deferred stock-based compensation which was provided for prior to the adoption of SFAS No. 123(R).

Unrecognized deferred stock-based compensation related to non-vested stock option and warrant awards granted prior to January 1, 2006 was approximately $304,000 at September 30, 2008. The expected future amortization expense for deferred stock-based compensation is $62,000 in 2008 and $242,000 in 2009.

The Company has included stock-based compensation expense in the statement of operations for all stock-based compensation arrangements as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Capitalized to inventory	$ 119	$ 159	$ 407	$ 408
Research and development expense	$ 65	$ 134	$ 402	$ 339
Sales, general and administrative expense	$ 385	$ 720	$1,548	$2,025
Net effect on basic and diluted net loss per share	$0.03	$0.05	$ 0.12	$ 0.14

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Note 6 Net Loss per Share

The following table shows the historical outstanding anti-dilutive securities that have not been included in the diluted net loss per share calculation:

	September 30, 2008	September 30, 2007
Warrants to purchase common stock	5,582,638	2,445,638
Options to purchase common stock	2,954,450	3,147,140
Restricted stock units	12,500	
	8,549,588	5,592,778

Note 7 Stockholders Rights Plan

On May 29, 2008, the Company s Board of Directors adopted a stockholders rights plan. Under the plan, the Board declared a dividend distribution of one Right for each outstanding share of the Company s common stock to stockholders of record as of the close of business on June 23, 2008. Since that time, the Company has issued and will continue to issue one Right with each newly issued share of common stock. Each Right entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A participating preferred stock at a purchase price of $50.00 per one-thousandth of a share, subject to adjustment. In general, under the plan, if a person or affiliated group acquires beneficial ownership of 20% or more of the Company s common stock, then each Right (other than those held by such acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of the Company s common stock (or, under certain circumstances, a combination of securities or other assets) having a value of twice the underlying purchase price of the Right. In addition, if following the announcement of the existence of an acquiring person or affiliated group the Company is involved in a business combination or sale of 50% or more of its assets or earning power, each Right (other than those held by the acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock of the acquiring entity having a value of twice the underlying purchase price of the Right. The Board also has the right, after an acquiring person or affiliated group is identified, to cause each Right to be exchanged for common stock or substitute consideration. The Company may redeem the Rights at a price of $0.00001 per Right prior to the identification of an acquiring person or affiliated group. The Rights expire on June 12, 2018.

Note 8 Fair Value Measurement

The Company applies fair value accounting to its derivatives in accordance with SFAS No. 133. These derivatives related to our Financing Arrangement with CHRP (see Note 4). The following table shows the fair value measurement for this and other financial assets at September 30, 2008 and the fair value hierarchy level, as defined in SFAS No. 157 (in thousands).

Description	Asset Total *(In Thousands)*	Quoted Price in Active Markets for Identical Assets *(Level 1)*	Significant Other Observable Inputs *(Level 2)*	Significant Unobservable Inputs *(Level 3)*
Cash and cash equivalents	$ 5,858	$ 5,858	$	$
Derivatives	$ 286	$	$	$ 286

Asset classes that fall within the Level 1 fair value hierarchy are those assets whose fair value assumptions are based on market data obtained from sources independent of the Company (observable inputs). Level 1 observable inputs are quoted prices for identical items in active markets that the Company has access to at the measurement date.
Asset classes that fall within the Level 2 fair value hierarchy are those assets whose fair value assumptions are also based on independent market data. Level 2 observable inputs are quoted prices for similar items in active markets or quoted prices for identical or similar items in inactive markets. An inactive market is one where there are few transactions, the prices are not current, price quotations vary substantially over time or among market makers, or where little information is released publicly.

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Asset classes that fall within the Level 3 fair value hierarchy are those assets whose fair value assumptions are based on the Company s information.

The Company did not have any transfers between levels during the quarter or any changes in the fair value of its level 3 derivative.

Note 9 Distribution Agreement

On July 7, 2008, the Company entered into a Distribution Agreement with Anika Therapeutics, Inc. (Anika) under which the Company obtained an exclusive right to market and sell Anika s FDA-approved Elevess® temporary dermal filler product in the United States. Elevess is a hyaluronic acid (HA) based filler formulated with Lidocaine for patient comfort and used for the correction of facial wrinkles and folds. Under the Distribution Agreement, Anika manufactures and supplies Elevess to the Company. The Company commenced shipping Elevess in August, 2008.

Note 10 Commitments and Contingencies

On September 4, 2008, a derivative action was filed by a stockholder, Barry Rubin, against certain of our current and former officers, and directors in San Diego Superior Court, Case No. 37-2008-00091039-CU-NP-CTL. The Company recently removed the case to federal court (U.S. District Court for the Southern District of California, Case No. 3:08-cv-1820 W JMA). The claims made in this lawsuit contain gross errors of fact, and the Company considers it to be frivolous and will contest it vigorously. On October 24, 2008 the Company filed a motion to dismiss this suit. The Company is covered by a claims-made liability insurance policy, subject to a deductible, which it believes will satisfy any potential liability of the Company resulting from this litigation. The claims made in this lawsuit are strikingly similar to claims made in a non-management preliminary proxy statement filed by a stockholder, H. Michael Shack, on August 11, 2008. The Company believes the Rubin lawsuit was filed to support Shack s efforts.

On August 29, 2008, the Company filed suit in San Diego Superior Court against Stefan Lemperle and Gottfried Lemperle, former officers of the Company, for, among other things, breach of contract, fraudulent inducement and intentional and negligent interference with prospective economic advantage. The Company s claims are based on the defendants attempts to interfere with the Company s management and operations by causing and supporting the filing of the Shack proxy statement. The Company amended the complaint on October 23, 2008 to include recent activity by the Lemperles, the proxy organizer and others relating to improper proxy solicitation conduct, filing of law suits having no merit and other misconduct intended to harm the Company financially and to interfere with its annual stockholders meeting and its business affairs.

The Company is also, from time to time, subject to legal proceedings and claims which arise in the normal course of business. In management s opinion, the amount of ultimate liability with respect to these actions will not have a material adverse effect on the Company s consolidated financial position, results of operations, or cash flows.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion of our financial condition and results of operations in conjunction with the condensed consolidated financial statements and related notes to those statements included in this report. This discussion contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of a variety of factors, such as those set forth under heading Risk Factors, and elsewhere in this report, and in our Annual Report on Form 10-K for the year ending December 31, 2007, filed with the SEC on March 14, 2008.

In light of these risks, uncertainties and assumptions, readers are cautioned not to place undue reliance on such forward-looking statements. These forward looking statements represent beliefs and assumptions only as of the date of this report. Except as required by applicable law, we do not intend to update or revise forward-looking statements contained in this report to reflect future events or circumstances.

Business Overview

We are a medical aesthetics company focused on developing, manufacturing and commercializing a new category of injectable aesthetic products for the dermatology and plastic surgery markets. On October 27, 2006, the FDA approved ArteFill, our non-resorbable aesthetic injectable implant for the correction of facial wrinkles known as smile lines, or nasolabial folds. Prior to the FDA s approval of ArteFill as the first and only non-resorbable injectable aesthetic product there were 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 (PMMA) microspheres and bovine collagen, or collagen derived from calf hides. PMMA is one of the most widely used artificial materials in implantable medical devices, and is not absorbed or degraded by the human body. Following injection, the PMMA microspheres in ArteFill remain intact at the injection site and provide a permanent support structure to fill in the existing wrinkle and help prevent further wrinkling. As a result, we believe that ArteFill will provide patients with aesthetic benefits that may last for years.

We commenced commercial shipments of ArteFill during the first quarter of 2007. Our strategy is to establish ArteFill as a leading injectable aesthetic product. We market and sell ArteFill to dermatologists, plastic surgeons and cosmetic surgeons in the United States through our direct sales force. We target dermatologists, plastic surgeons and cosmetic surgeons whom we have identified as having performed a significant number of procedures involving injectable aesthetic products. We provide physicians with comprehensive education and training programs. We believe our education and training programs enable physicians to improve patient outcomes and satisfaction. In addition, we may expand our product offering by acquiring complementary products, technologies or businesses. In April 2008, we initiated a plan to significantly reduce certain administrative and operating costs to realign our overall cost structure to our revised operating plan for fiscal 2008.

On July 7, 2008, we entered into a Distribution Agreement with Anika Therapeutics, Inc. (Anika) under which we obtained an exclusive right to market and sell Anika s FDA-approved Elevess® temporary dermal filler product in the United States. Elevess is a hyaluronic acid (HA) based filler formulated with Lidocaine for patient comfort and used for the correction of facial wrinkles and folds. Under the Distribution Agreement, Anika will manufacture and supply us with Elevess. We began shipping Elevess in August 2008.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States and regulations of the Securities and Exchange Commission. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to bad debts, inventories, long-term assets and income taxes. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the

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circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates.

For further information about our critical accounting policies and estimates, see discussion under the heading Critical Accounting Policies and Estimates in our Annual Report on Form 10-K for the year ended December 31, 2007. There were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2008.

Results of Operations

Comparison of the Three Months Ended September 30, 2008 and 2007

Revenues. Our product sales for the third quarter of 2008 increased by $1.1 million or 85% to $2.3 million from the third quarter of 2007. The increase resulted from the planned expansion of our field sales force to 42 sales representatives in March of 2008, increased consumer marketing activities and promotional programs, a continued increase in the number of Artefill trained physicians, and launch of Elevess, our new FDA-approved temporary dermal filler manufactured by Anika. Our increase in product sales during the third quarter of 2008 was offset by a decrease in license fee revenue of $5.5 million in the third quarter of 2007 which represented a one-time payment from a licensee.

Cost of product sales. Our cost of product sales as a percentage of our net sales was 104% during the third quarter of 2008 compared to 246% during the third quarter of 2007. This resulted in a negative gross profit on product sales for the third quarter of 2008 of ($82) thousand compared to a negative ($1.8) million for the third quarter of 2007. The higher gross profit on product sales is a direct result of the increase in our product sales during the second quarter of 2008 and the fact that a significant portion of our manufacturing costs are fixed.

Selling and marketing. Our selling and marketing expenses increased by $1.5 million or 53% to $4.3 million during the third quarter of 2008 as compared to the third quarter of 2007. The increase is due to a concerted effort to increase selling and marketing efforts through a combination of an increase in the number of field sales representatives and an increase in the amount consumer advertising and promotional programs, as well as costs in connection with the launch of Elevess. Our selling and marketing expenses as a percentage of our net product sales were 192% and 233% during the third quarter of 2008 and 2007, respectively.

General and administrative. Our general and administrative expenses during the third quarter of 2008 decreased by $79 thousand or 3% to $2.9 million as compared to the third quarter of 2007. The decrease is primarily due a reduction in personnel and related salaries. Our general and administrative expenses as a percentage of our net product sales were 130% and 248% during the third quarter of 2008 and 2007, respectively.

Research and development. Our research and development expenses increased by $1.5 million or 100% to $3.1 million during the third quarter of 2008 as compared to the third quarter of 2007. The increase is due primarily to increased expenses related to the initiation of a five year post-marketing safety study, initiation of a skin test removal study and product development activities. As of September 30, approximately 1,000 patients were enrolled in the five-year post marketing study and approximately 500 patients were enrolled in the skin test removal study. These studies were essentially fully enrolled at September 30, 2008. Our research and development expenses as a percentage of our net product sales were 137% and 126% during the third quarter of 2008 and 2007, respectively. In August 2008, we decided to outsource our research and development activities, and as a result of this decision, and completion of enrollment in the five year post-marketing safety study and the skin test removal study, Research and Development expenses are expected to decrease during coming quarters.

Interest, net. Our net interest expense increased by $1.0 million to $1.0 million during the third quarter of 2008 as compared to the third quarter of 2007. The increase is due to interest expense incurred under the new financing agreements with CHRP and lower interest income earned on our cash balances.

Other income, net Our other income increased by $0.2 million to $0.2 million during the third quarter of 2008 as compared to the third quarter of 2007. The increase is due to an insurance settlement for product damaged in transit.

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Comparison of the Nine Months Ended September 30, 2008 and 2007.

Revenues. Our product sales for the nine months ended September 30, 2008 increased by $2.4 million or 50% to $7.1 million from the nine months ended September 30, 2007. The increase resulted from the planned expansion of our field sales force to 42 sales representatives in March of 2008, increased consumer marketing activities and promotional programs, a continued increase in the number of Artefill trained physicians and launch of Elevess, our new FDA-approved temporary dermal filler manufactured by Anika. Our increase in product sales during the nine months ended September 30, 2008 was partially offset by a decrease in license fee revenue of $6.2 million for non-recurring payments from a licensee.

Cost of product sales. Our cost of product sales as a percentage of our net sales was 104% during the nine months ended September 30, 2008 compared to 146% during the nine months ended September 30, 2007. This resulted in a negative gross profit on product sales for the nine months ended September 30, 2008 of ($0.3) million compared to ($2.2) million for the nine months ended September 30, 2007. The higher gross profit is primarily due to the increase in our product sales during the nine months ended September 30, 2008, and the fact that a significant portion of our manufacturing costs are fixed. During the first quarter of 2008 we expensed an excess capacity charge of $1.1 million related to adjustments in our inventory management process, which we believe will allow us to be both more responsive to market needs and maximize the shelf life of product shipped to our customers.

Selling and marketing. Our selling and marketing expenses increased by $6.4 million or 78% to $14.7 million during the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. The increase is due to a concerted effort to increase selling and marketing efforts through a combination of an increase in the number of field sales representatives and an increase in the amount consumer advertising and promotional programs. Our selling and marketing expenses as a percentage of our product net sales were 207% and 175% during the nine months ended September 30, 2008 and 2007, respectively.

General and administrative. Our general and administrative expenses during the nine months ended September 30, 2008 increased by $1.0 million or 11% to $10.5 million as compared to the nine months ended September 30, 2007. The increase is primarily due to severance expenses partially offset by a reduction in personnel and related salaries. Our general and administrative expenses as a percentage of our net sales were 148% and 202% during the nine moths ended September 30, 2008 and 2007, respectively.

Research and development. Our research and development expenses increased by $4.2 million or 112% to $7.9 million during the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. The increase is due primarily to increased expenses related to the initiation of a five year post-marketing safety study, initiation of a skin test removal study and product development activities. As of September 30, approximately 1,000 patients were enrolled in the five-year post marketing study and approximately 500 patients were enrolled in the skin test removal study. These studies were essentially fully enrolled at September 30, 2008. Our research and development expenses as a percentage of our net product sales were 111% and 79% during the third quarter of 2008 and 2007, respectively. In August 2008, we decided to outsource our research and development activities, and as a result of this decision, and completion of enrollment in the five year post-marketing safety study and the skin test removal study, Research and Development expenses are expected to decrease during coming quarters.

Interest, net. Our net interest expense increased by $2.8 million during the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. The increase is due to interest expense incurred under the new financing agreements with CHRP and lower interest income earned on our cash balances.

Other income, net Our other income increased by $0.2 million to $0.2 million during the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. The increase is due to an insurance settlement for product damaged product in transit.

Liquidity and Capital Resources

Since our inception in 1999, we have incurred significant losses and have never been profitable. Prior to the commercial launch of ArteFill in the first quarter of 2007, we were a development stage company, and devoted substantially all of our efforts to developing and completing clinical trials for ArteFill, acquiring international rights to certain intangible assets and know-how related to our technology, and establishing our commercial manufacturing capabilities.

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We have a history of recurring losses from operations, and as of September 30, 2008, had an accumulated deficit of $141.7 million, cash and cash equivalents of $5.9 million and working capital of $4.6 million. We have an immediate need to raise additional funding to support our operations. These factors raise substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Our successful transition to achieving and maintaining profitable operations is dependent upon a number of factors, including our success in raising additional funds to support our operations, achieving a level of revenues adequate to support our cost structure, and our ability to reduce and control our operating expenses. In April 2008, we initiated a plan to significantly reduce certain administrative and operating expenses to realign our overall cost structure to our revised operating plan for fiscal 2008. As part of this cost containment plan, we had a reduction in force of approximately 15%. Additionally, in August 2008, we decided to outsource our research and development activities, as part of the ongoing transition from a research and development stage Company to a sales and marketing based Company.

In addition to the capital raised in September 2008 and February 2008, we are seeking additional debt or equity financing to support our operations. There can be no assurances that there will be adequate financing available to us on acceptable terms or at all. Further, the cost reduction measures we have taken may not be successful and our actual revenues may not meet our expectations. If we are unable to obtain additional financing, and achieve our forecasted revenues during the remainder of 2008, we will need to begin curtailing or reorienting our operations, which will have a material adverse effect on our ability to achieve our business objectives.

We believe that our cash and cash equivalents at September 30, 2008, together with the interest thereon, proceeds from product sales, along with our recent and planned future reduction of operating costs, will be sufficient to meet our anticipated cash requirements through the end of 2008.

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

- growth in sales and related collections, including future sales of ArteFill and Elevess;
- the costs of maintaining and expanding the sales and marketing organization required for successful commercialization of ArteFill and Elevess;
- the costs and effectiveness of our sales, marketing, advertising and promotion activities related to ArteFill and Elevess, including physician training and education;
- the effectiveness of our implementation and maintenance of the operating cost reductions we began in April 2008;
- the costs related to maintaining and utilizing our ArteFill manufacturing and distribution capabilities;
- the clinical trial costs for ArteFill required to meet FDA post-market safety study requirements and to investigate the removal of the skin test requirement;
- the costs relating to changes in regulatory policies or laws that affect our operations;
- the level of investment in research and development to maintain and improve our competitive position, as well as to maintain and expand our technology platform;
- the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights for ArteFill;

the costs of maintaining our agreement with Anika Therapeutics, Inc., including satisfying minimum purchase amounts of Elevess; and

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

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Net cash used by operating activities was $26.3 million during the nine months ended September 30, 2008 compared to $21.6 million for the nine months ended September 30, 2007, an increase of $4.7 million. The increase in cash used was due primarily to the Company s expanded sales force and accelerated marketing initiatives to commercialize and sell ArteFill, as well as costs associated with our five-year post-marketing efficacy study and costs associated with our 2008 reduction in force. Included in net cash used by operating activities are cash disbursements of approximately $2.4 million in connection with our five-year post-marketing efficacy study and our skin test removal study for the nine months ended September 30, 2008, which we expect to decrease in future periods, and $1.2 million in non-recurring severance payments associated with our 2008 reduction in force.

In September 2008, we completed a private financing with accredited investors raising approximately $2.4 million in gross proceeds from a private placement of its common stock and related warrants..

In January 2008, we entered into a financing arrangement with CHRP to raise $21.5 million, and up to an additional $1 million in 2009 contingent upon our satisfaction of a net product sales milestone in fiscal 2008. We are using the proceeds to expand both our dedicated U.S. sales force and consumer outreach programs. We used $8.6 million of the proceeds to payoff and terminate our existing credit facility with Comerica Bank. The financing closed on February 12, 2008, resulting in net proceeds of $12.3 million after the payoff of our credit facility with Comerica Bank and after certain transaction expenses.

Under the Revenue Agreement, CHRP acquired the right to receive a revenue interest on our U.S. net product sales from October 2007 through December 2017. We are required to pay a revenue interest on U.S. net product sales of ArteFill , any improvements to ArteFill , any internally developed, in-licensed or purchased dermal fillers products. The revenue interest payable to CHRP on net product sales starts as a high single digit rate and declines to a low single digit rate following our satisfaction of an aggregate net product sales threshold during the term. In addition to the revenue interest payments, we are required to make two lump sum payments of $7.5 million to CHRP, the first in January 2012 and the second in January 2013. Once the cumulative revenue interest and lump sum payments to CHRP reach a specified multiple of the consideration paid by CHRP for the revenue interest, the rate will automatically step down for the balance of the term. We have the right to prepay the revenue interest and lump sum payments without penalty at any time to reach the step-down rate early.

As part of the financing, we also entered into a Note and Warrant Agreement with CHRP pursuant to which we issued CHRP a 10% senior secured note in the principal amount of $6.5 million. The note has a term of five (5) years and bears interest at 10% per annum, payable monthly in arrears. We have the option to prepay all or a portion of the note at a premium.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our market risk consists primarily of the potential for changes in interest rates.

Interest Rate Risk

During 2007, our exposure to interest rate risk was primarily the result of borrowings under our then existing credit facility with Comerica Bank. At December 31, 2007, $8.6 million was outstanding under our credit facility. In February 2008, we repaid the total amount due of $8.6 million to Comerica Bank and terminated the credit facility, in accordance to our financing arrangement with CHRP.

The primary objective of our cash management activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. As of September 30, 2008, we had cash and cash equivalents in a bank operating account that provides daily liquidity and through an overnight sweep account that is a money market mutual fund and invests primarily in money market investments and corporate and U.S. government debt securities. Due to the liquidity of our cash and cash equivalents, a 1% movement in market interest rates would not have a material impact on the total value of our cash, cash equivalents and investment securities. We do not have any holdings of derivative financial or commodity instruments, or any foreign currency denominated transactions.

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

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Item 4. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures.

Under the supervision and with the participation of our management, including our Executive Chairman of the Board, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, or the Exchange Act, as amended, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Executive Chairman and our Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in Internal Control over Financial Reporting.

During the quarter ended September 30, 2008, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. There are inherent limitations in the effectiveness of any internal control, including the possibility of human error and the circumventions or overriding of controls. Consequently, even effective internal controls can only provide reasonable assurances with respect to any disclosure controls and procedures and internal control over financial statement preparation and presentation.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

Barry Rubin Litigation On September 4, 2008, a derivative action was filed by a stockholder, Barry Rubin, against our officers and directors in San Diego Superior Court, Case No. 37-2008-00091039-CU-NP-CTL. The Company recently removed the case to federal court (U.S. District Court for the Southern District of California, Case No. 3:08-cv-1820 W JMA). The claims made in this lawsuit contain gross errors of fact, and the Company considers it to be frivolous and will contest it vigorously. On October 24, 2008 the Company filed a motion to dismiss this suit. The Company is covered by a claims-made liability insurance policy, which it believes will satisfy any material potential liability of the Company resulting from this litigation.

The claims made in this lawsuit are strikingly similar to claims made in a non-management preliminary proxy statement filed by a stockholder, H. Michael Shack, on August 11, 2008. The Company believes the Rubin lawsuit was filed to support Shack s efforts.

On August 29, 2008, the Company filed suit in San Diego Superior Court against Stefan Lemperle and Gottfried Lemperle, former officers of the Company, for, among other things, breach of contract, fraudulent inducement and intentional and negligent interference with prospective economic advantage. The Company s claims are based on the defendants attempts to interfere with the Company s management and operations by causing and supporting the filing of the Shack proxy statement. The Company amended the complaint on October 23, 2008 to include recent activity by the Lemperles, the proxy organizer and others relating to improper proxy solicitation conduct, filing of law suits having no merit and other misconduct intended to harm the Company financially and to interfere with its annual stockholders meeting and its business affairs.

Sandor Litigation We disclosed information relating to the Sandor Litigation in our Annual Report on Form 10-K for the year ended December 31, 2007, filed with the SEC on March 14, 2008. Since that date, discovery has commenced in the case, and the plaintiff has been deposed.

FDA Investigation We disclosed information regarding this matter in our Annual Report on Form 10-K for the year ended December 31, 2007, filed with the SEC on March 14, 2008. There have been no changes or developments in this matter since that time.

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Item 1A. Risk Factors.

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

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

Prior our commercial launch of ArteFill during the first quarter of 2007, we were a development stage company, and devoted substantially all of our efforts to developing and completing clinical trials for ArteFill, acquiring international rights and know-how related to our technology, and establishing our commercial manufacturing capabilities. We have a history of recurring losses from operations, and as of September 30, 2008, we had an accumulated deficit of $141.7 million. For the nine months ended September 30, 2008, we used net cash in operating activities of $26.3 million. We will continue to incur significant sales, marketing and manufacturing expenses in connection with the commercial distribution of ArteFill and Elevess, and expect to incur significant operating losses for the foreseeable future as we continue to expand and maintain our marketing efforts. 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. Further, because of our limited commercial operating experience 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 would harm our business.

We need to raise additional funds to support our operations, and these funds may not be available on a timely basis or on acceptable terms.

We believe that our existing cash and cash equivalents, together with the interest thereon, proceeds from sales of ArteFill and Elevess, and the funds received from our September 2008 and February 2008 financing, along with our recent and planned future reduction of operating costs, will be sufficient to meet our anticipated cash requirements through the end of 2008. Our auditors, Ernst & Young LLP, have issued a going concern qualification in their report accompanying our consolidated financial statements for the year ended December 31, 2007, expressing substantial doubt about our ability to continue as a going concern. We will need to raise significant additional capital to support our planned operations. Any future funding transaction may require us to relinquish rights to some of our intellectual property or product royalties, and we may be required to issue securities at a discount to the prevailing market price, resulting in further dilution to our existing stockholders. In addition, depending upon the market price of our common stock at the time of any transaction, we may be required to sell a significant percentage of common stock, potentially requiring a stockholder vote pursuant to Nasdaq rules, which could lead to a significant delay and closing uncertainty. We cannot guarantee that we will be able to complete any such transaction or secure additional capital on a timely basis, or at all, and we cannot assure that such transaction will be on reasonable terms. If we are unable to secure additional capital during the fourth quarter of 2008, we will need to begin curtailing or reorienting our business activities and may be unable to sustain operations, and you may lose your entire investment in our company. Further, our ability to continue our operations into the first quarter of 2009 with our existing resources depends on the success of the cost reduction measures we have taken and plan to take in the future and our success in meeting our revenue expectations for the remainder of 2008. If the measures we implement to reduce our operating costs are not successful and our revenues do not meet our expectations, we will need to significant curtail or reorient our business activities sooner than planned.

Our debt obligations expose us to risks that could restrict our ability to raise additional funds to support our operations and adversely affect our business, operating results and financial condition.

We have a substantial level of debt. As of September 30, 2008, we had approximately $20.9 million of indebtedness outstanding. We are required to make two principal payments of $7.5 million each in January 2012 and January 2013.

To secure these obligations, we granted the holders of our indebtedness a security interest in substantially all of our tangible and intangible assets, including the U.S. rights to ArteFill. In addition, the agreements governing our debt instruments contain negative and other restrictive covenants. The level, the secured nature of our indebtedness and the financial and business restrictions in our agreements with our debt holders, among other things, could:

make it difficult for us to raise the necessary funds or additional debt to support our operations;

limit our flexibility in planning for or reacting to changes or downturns in our business;

reduce funds available for use in our operations;

restrict the operations of our business as a result of financial and other restrictive covenants; or

impair our ability to merge or otherwise effect the sale of the company due to the rights of the holders of our indebtedness to accelerate our indebtedness in such an event.

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We need to raise additional funds to support our operations, which raises substantial doubt about our ability to continue as a going concern. Even if we do raise additional funds, if we do not grow our revenues as we expect and control our operating expenses, we could have difficulty making required payments on our indebtedness. If we are unable to make the required payments, or if we fail to comply with the various requirements, restrictions and covenants of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness, impose penalties, foreclose on the assets that secure our obligations and enforce their other rights under the agreements governing the indebtedness. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition.

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 and Elevess, including seasonality in patient elective procedures and physician ordering;
- the costs of our sales and marketing activities;
- the introduction of new technologies and competing products that may make ArteFill or Elevess less attractive treatment options for physicians and patients;
- negative publicity concerning ArteFill or Elevess, including concerns expressed about ArteFill based on negative perceptions of non-FDA approved dermal fillers sold outside the United States;
- our pricing strategy and ability to protect the price of ArteFill or Elevess 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, obtaining clinical information to support the removal of the ArteFill skin test requirement, 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;
- general economic conditions affecting the ability of patients to pay for elective cosmetic procedures.

We expect that we will continue to incur significant sales, marketing and manufacturing expenses in connection with the commercial distribution of ArteFill and Elevess. Our planned expense levels are based in part on our expectations concerning future revenues. However, the amount of any future revenues will depend on the choices and demand of physicians and patients, which are difficult to forecast accurately. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected or continued shortfall in revenues. Accordingly, a significant shortfall in demand or a significant delay in the market acceptance of our product offerings will have a material adverse effect on our business, results of operations and financial condition. Further, to the extent that expenses precede or are not followed by increased revenue, our business results will be harmed.

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We expect to derive a substantial portion 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 a substantial portion 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. 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, including newly introduced 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 to the satisfaction of the FDA regarding the removal of the skin test requirement and 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
- negative publicity concerning ArteFill or competing products, including negative publicity concerning non-FDA approved dermal fillers sold outside the United Sates, and alternative treatments.

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

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

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

- Allergan, Inc., which markets and sells Botox® Cosmetic, a temporary muscle paralytic and the most widely used injectable aesthetic product in the United States, CosmoDerm® and CosmoPlast®, which are human collagen-based temporary dermal fillers, Zyderm® and Zyplast®, which are bovine collagen-based temporary dermal fillers, and Juvederm®, Hylaform®, Hylaform® Plus, and Captique®, which are temporary dermal fillers

comprised primarily of hyaluronic acid, a jelly-like substance that is found naturally in living organisms and acts to hydrate and cushion skin tissue;

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

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

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

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.

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

We have limited experience with commercialized products, and the successful commercialization of ArteFill will require us to build and maintain a sophisticated sales and marketing organization.

Prior to 2007, we had no prior experience with commercializing any product, and we need to build and maintain a sophisticated sales and marketing organization in order to successfully commercialize ArteFill. We have rapidly increased the size of our direct sales force. We have and intend to continue 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 requires us to educate them on the comparative advantages of ArteFill over other injectable aesthetic products and alternative treatments. Experienced sales representatives may be difficult to locate and retain, and all new sales representatives will need to undergo extensive training. We anticipate that it will take up to six months for each of our new sales representatives to achieve full productivity, yet we will be incurring the costs of these sales representatives from the date of hire. There is no assurance that we will be able to recruit and retain sufficiently skilled sales representatives, or that any new sales representatives will ultimately become productive. If we are unable to recruit and retain qualified and productive sales personnel, our ability to commercialize ArteFill and to generate revenues will be impaired, and our business and financial prospects will be harmed.

Potential sales of ArteFill could be delayed or lost 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, physicians who are concerned that patients may not return for an ArteFill treatment have an incentive to provide an immediate treatment option to patients. We believe a number of these physicians recommend that patients get treated with a temporary dermal filler first, and then return for ArteFill treatment in the future, which could delay our sales to these patients by six months or more. Further, 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 delay our sales and harm our ability to generate revenues.

In February 2008, we met with the FDA to discuss what data would be needed in order for the FDA to approve treatment with ArteFill without a skin test. Approximately 500 patients were enrolled in the skin test removal study initiated by us. This study was essentially fully enrolled at September 30, 2008. There can be no assurance, however, that any data that we gather will be acceptable by the FDA or sufficient for the FDA to approve treatment with ArteFill without a skin test.

Continued adverse changes in the economy and consumer spending levels may reduce demand for ArteFill.

We have and we intend to continue to position ArteFill as a premium-priced product in the injectable aesthetic product market. Treatment with ArteFill is an elective procedure, directly paid for by patients without reimbursement. As a result, sales of ArteFill will require that patients have sufficient disposable income to spend on an elective aesthetic treatment. Adverse changes in the economy may cause consumers to reassess their spending choices and choose less expensive alternative treatments over ArteFill, or may reduce the demand for elective aesthetic procedures in general. The United States has experienced a slow down in consumer spending during 2008, and many economists are

predicting this slow down will continue throughout the remainder of the year. A shift of this nature could impair our ability to generate sales and could harm our business, financial condition and results of operations.

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We have in the past and may continue to experience negative publicity concerning our product ArteFill, including concerns expressed about ArteFill based on negative perceptions of non-FDA approved dermal fillers sold outside the United States, and this negative publicity may harm our reputation and business.

ArteFill is a proprietary formulation comprised of polymethylmethacrylate, or PMMA, microspheres and bovine collagen, and is the only PMMA-based injectable product that has been approved by the FDA for the treatment of facial wrinkles. We are the sole manufacturer and distributor of ArteFill, and ArteFill is only available in the United States. We do not sell any other PMMA-based products, and we have not entered into distribution or licensing arrangements anywhere in the world with any third party for the distribution or sale of ArteFill or any other PMMA-based products. ArteFill is a third-generation product that resulted from agreements with the FDA regarding product formulation improvements and improvements to the manufacturing process used to generate the predecessor products.

There are a large number of dermal fillers offered in Europe and in other international markets that contain a permanent component, and are marketed as providing long-lasting or permanent treatment results. Several of these permanent dermal fillers contain some form of PMMA, including a dermal filler currently marketed as Artecoll. Artecoll is a predecessor product to ArteFill, and has been manufactured by third parties over the past 11 years using materials from various sources and with various specifications. None of the PMMA-based products marketed in other countries, including Artecoll, have the same formulation as ArteFill and are not manufactured using the same processes or material sources we utilize to prepare ArteFill. In addition, none of the parties offering dermal fillers containing a permanent component, including the PMMA-based products, have completed clinical trials in the United States, none have received FDA approval, and none have obtained FDA approval of their manufacturing facilities and quality control processes.

Several permanent dermal fillers, including Artecoll, have and may continue to generate or receive negative publicity in the news and other media. Statements by our competitors and other publicity regarding our company or ArteFill may include coverage that is negative in nature based on the negative perceptions of the permanent dermal fillers that are offered outside the United States. In addition, any negative side effects, or alleged or perceived negative side effects, relating to the use of ArteFill may result in negative publicity. Negative publicity regarding our company or ArteFill could reduce or delay market acceptance of ArteFill, and harm our reputation and business.

Countries within the European Union, or EU, may request the EU to more strictly regulate permanent dermal fillers based on the negative side effects, alleged or perceived negative side effects or concerns about the safety of the current permanent dermal fillers being offered in Europe. A number of the permanent dermal fillers offered in Europe obtained a CE mark based on limited review and approval requirements. We are aware that stricter registration processes for dermal fillers in the EU have been implemented over the last five years, and further requirements may be imposed in the EU. We support these initiatives and are cooperating with the regulatory bodies in Europe to ensure that all manufacturers of permanent dermal fillers comply with strict and rigorous requirements that ensure patient safety, similar to the processes currently employed by the FDA and to which ArteFill was subject to, during our FDA review and approval process. We have also sent cease and desist letters to the entities we have knowledge of that are manufacturing and distributing PMMA-based dermal fillers that infringe our patent, and have forwarded such letters to appropriate European authorities.

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 two of our former officers, Drs. Gottfried Lemperle, Stefan Lemperle, and Dr. Steven Cohen in the Superior Court of the State of California for the County of San Diego. On June 1, 2006, the parties filed a stipulation to dismiss the case without prejudice and toll the statute of limitations. The court dismissed the case on June 5, 2006 as stipulated by the parties. On December 5, 2007, Ms. Sandor re-filed a complaint for personal injury, compensatory and punitive damages against us and Drs. Gottfried Lemperle, Stefan Lemperle and Steven Cohen. The complaint sets

forth various causes of action and alleges that Dr. Gottfried Lemperle administered injections of a product of ours in violation of medical licensure laws, that the product was defective and unsafe in that 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

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of the injections. Ms. Sandor is seeking damages in an unspecified amount for special and actual damages, medical and incidental expenses, incidental and consequential damages, punitive and exemplary damages, reasonable attorney s fees and costs of litigation. We have filed a demurrer to the complaint and discovery has commenced in this matter. Negative publicity surrounding these events and this case may harm our business and negatively impact the price of our stock. Additionally, if it is determined that either Dr. Gottfried Lemperle or Dr. Stefan Lemperle did not act in their individual capacities or that we are liable because of the actions of Dr. Cohen, we may need to pay damages, which would reduce resources we intend to use to support our operations.

To limit our product liability exposure, we have developed a physician training and education program. We cannot provide any assurance that our training and education program will help avoid complications resulting from the administration of ArteFill. In addition, although we intend to sell our product only to physicians, we will not be able to control whether other medical professionals, such as nurse practitioners or other cosmetic specialists, administer ArteFill to their patients, and we may be unsuccessful at avoiding significant liability exposure as a result. We maintain product liability insurance in an amount up to $20 million in the aggregate, but any insurance we maintain may not sufficient to provide coverage against any asserted claims. In addition, we may be unable to maintain our insurance or obtain insurance in the future on acceptable terms, or at all. In addition, regardless of merit or eventual outcome, product liability and other claims may result in:

- the diversion of management s time and attention from our business and operations;
- the expenditure of large amounts of cash on legal fees, expenses and payment of settlements or damages;
- decreased demand for ArteFill among physicians and patients;
- voluntary or mandatory recalls of our products; or
- injury to our reputation.

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

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 above, Dr. Gottfried Lemperle s counsel informed us that she had contacted an investigator at the FDA s Office of Criminal Investigations to determine whether any investigation of Dr. Gottfried Lemperle was ongoing. She also informed us that the FDA investigator had informed her that the FDA has an open investigation regarding us, Dr. Gottfried Lemperle and Dr. Stefan Lemperle, that the investigation had been ongoing for many months, that the investigation would not be completed within six months, and that at such time the investigation is completed, it could be referred to the U.S. Attorney s office for criminal prosecution. In November 2006, we contacted the FDA s Office of Criminal Investigations. That office confirmed the ongoing investigation but declined to provide any details of the investigation, including the timing, status, scope or targets of the investigation. We contacted the FDA s Office of Criminal Investigations again in February 2008. The Office of Criminal Investigations again confirmed that an investigation is ongoing and has been referred to the U.S. Attorney s office, but did not provide any additional information regarding this investigation or whether the U.S. Attorney s office will commence an action.

To our knowledge, prior to or following this inquiry, none of our current or former officers or directors had been contacted by the FDA in connection with an FDA investigation. As a result, we have no direct information from the FDA regarding the subject matter of this investigation. We believe that the investigation may relate to the facts alleged in the Sandor litigation and the matters identified in the following correspondence from the FDA. In July 2004, we received a letter from the FDA s Office of Compliance indicating that the FDA had received information suggesting that we may have improperly marketed and promoted ArteFill prior to obtaining final FDA approval. We also received a letter from the FDA s MedWatch program, the FDA s safety information and adverse event reporting

program, on April 21, 2005, which included a Manufacturer and User Facility Device Experience Database, or MAUDE, report. The text of the MAUDE report contained facts similar to those alleged by the plaintiff in the Sandor litigation.

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

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

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

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

Prior to receiving FDA approval, we manufactured ArteFill, including the PMMA microspheres used in the product, in limited quantities sufficient only to meet the needs for our clinical studies. To be successful, we will need to manufacture ArteFill in substantial quantities at acceptable costs. 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 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.

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

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

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

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 more than a two year supply of calf hides in stock and intend to maintain a supply of calf hides that will last for more than two years. If our stockpiled supply is damaged or contaminated, and we are unable to obtain acceptable calf hides in the time frames desired, or at all, our business and results of operations will be harmed.

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

Our U.S. clinical trial demonstrated the efficacy of ArteFill for the treatment of nasolabial folds, or smile lines, at primary efficacy endpoints of up to six months by comparison to the control products. As a result, the FDA requires us to label, advertise and promote ArteFill only for the treatment of nasolabial folds with an efficacy of six months. This limitation restricts our ability to market or advertise ArteFill and could negatively affect our growth. If we wish to market and promote ArteFill for other indications or claim efficacy benefits beyond six months, we may have to conduct further clinical trials or studies to gather clinical information for submission to the FDA, which would be costly and take a number of years. In early 2007, we completed a five-year follow-up study of 145 patients who were treated with ArteFill in our U.S. clinical trial. Dr. Mark G. Rubin, presented the results of this study at a meeting of the American Academy of Dermatology in Washington, D.C. in February 2007. We submitted the results of the five-year follow-up study to the FDA in March 2007 to seek approval to enhance product labeling that would allow us to claim efficacy benefits of ArteFill beyond six months. The FDA issued several comments to our submission and requested additional information, which we have provided. 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 or to expand our product labeling to cover additional indications. Without FDA approval to market ArteFill beyond six months,

physicians may be slow to adopt ArteFill.

We are not permitted to market, advertise or promote ArteFill for off-label uses, which are uses that the FDA has not approved. Off-label use of ArteFill may occur in areas such as the treatment of other facial wrinkles, creases and other soft tissue defects. While off-label uses of aesthetic products are common and the FDA does not regulate physicians choice of treatments, the FDA does restrict a manufacturer s communications regarding such off-label use. As a result, we may not actively promote or advertise ArteFill for off-label uses, even if physicians use ArteFill to treat such conditions. This limitation will restrict our ability to

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market our product and may substantially limit our sales. The U.S. Attorney s offices and other regulators, in addition to the FDA, have recently focused substantial attention on off-label promotional activities and, in certain cases, have initiated civil and criminal investigations and actions related to such practices. If we are found to have promoted off-label uses of ArteFill in violation of the FDA s marketing approval requirements, we could face warning letters, significant adverse publicity, fines, legal proceedings, injunctions or other penalties, any of which would be harmful to our business.

We 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 and Michael K. Green, our Chief Operating Officer and Chief Financial Officer. We have entered into change of control agreements with each of our other executive officers, including Messrs. Reinhard and Green. 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, for any or no reason. In addition, 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.

Our business may be disrupted, we may experience increased operating costs and the attention of our management may be diverted by our acquisition or license of technologies and products.

In July 2004, we acquired assets and intellectual property from FormMed Biomedicals AG in connection with the establishment of our manufacturing facility in Germany. 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. In July 2008, we entered into a Distribution Agreement with Anika Therapeutics, Inc. under which we obtained an exclusive right to market Elevess, Anika s FDA-approved temporary dermal filler, in the United States. The initial term of the Agreement runs through December 31, 2010, but may be automatically extended through December 31, 2012 upon our satisfaction of certain marketing and sales conditions, as well as a one-time extension payment. In the Agreement, we agreed to use commercially reasonable efforts to market and sell Elevess and to purchase a minimum amount of Elevess during each year of the Agreement.

We intend to pursue the acquisition or license of additional products and technologies in the future. Any acquisitions or licensing arrangements will require the assimilation of new products into our sales and marketing organization and may require the assimilation of the operations and personnel of the acquired businesses and the training and motivation of these individuals. Acquisitions and licensing arrangements may disrupt our operations, add additional operating expenses and divert our 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 or maintain our rights under any future acquisitions or licensing arrangements. The issuance of equity securities for an acquisition or licensing arrangement 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 or license arrangements if management is unable to fully integrate the acquired or licensed businesses, products, technologies or personnel with our existing operations, and control any additional operating costs as a result of such transactions.

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 $28.0 million for property damage and up to $15.0 million for business interruption in these events and may not adequately compensate us for any losses that may occur. These policies do not include earthquake or flood coverage in California. 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.

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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 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 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;
- 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.

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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 and protectability of our confidential information, and failure to maintain the confidentiality of our confidential information could adversely affect our business by causing us to lose a competitive advantage maintained through such confidential information.

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

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

In October 2005, we and Dr. Martin Lemperle, the brother of Dr. Stefan M. Lemperle, our former Chief Executive Officer and a former director, entered into a settlement and license agreement with BioForm Medical, Inc. and BioForm Medical Europe B.V., or the BioForm entities, pursuant to which all outstanding disputes and litigation matters among the parties were settled. In connection with the settlement, we granted to the BioForm entities, which are competitors of us, an exclusive, world-wide, royalty-bearing license under certain of our patents to make and sell implant products containing calcium hydroxylapatite, or CaHA, particles and a non-exclusive, world-wide, royalty-bearing license under the same patents to make and sell certain other non-polymeric implant products. In September 2007, we entered into a second license agreement with the BioForm entities. Under the second agreement, the BioForm entities elected to pre-pay all future royalty obligations to us by making two payments totaling $5.5 million. These payments satisfied any future royalty obligation of the BioForm entities to us under the settlement and license agreement. Our license grants allow BioForm to market and sell its Radiesse and Coaptite® products and other potential future products. Sale of these products by BioForm may impair our ability to generate revenues from sales of ArteFill. In addition, if we become involved in litigation or if third parties infringe or threaten to infringe our intellectual property rights in the future, we may choose to make further license grants with respect to our technology, which could further harm our ability to market and sell ArteFill.

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

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

to:

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

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

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

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

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

Although we acquired all of the international intellectual property rights related to Artecoll and the ArteFill technology platform in 2004, we are aware that third parties located in Germany, the Netherlands and Canada have in the past, and may be currently, manufacturing and selling products for the treatment of facial wrinkles under the name Artecoll or ArteSense outside the United States. Following the establishment of ArteFill in the United States, we plan to explore opportunities to market and sell ArteFill in select international markets. To successfully enter into these markets and achieve desired revenues internationally, we may need to enforce our patent and trademark rights against third parties that we believe may be infringing on our rights. We have recently sent cease and desist letters to the entities we have knowledge of that are manufacturing and distributing PMMA-based dermal fillers that we believe infringe our patent, and have forwarded such letters to the appropriate European authorities.

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.

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

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

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

- impose labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contraindications or use limitations that could have a material impact on the future profitability of our product candidates;
- impose testing and surveillance to monitor our products and their continued compliance with regulatory requirements; and
- require us to submit products for inspection

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

- issue warning letters;
- impose fines and other civil or criminal penalties;
- suspend or withdraw regulatory approvals for our products;
- refuse to approve pending applications or supplements to approved applications filed by us;
- delay, suspend or otherwise restrict our manufacturing, distribution, sales and marketing activities;
- close our manufacturing facilities; or
- seize or detain products or require a product recall.

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

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

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

The discovery of previously unknown problems with ArteFill may result in restrictions on the product, including withdrawal from manufacture. In addition, the FDA may revisit and change its prior determinations with regard to the safety or efficacy of ArteFill or our future products. If the FDA s position changes, we may be required to change our labeling or cease to manufacture and market our products. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale of, or to recall ArteFill if concerns about its safety or efficacy develop. In their regulation of advertising, the FDA and the Federal Trade Commission, or FTC, may issue correspondence alleging that our advertising or promotional practices are false, misleading or deceptive. The FDA and the FTC may impose a wide array of sanctions on companies for such advertising practices, which could result in any of the following:

- incurring substantial expenses, including fines, penalties, legal fees and costs to comply with applicable regulations;
- changes in the methods of marketing and selling products;
- 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.

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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. 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. In addition, other countries within the European Union, or EU, may request the EU to more strictly regulate dermal fillers based on the negative side effects, alleged or perceived negative side effects or concerns about the safety of dermal fillers that contain a permanent component being offered in Europe. A number of the permanent dermal fillers offered in Europe obtained a CE mark based on limited review and approval requirements. We are aware that stricter registration processes for dermal fillers in the EU have been implemented over the last five years, and further requirements may be imposed in the EU. We support these initiatives and are cooperating with the regulatory bodies in Europe to ensure that all manufacturers of permanent dermal fillers comply with strict and rigorous requirements that ensure patient safety, similar to the processes currently employed by the FDA and to which ArteFill was subject to, during our FDA review and approval process. Nevertheless, government actions such as these could increase our regulatory approval costs and delay or prevent the introduction of ArteFill in international markets.

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 and Elevess 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 or Elevess to their patients. If our operations, including our anticipated business relationships with physicians who use ArteFill or Elevess, 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.

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

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

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

Prior to our initial public offering in December 2006, there has been no public market for our common stock. The market price for our common stock has been and is likely to remain volatile, and the stock markets in general, and the markets for medical technology stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. There have also been periods, sometimes extending for many months and even years, where medical technology stocks, especially of smaller earlier stage companies like us, have been out of favor and trading prices have remained low relative to other sectors. In addition, the average daily trading volume in our common stock has been relatively low, which can lead to volatility in our stock price.

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

- news that we will be required to raise additional capital to support our operations during 2008, the risks that we will not be able to raise the capital on a timely basis on acceptable terms or at all, and concerns regarding the potential dilution of such financing transaction;
- negative publicity concerning ArteFill, including concerns expressed about ArteFill based on negative perceptions of non-FDA approved dermal fillers sold outside the United States;
- adverse actions taken by regulatory agencies with respect to open investigations, including the ongoing investigation by the FDA s Office of Criminal Investigations involving Drs. Gottfried and Stefan Lemperle and our company;
- other adverse actions taken by regulatory agencies with respect to our products, manufacturing processes or sales and marketing activities or those of our competitors;
- developments in any lawsuit involving us, our intellectual property or our product or product candidates;
- announcements of technological innovations or new products by our competitors;
- announcements of adverse effects of products marketed or in clinical trials by our competitors;
- regulatory developments in the United States and foreign countries;
- announcements concerning our competitors or the medical device, cosmetics or pharmaceutical industries in general;
- developments concerning any future collaborative arrangements;
- actual or anticipated variations in our operating results;
- lack of securities analyst coverage or changes in recommendations by analysts;
- deviations in our operating results from the estimates of analysts;
- sales of our common stock by our founders, executive officers, directors, or other significant stockholders or other sales of substantial amounts of common stock;
- changes in accounting principles; and

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

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.

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

As of September 30, 2008, we had reserved approximately 10.6 million shares of our common stock for potential issuance upon the exercise of warrants and options (including outstanding warrants to purchase common stock, options already granted under our stock option plans, non-plan stock options already granted and shares reserved for future grant under our stock option plans), which represented approximately 35% of our common stock on a fully diluted basis (assuming the exercise of all outstanding warrants and options). Of the 10.6 million shares of common stock reserved at September 30, 2008, 3.0 million shares of common stock are reserved for outstanding stock options at a weighted average exercise price of $5.16 per share; 5.6 million shares of common stock are reserved for outstanding warrants to purchase common stock (after considering the impact of the warrant holder elections eliminating the automatic expiration and extending the terms of the warrants upon the closing of our initial public offering), at a weighted average exercise price $4.45 per share; and 2.1 million shares of common stock are reserved for future stock option grants under our 2006 Equity Incentive Plan. The issuance of these additional shares could dilute your ownership interest in our company.

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

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

In addition, on May 29, 2008, our Board of Directors adopted a stockholders rights plan. Under the plan, the Board declared a dividend distribution of one "Right" for each outstanding share of our common stock to stockholders of record as of the close of business on June 23, 2008. Since that time, we have issued and will continue to issue one Right with each newly issued share of common stock. Each Right entitles the registered holder to purchase from us one one-thousandth of a share of Series A participating preferred stock at a purchase price of $50.00 per one-thousandth of a share, subject to adjustment. In general, under the plan, if a person or affiliated group acquires beneficial ownership of 20% or more of our shares of common stock, then each Right (other than those held by such acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of our common stock (or, under certain circumstances, a combination of securities or other assets) having a value of twice the underlying purchase price of the Right. In addition, if following the announcement of the existence of an acquiring person or affiliated group we are involved in a business combination or sale of 50% or more of our assets or earning power, each Right (other than those held by the acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock of the acquiring entity having a value of twice the underlying purchase price of the Right. The Board also has the right, after an acquiring person or affiliated group is identified, to cause each Right to

be exchanged for common stock or substitute consideration. We may redeem the Rights at a price of $0.00001 per Right prior to the identification of an acquiring person or affiliated group. The Rights expire on June 12, 2018.

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

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

In September 2008, the Company completed a private financing with accredited investors raising approximately $2.4 million in gross proceeds from a private placement of its common stock and related warrants.

Pursuant to the financing, the Company issued 2,735,817 shares of common stock at a purchase price of $0.73 per share. The Company also issued to the investors warrants to purchase an additional 1,367,916 shares of common stock at an exercise price of $0.75 per share. The warrants are exercisable no sooner than six months following the closing of the private placement and will expire on March 26, 2014. In addition, the Company issued 497,228 shares of common stock at a purchase price of $0.8125 per share and warrants to purchase 248,616 shares of common stock, at an exercise price of $0.75 per share, to investors who may be deemed to be affiliated with a member of the Company s board of directors.

In connection with the financing, the Company has agreed, subject to certain terms and conditions, to provide piggyback registration rights with respect to the resale of the shares purchased and the shares issuable upon exercise of the warrants. Also, the Company paid its placement agent a cash fee equal to 8% of the aggregate proceeds raised in the financing. The 8% placement fee and other costs totaling $0.3 million were recorded as issuance cost and netted against the proceeds. The Company also issued warrants to its placement agent to purchase up to 218,865 shares of common stock at an exercise price of $0.73 per share, up to 129,322 shares of common stock at an exercise price of $0.75 and up to 39,778 shares of common stock at an exercise price of $0.8125 per share.

Item 3. Defaults Upon Senior Securities.

None.

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

None.

Item 5. Other Information.

None.

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Item 6. Exhibits.

EXHIBIT INDEX

Exhibit number	Exhibit Description
3.4 (1)	Amended and Restated Certificate of Incorporation.
3.6 (1)	Amended and Restated Bylaws.
3.7 (1)	Certificate of Amendment to Amended and Restated Bylaws.
3.8(3)	Certificate of Designations of Rights, Preferences and Privileges of Series A Preferred Stock.
4.1 (1)	Specimen common stock certificate.
4.2 (1)	Amended and Restated Investor Rights Agreement dated June 23, 2006, by and among us and the holders of our preferred stock listed on Schedule A thereto.
4.3 (1)#	Form of warrant to purchase common stock, issued to employees, consultants and service providers.
4.4 (1)#	Amended warrant to purchase up to 650,000 shares of common stock, dated June 9, 2006, issued to Christopher J. Reinhard, as corrected.
4.5 (1)	Form of warrant to purchase common stock, issued to certain investors in a bridge loan financing transaction.
4.6 (1)	Form of warrant to purchase Series C-1 preferred stock, issued to certain investors in a bridge loan financing transaction.
4.7 (1)	Form of warrant to purchase common stock, issued to certain investors in our Series D preferred stock financing.
4.8 (1)	Form of warrant to purchase Series D preferred stock, issued to certain investors in a bridge loan financing transaction.
4.9 (1)	Warrant to purchase 200,000 shares of Series E preferred stock issued to Legg Mason Wood Walker, Inc. on December 22, 2005.
4.10 (1)	Form of warrant to purchase Series E preferred stock issued to certain investors in our Series E preferred stock financing.
4.11(1)	Form of warrant to purchase Series E preferred stock issued to National Securities Corporation in consideration for placement agent services provided to us in our Series E preferred stock financing.
4.12 (1)#	Amended warrant to purchase up to 150,000 shares of common stock, dated June 9, 2006, issued to Christopher J. Reinhard, as corrected.
4.13 (1)#	Amendment dated June 23, 2006, to warrant to purchase common stock, issued to employees, consultants and service providers, entered into by us and each of the warrant holders listed on Exhibit A thereto.

4.14 (1) Amendment dated June 23, 2006, to warrant to purchase common stock, issued to certain investors in a bridge loan financing transaction, entered into by us and each of the warrant holders listed on Exhibit A thereto.

4.15 (1) Amendment dated June 23, 2006, to warrant to purchase Series C-1 preferred stock, issued to certain investors in a bridge loan financing transaction, entered into by us and each of the warrant holders listed on Exhibit A thereto.

4.16 (1) Amendment dated June 23, 2006, to warrant to purchase common stock, issued to certain investors in our Series D preferred stock financing, entered into by us and each of the warrant holders listed on Exhibit A thereto.

4.17 (1) Amendment dated June 23, 2006, to warrant to purchase Series D preferred stock, issued to certain investors in a bridge loan financing transaction, entered into by us and each of the warrant holders listed on Exhibit A thereto.

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Exhibit number	Exhibit Description
4.18 (1)	Warrant to purchase 28,235 shares of Series E preferred stock issued to Comerica Bank on November 27, 2006.
4.19 (2)	Investor Rights Agreement, dated February 12, 2008, by and between us and CHRP.
4.20 (2)	Warrant to purchase 1,300,000 shares of common stock issued to CHRP on February 12, 2008.
4.21 (2)	Warrant to purchase 375,000 shares of common stock issued to CHRP on February 12, 2008.
4.22(3)	Preferred Shares Rights Agreement, dated June 13, 2008, by and between us and Mellon Investor Services LLC.
4.23(4)	Form of Warrant re private placement investors.
4.24(4)	Form of Form of Placement Agent Warrant
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.
32.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.

# Indicates management contract or compensatory plan.

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

an unredacted copy of the exhibit.

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

(2) Incorporated by reference to the same numbered exhibit filed with our Annual Report on Form 10-K (File No. 001-33205), dated March 14, 2008.

(3) Incorporated by reference to the same named exhibit filed with our Registration Statement on Form 8-A (File No. 000-53281), dated June 16, 2008.

(4) Incorporated by reference to the same named exhibits with our Current Report on Form 8-K, dated September 29, 2008.

* These certifications are

being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Artes Medical, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Artes Medical, Inc.

Date: November 10, 2008

By: \s\ Christopher J. Reinhard

Christopher J. Reinhard
Executive Chairman of the Board

Date: November 10, 2008

By: \s\ Michael K. Green

Michael K. Green
Chief Financial Officer