ARTES MEDICAL INC
Form 10-Q
May 08, 2007

Table of Contents

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 March 31, 2007

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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No þ

As of March 31, 2007, there were 16,442,604 shares of the registrant s common stock outstanding.

ARTES MEDICAL, INC.
QUARTERLY REPORT ON FORM 10-Q
March 31, 2007
TABLE OF CONTENTS

		Page
PART I FINANCIAL INFORMATION		
Item 1.	Financial Statements (unaudited)	3
	Condensed Consolidated Balance Sheets as of March 31, 2007 and December 31, 2006	3
	Condensed Consolidated Statements of Operations for the three months ended March 31, 2007 and 2006	4
	Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2007 and 2006	5
	Notes to Financial Statements	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	19
Item 4.	Controls and Procedures	19
PART II OTHER INFORMATION		
Item 1.	Legal Proceedings	19
Item 1A.	Risk Factors	21
Item 5.	Other Information	21
Item 6.	Exhibits	21
SIGNATURES		23

Exhibits
EXHIBIT 10.33
EXHIBIT 31.1
EXHIBIT 31.2
EXHIBIT 32.1
EXHIBIT 32.2

Table of Contents

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	March 31, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,257	$ 46,258
Accounts receivable	960	
Inventory, net	5,484	4,761
Prepaid expenses and other assets	654	406
Total current assets	45,355	51,425
Property and equipment, net	5,227	5,271
Intellectual property, net	3,280	3,578
Deposits and other assets	346	339
Total assets	$ 54,208	$ 60,613
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,417	$ 2,981
Accrued compensation and benefits	2,619	2,694
Revolving credit line	5,000	5,000
Term note payable, current portion	1,250	1,250
Capital lease obligations, current portion	46	45
Deferred rent, current portion	62	49
Total current liabilities	11,394	12,019
Term note payable (net of discount of $297 and $305 at March 31, 2007 and December 31, 2006, respectively)	3,036	3,341
Capital lease obligations, less current portion	9	21
Deferred rent, less current portion	654	678
Deferred tax liability	1,321	1,368
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.001 par value 200,000,000 shares authorized at March 31, 2007 and December 31, 2006; 16,442,604 and 16,361,246 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively	16	16
Additional paid-in capital	123,789	122,572
Accumulated deficit	(86,011)	(79,402)
Total stockholders equity	37,794	43,186
Total liabilities and stockholders equity	$ 54,208	$ 60,613

See accompanying notes to unaudited condensed consolidated financial statements

Table of Contents

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

	Three Months Ended March 31,	
	2007	**2006**
Sales	$ 1,442	$
Cost of sales	1,720	
Gross profit	(278)	
Operating expenses:		
Research and development	1,032	2,949
Selling, general and administrative	5,570	3,194
Total operating expenses	6,602	6,143
Loss from operations	(6,880)	(6,143)
Interest income	477	69
Interest expense	(268)	(1,930)
Other income (expense), net	13	(19)
Net loss before benefit for income taxes	(6,658)	(8,023)
Benefit for income taxes	49	42
Net loss	$ (6,609)	$ (7,981)
Historical net loss per share:		
Basic and diluted	$ (0.40)	$ (6.14)
Weighted average shares basic and diluted	16,380,633	1,300,634

See accompanying notes to unaudited condensed consolidated financial statements

Table of Contents

Artes Medical, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited and in thousands)

	Three Months Ended March 31,	
	2007	**2006**
Operating activities		
Net loss	$ (6,609)	$ (7,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	653	552
Provision for obsolete inventory	206	(35)
Benefit for income taxes	(47)	(47)
Non-cash interest expense associated with issuance of warrants and convertible notes	8	1,871
Stock-based compensation	845	610
Issuance of common stock for services		62
Issuance of common stock for intellectual property		49
Loss on disposal of property and equipment		39
Deferred rent	(11)	12
Deferred taxes		
Changes in operating assets and liabilities:		
Inventory	(930)	(93)
Accounts receivable	(960)	
Prepaid expenses and other assets	(253)	282
Accounts payable and accrued liabilities	(564)	(2,329)
Accrued compensation and benefits	(75)	40
Net cash used in operating activities	(7,737)	(6,968)
Investing activities		
Purchases of property and equipment	(311)	(686)
Deposits and other assets		(65)
Net cash used in investing activities	(311)	(751)
Financing activities		
Payments on capital lease obligations	(12)	(17)
Payments on term note payable	(313)	
Payments on convertible notes payable		(6,476)
Proceeds from issuance of preferred stock, net		31,816
Proceeds from issuance of common stock	(57)	
Proceeds from exercise of stock options and warrants	429	81
Net cash provided by financing activities	47	25,404
Net (decrease) increase in cash and cash equivalents	(8,001)	17,685
Cash and cash equivalents at beginning of period	46,258	6,930
Cash and cash equivalents at end of period	$ 38,257	$ 24,615
Noncash financing activities		

Issuance of subscribed preferred stock	$	$ 6,900
Issuance of warrants and common stock in connection with intellectual property acquisition	$	$ 49
Supplemental activities		
Cash paid for income taxes	$	$ 5
Cash paid for interest	$ 260	$ 58

See accompanying notes to unaudited condensed consolidated financial statements

Table of Contents

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

1. Organization and Summary of Significant Accounting Policies

Organization and Business

Artes Medical, Inc. (the Company), formerly known as Artes Medical USA, Inc., was incorporated in Delaware on August 24, 1999, and is focused on the development, manufacture and commercialization of a new category of injectable aesthetic products for the dermatology and plastic surgery markets. The Company s initial product, ArteFill, is a non-resorbable aesthetic injectable implant for the correction of facial wrinkles known as smile lines, or nasolabial folds. The Company received FDA approval to market ArteFill on October 27, 2006 and commenced commercial shipment of ArteFill during the first quarter of 2007.

Principles of Consolidation

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

Initial Public Offering and Conversion of Preferred Stock

On December 26, 2006, the Company closed its initial public offering. Immediately prior to the closing of the Company s initial public offering, all outstanding shares of the Company s preferred stock were converted into shares of common stock and warrants to purchase shares of common stock were exercised. The impact of the Company s initial public offering on its common stock outstanding is as follows at December 31, 2006:

Capitalization summary upon closing of initial public offering:	
Common stock issued and outstanding prior to initial public offering	1,427,400
Initial public offering sale of common stock	5,290,000
Conversion of preferred stock upon initial public offering into common stock	9,367,512
Cash exercise of warrants to purchase common stock upon initial public offering	276,334
	16,361,246

Recent Accounting Pronouncements

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement No. 109, *Accounting for Income Taxes* (FIN 48). FIN 48 creates a single model to address accounting for uncertainty in income tax positions. FIN 48 prescribes a minimum threshold that an income tax position is required to meet before being recognized in the financial statements. The interpretation also provides guidance on derecognition and measurement criteria in addition to classification, interest and penalties and interim period accounting, and it significantly expands disclosure provisions for uncertain tax positions that have been or are expected to be taken in a company s tax return. The Company adopted this statement as of January 1, 2007.

As a result of the adoption of FIN 48, the Company has not recorded any change to retained earnings at January 1, 2007 as the Company had no unrecognized tax benefits that, if recognized, would favorably affect the Company s effective income tax rate in future periods. At March 31, 2007, the Company had no unrecognized tax benefits. The Company s continuing practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrued interest or penalties at January 1, 2007 and no accrued interest or penalties at March 31, 2007.

Table of Contents

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared pursuant to 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 accounting principles generally accepted in the United States (GAAP). In management s opinion, the consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company s financial position and of the results of operations and cash flows for the periods presented.

These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2006 included in Artes Medical, Inc. s Annual Report on Form 10-K filed with the Securities and Exchange Commission. Operating results for the three months ended March 31, 2007 are not necessarily indicative of the results that may be expected for any other interim period or for the full year ended December 31, 2007. The consolidated balance sheet at December 31, 2006 has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

Certain reclassifications to prior period information have been made for consistent presentation. Prior to 2006, stock compensation expense was disclosed in the statement of operations as a separate element of operating expense. In 2006, stock compensation expense is included in total operating expense for the related expense category.

3. Net Loss Per Common Share

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

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

	March 31.	
	2007	**2006**
	(unaudited)	
Convertible preferred stock		9,352,029
Warrants to purchase preferred and common stock	2,427,844	3,362,377
Options to purchase common stock	2,659,604	1,441,941
	5,087,448	14,156,347

4. Comprehensive Income (Loss)

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

Table of Contents

5. Balance Sheet Details

Inventory

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

Inventory consisted of the following at (in thousands):

	March 31, 2007 (unaudited)	December 31, 2006
Raw materials	$ 681	$ 727
Work in process	2,364	1,619
Unpackaged finished goods	2,111	3,169
Finished Goods	964	
	6,120	5,515
Less: reserve for obsolete inventory	(636)	(754)
Total	$ 5,484	$ 4,761

6. Stock-based Compensation

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

For purposes of calculating the stock-based compensation under SFAS 123(R), the Company estimates the fair value of stock options using a Black-Scholes option-pricing model which is consistent with the model used for pro forma disclosures under SFAS 123 prior to the adoption of SFAS 123(R). The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. In accordance with SFAS 123(R) share-based compensation expense recognized in the statement of operations for the first quarter of 2006 is based on awards ultimately expected to vest and is reduced for estimated forfeitures. Prior to the adoption of SFAS 123(R), the Company used the minimum value method for valuing stock options granted to employees and directors. In the Company s pro forma information required under SFAS 123 for the periods prior to 2006, the Company accounted for forfeitures as they occurred.

The assumptions used to estimate the fair value of stock options granted to employees and directors during the three months ended March 31, 2007 and 2006 are as follows:

	Three Months Ended March 31,	
	2007	2006
Volatility	48%	60%
Expected term (years)	6.0	6.0

Risk free interest rate	4.75%	4.55%
Expected dividend yield	0%	0%

Table of Contents

The risk-free interest rate assumption was based on the United States Treasury s rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company s expectation of not paying dividends in the foreseeable future. The weighted average expected life of options was calculated using the simplified method as prescribed by the SEC s SAB No. 107 (SAB No. 107).

This decision was based on the lack of relevant historical data due to the Company s limited historical experience. In addition, due to the Company s limited historical data, the estimated volatility also reflects the application of SAB No. 107, incorporating the historical volatility of comparable companies whose share prices are publicly available.

The weighted average grant-date fair value of stock options granted during the three months ended March 31, 2007 was $9.27 per share.

During the three months ended March 31, 2007, the Company recorded approximately $691,000 of stock compensation expense under SFAS No. 123(R). Of this amount, $81,000 has been capitalized to inventory, $67,000 is included in research and development expenses and $543,000 is included in selling, general and administrative expenses.

Total unrecognized stock-based compensation costs related to non-vested stock options at March 31, 2007 was approximately $11,682,000, which related to 1,266,849 options issued and outstanding. This unrecognized cost is expected to be recognized on a straight-line basis over a weighted average period of approximately 3.5 years.

Equity instruments issued to non-employees are recorded at their fair values as determined in accordance with SFAS 123, *Accounting for Stock-Based Compensation*, and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the options vest and are recognized as expense over the related service period. During the three months ended March 31, 2007 and 2006, the Company recognized $4,000 and $373,000, respectively, for stock options and warrants issued to non-employees.

Deferred Stock-Based Compensation

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

On September 13, 2005, the Company commenced the initial public offering process, and based on discussions with its investment bankers, reassessed the fair value of its common stock going back to July 1, 2004. The Company s management, all of whom qualify as related parties, determined that the stock options granted from July 1, 2004 forward were granted at exercise prices that were below the reassessed fair value of the common stock on the date of grant. The Company completed the reassessment of its fair value without the use of an unrelated valuation specialist and started with the proposed valuation from its investment bankers, considering a number of accomplishments in 2004 and 2005 that would impact its valuation, including achievement of key clinical milestones, hiring executive officers, and the increased possibility of completing an initial public offering. Accordingly, deferred stock-based compensation of $740,000 was recorded within Stockholders Equity (deficit) during 2004 which represented the difference between the weighted-average exercise price of $4.25 and the weighted-average fair value of $6.38 on 324,705 options granted to employees during 2004. Deferred stock-based compensation of $2,383,000, net of forfeitures, was recorded within Stockholders Equity (deficit) during 2005 which represented the difference between the weighted-average exercise price of $5.31 and the weighted-average fair value of $9.18 on 620,000 options granted to employees during 2005.

The deferred stock-based compensation is being amortized on a straight-line basis over the vesting period of the related awards, which is generally four years.

Table of Contents

During the three months ended March 31, 2007 and 2006, we recognized $150,000 and $197,000, respectively, in amortization of deferred stock-based compensation which was provided for prior to the adoption of SFAS 123(R).

Unrecognized deferred stock-based compensation related to non-vested stock option and warrant awards granted prior to January 1, 2006 was approximately $1,313,000 at March 31, 2007.

The expected future amortization expense for deferred stock-based compensation for stock options granted through March 31, 2007, is as follows (in thousands):

2007	$ 415
2008	527
2009	371
Total	$ 1,313

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

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

	Three Months Ended March 31,	
	2007	2006
	(In thousands, except per share amounts)	
Capitalized to inventory	$ 125	$
Research and development expense	$ 102	$ 166
Sales, general and administrative expense	618	444
	$ 720	$ 610
Net effect on basic and diluted net loss per share	$ 0.05	$ 0.47

Stock Option Plans

In 2006, the Company adopted the 2006 Equity Incentive Plan (the 2006 Plan) for eligible employees, officers, directors, advisors, and consultants that provides for the grant of incentive and nonstatutory stock options and other awards. The Company has 5,882,353 shares of common stock options authorized under the 2006 Plan. Terms of the stock option agreements, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the 2006 Plan.

Options granted by the Company generally vest over four years and vested options are exercisable from the date of grant for a period of ten years. The exercise price of the incentive stock options must equal at least the fair market value of the stock on the date of grant.

In 2001, the Company adopted the 2001 Stock Option Plan (the 2001 Plan) for eligible employees, officers, directors, advisors, and consultants that provides for the grant of incentive and nonstatutory stock options. The 2001 Plan superseded the Company s 2000 Stock Option Plan (the 2000 Plan). Following the adoption of the 2001 Plan, no further option grants were made under the 2000 Plan. Terms of the stock option agreements, including vesting requirements, are determined by the Board of Directors, subject to the applicable provisions of the 2000 Plan or 2001 Plan. Options granted by the Company generally vest over four years and vested options are exercisable from the date of grant for a period of ten years. The exercise price of the incentive stock options must equal at least the fair market value of the stock on the date of grant. All the shares of stock that remained available for issuance and not subject to

outstanding options under the 2000 Plan and 2001 Plan became part of the available pool of shares under the 2006 Plan. No further option grants will be made under the 2000 Plan or 2001 Plan.

The exercise price of nonstatutory stock options under the 2000 Plan and the 2001 Plan must equal at least 85% of the fair market value of the stock on the date of grant.

Table of Contents

The exercise price of any incentive stock option granted to a 10% stockholder may be no less than 110% of the fair value of the Company s common stock on the date of grant. As of March 31, 2007, there were 25,880, 2,008,844 and 595,000 options outstanding under the 2000 Plan, 2001 Plan and 2006 Plan, respectively, and 29,880 options granted outside the 2000 Plan and 2001 Plan.

The Company recorded stock-based compensation for options granted to nonemployees of $4,000 and $25,000 for the three months ended March 31, 2007 and 2006, respectively. The fair value of each option was determined using the Black-Scholes valuation model and periodically re-measured and recognized over the related service period.

The following table summarizes stock option activity under the Company s stock option plans, as well as outside of these plans (shares in thousands):

	Options	Weighted-Average Exercise Price
Outstanding, December 31, 2006	2,134	6.65
Granted	595	9.27
Exercised	(2)	5.35
Canceled	(67)	6.73
Outstanding, March 31, 2007	2,660	7.24

The following table summarizes information about options outstanding and exercisable at March 31, 2007 under the 2000 and 2001 Plans and outside the Plans:

		Options Outstanding			Options Exercisable	
	Grant Exercise Price	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$0.43	$0.64	29,880	2.8 years	$ 0.52	27,306	$ 0.50
$0.65	$2.34	88,231	4.4 years	1.74	77,324	1.71
$2.35	$6.38	975,777	8.4 years	5.15	487,381	5.05
$6.39	$10.63	1,565,716	9.6 years	8.97	242,681	8.51
		2,659,604	8.9 years	7.24	834,692	5.60

Common Shares Reserved

The following table summarizes common shares reserved for issuance at March 31. 2007 on exercise or conversion of *(in thousands)*:

Warrants for common stock	2,427,844
Common stock options:	
Common stock options outstanding	2,659,604
Common stock options available for future grant	3,133,037
Total common shares reserved for issuance	8,220,485

Table of Contents

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 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, 2006. In light of these risks, uncertainties and assumptions, readers are cautioned not to place undue reliance on such forward-looking statements. These forward looking statements represent beliefs and assumptions only as of the date of this report. Except as required by applicable law, we do not intend to update or revise forward-looking statements contained in this report to reflect future events or circumstances.

Overview

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

We commenced commercial shipments of ArteFill during the first quarter of 2007. Our strategy is to establish ArteFill as a leading injectable aesthetic product. We plan to drive the adoption of our product through a direct sales and marketing effort to dermatologists, plastic surgeons and cosmetic surgeons in the United States. We initially intend to target dermatologists, plastic surgeons and cosmetic surgeons whom we have identified as having performed a significant number of procedures involving injectable aesthetic products. In connection with our product launch, we intend to provide these physicians with comprehensive education and training programs. We believe our education and training programs will enable physicians to improve patient outcomes and satisfaction. After establishing ArteFill in the United States, we plan to explore opportunities to register and sell ArteFill in selected international markets. In addition, we may expand our product offering by acquiring complementary products, technologies or businesses.

Since our inception in 1999, we have incurred significant losses and have never been profitable. We have devoted substantially all of our efforts to product development and clinical trials, to acquire international rights to certain intangible assets and know-how related to our technology, and to establish commercial manufacturing capabilities. We commenced commercial shipments of ArteFill during the first quarter of 2007. From inception to March 31, 2007, we have recognized $1.4 million in revenue from the sales of ArteFill. As of March 31, 2007, our accumulated deficit was approximately $86.0 million.

Financial Operations Overview

Sales

We commenced commercial shipments of ArteFill during the first quarter of 2007 and began generating product sales from ArteFill. From our inception in 1999 through March 31, 2007, we have generated $1.4 million in product sales.

Table of Contents

Cost of Sales

Cost of sales consist primarily of expenses related to the manufacturing and distribution of ArteFill, including expenses related to our direct and indirect manufacturing personnel, quality assurance and quality control, manufacturing and engineering, supply chain management, facilities and occupancy costs. We also incur expenses related to manufacturing yield losses, product returns and rejects, procurement from our manufacturing materials supply and distribution partners and amortization of deferred stock-based compensation for our direct and indirect manufacturing personnel.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses are comprised of the following:

- sales and marketing expenses, which primarily consist of the personnel and related costs of our U.S. sales force, customer service, marketing and brand management functions, including direct costs for advertising and promotion of our product; and
- general and administrative costs, which primarily consist of corporate executive, finance, legal, human resources, information systems, investor relations and general administrative functions.

Research and Development Expenses

A significant majority of our research and development expenses consist of expenses incurred by external service providers for preclinical, clinical trials, technology and regulatory development projects.

Research and development expenses also include costs incurred for process development and validation to scale up our commercial operations to meet cGMP manufacturing requirements prior to final approval from the FDA to market our product. We have also incurred personnel costs related to internal development of our product.

Because we have been focused on obtaining final FDA approval for ArteFill, we currently maintain a limited in-house research and development organization for new product development and have concentrated our resources on manufacturing and process development to meet FDA cGMP requirements. In January 2004, we received an approvable letter from the FDA for our PMA application, indicating that ArteFill is safe and effective for the correction of facial wrinkles known as smile lines, or nasolabial folds. In January 2006, we submitted an amendment to our PMA application to address certain conditions to final marketing approval set forth in the FDA s approvable letter, and in April 2006, the FDA completed comprehensive pre-approval inspections of our manufacturing facilities in San Diego, California and Frankfurt, Germany. On May 3, 2006, the FDA issued an EIR, indicating that its inspection of our facilities was completely closed, requiring no further action on the part of our company related to the inspection. On October 27, 2006, the FDA approved ArteFill for commercial sale in the United States.

Amortization of Acquired Intangible Assets

Acquired intangible assets, consisting of core technology and international patents, are recorded at fair market value as of the acquisition date. Fair market value is determined by an independent third party valuation and is amortized over the estimated useful life. This determination is based on factors such as technical know-how and trade secret development of our core PMMA technology, patent life, forecasted cash flows, market size and growth, barriers to competitive entry and existence and the strength of competing products.

Table of Contents

Critical Accounting Policies

Our 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 accounting principles generally accepted in the United States (GAAP) 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 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.

We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We follow the provisions of the Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, which sets forth guidelines for the timing of revenue recognition based upon factors such as passage of title, installation, payment and customer acceptance. We recognize revenue from product sales when all four of the following criteria are met: (i) there is persuasive evidence that an arrangement exists, (ii) delivery of the product has occurred and title has transferred to our customers, (iii) the selling price is fixed and determinable and (iv) collection is reasonably assured. Provisions for discounts to customers, returns or other adjustments will be recorded as a reduction of revenue and provided for in the same period that the related product sales are recorded based upon analysis of historical discounts and returns.

When terms of sale are Free on Board, or FOB, shipping point, revenue will be recognized at the time of shipment and when the terms of sale are FOB destination point, revenue will be recognized when the products have reached the destination point and other criteria for revenue recognition have been met.

We expect a substantial amount of our business to be transacted using credit cards. We may offer an early payment discount to certain customers.

We also may provide customers with certain product return rights in the case of damaged or defective product. Once we have experience with actual product sales and customer product returns, we will determine the appropriate reserve for product returns. Our inability to accurately estimate product returns in the future may cause us to defer recognition of revenue.

Allowance for Doubtful Accounts

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

Valuation of Inventory

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

Table of Contents

Impairment of Long-Lived Assets

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

Intangible Assets

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

Deferred Taxes

Asset Valuation Allowance

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

Deferred Tax Liability

A deferred tax liability was created on the date of purchase of our wholly-owned German-based manufacturing subsidiary as there was no allocation of the purchase price to the intangible asset for tax purposes, and the foreign subsidiary s tax basis in the intangible asset remained zero.

Emerging Issues Task Force, or EITF, Issue No. 98-11, *Accounting for Acquired Temporary Differences in Certain Purchase Transactions That Are Not Accounted for as Business Combinations*, requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability.

Valuation of Stock-Based Compensation

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-Based Payment* (SFAS No. 123(R)), which revises SFAS No. 123, *Accounting for Stock-Based Compensation* and (SFAS No. 123), supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). SFAS No. 123(R) requires that share-based payment transactions with employees and directors be recognized in the financial statements based on their grant-date fair value and recognized as compensation expense over the requisite service period. In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) 107, which provided supplemental implementation guidance for SFAS 123 (R). We have applied to provisions of SAB 107 in our adoption of SFAS 123 (R). Prior to January 1, 2006, we accounted for our stock-based employee and director compensation plans using the intrinsic value method under the recognition and measurement provisions of Accounting Principles Board Opinion (APB) 25, *Accounting for Stock Issued to Employees*, and related guidance. Equity instruments issued to non-employees are recorded at their fair values as determined in accordance with SFAS 123, *Accounting for Stock-Based Compensation*, and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the options vest and are recognized as expense over the related service period.

Table of Contents

Deferred Stock-Based Compensation

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

As a result of initiating the public offering process, in 2005, and based on discussions with our investment bankers, we have revised our estimate of the fair value of our common stock for periods beginning on and after July 1, 2004 for financial reporting purposes. Our management, all of whom qualify as related parties, determined that the stock options granted on and after July 1, 2004 were granted at exercise prices that were below the reassessed fair value of our common stock on the date of grant. We completed the reassessment of the fair value without the use of an unrelated valuation specialist and started with the proposed valuation from our investment bankers, considering a number of accomplishments in 2004 and 2005 that would impact our valuation, including achievement of key clinical milestones, hiring executive officers, and the increased possibility of completing this offering. Accordingly, deferred stock-based compensation of $740,000 was recorded within stockholders equity (deficit) during 2004 which represented the difference between the weighted-average exercise price of $4.25 and the weighted-average fair value of $6.38 on 324,705 options granted to employees during 2004. Deferred stock-based compensation of $2,383,000, net of forfeitures, was recorded within stockholders equity (deficit) during 2005 which represented the difference between the weighted-average exercise price of $5.31 and the weighted-average fair value of $9.18 on 620,000 options granted to employees during 2005. The deferred stock-based compensation is being amortized on a straight-line basis over the vesting period of the related awards, which is generally four years.

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

Recent Accounting Pronouncements

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement No. 109, *Accounting for Income Taxes* (FIN 48). FIN 48 creates a single model to address accounting for uncertainty in income tax positions. FIN 48 prescribes a minimum threshold that an income tax position is required to meet before being recognized in the financial statements. The interpretation also provides guidance on derecognition and measurement criteria in addition to classification, interest and penalties and interim period accounting, and it significantly expands disclosure provisions for uncertain tax positions that have been or are expected to be taken in a company s tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006 and we adopted this statement as of January 1, 2007.

As a result of the adoption of FIN 48, we have not recorded any change to retained earnings. At January 1, 2007 we did not have any unrecognized tax benefits that, if recognized, would favorably affect our effective income tax rate in future periods. At March 31, 2007, we had no unrecognized tax benefits. Our continuing practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrued interest or penalties at January 1, 2007 and no accrued interest or penalties at March 31, 2007.

Table of Contents

Results of Operations

Comparison of the Three Months Ended March 31, 2006 to March 31, 2007

Sales. We commenced commercial shipments of ArteFill during the first quarter of 2007 and began generating product sales from ArteFill. Revenues increased by $1.4 million from no revenues for the three months ended March 31, 2006 to $1.4 million for the three months ended March 31, 2007.

Cost of sales. Cost of sales increased by $1.7 million from no cost of sales for the three months ended March 31, 2006 to $1.7 million for the three months ended March 31, 2007. The increase was attributable to the commercial launch of ArteFill during the first quarter of 2007.

Research and development. Research and development expense decreased by $1.9 million from $2.9 million for the three months ended March 31, 2006 to $1.0 million for the three months ended March 31, 2007. The decrease was primarily attributable to our transition from the process development stage to the manufacturing of our product. Included in our research and development expenses is $0.3 million of amortization of core technology and patents for each of the three months ended March 31, 2006 and 2007.

Selling, general and administrative. The following table sets forth our selling, general and administrative expense for the three months ended March 31, 2006 and 2007 (in thousands):

	2006	2007	Amount of Change
Sales and marketing	$ 1,071	$ 2,471	$ 1,400
General and administrative	2,123	3,099	976
Total selling, general and administrative	$ 3,194	$ 5,570	$ 2,376

Sales and marketing expense increased by $1.4 million from $1.1 million for the three months ended March 31, 2006 to $2.5 million for the three months ended March 31, 2007. The increase was primarily attributable to (i) $1.1 million in payroll and travel expenses for additional personnel, primarily for our direct U.S. sales force (ii) $0.1 million for the development of marketing and promotion programs, (iii) $0.2 million in non-cash compensation.

General and administrative expense increased by $1.0 million from $2.1 million for the three months ended March 31, 2006 to $3.1 million for the three months ended March 31, 2007. The increase was primarily attributable to (i) a $0.3 million increase due to additional personnel and related travel expenses, (ii) $0.3 million in facilities occupancy costs, (iii) $0.1 million in office related expenses, and (iv) $0.3 million in professional service fees primarily related to higher legal costs.

Interest, net. Net interest expense decreased by $2.1 million from $1.9 million of net interest expense for the three months ended March 31, 2006 to $0.2 million of net interest income for the three months ended March 31, 2007. The net decrease was primarily attributable to a decrease in non-cash interest expense associated with common stock warrants issued with promissory notes offset by an increase in interest income earned on our cash balances.

Income tax benefit. We recognized an income tax benefit of $42,000 and $49,000 for the three months ended March 31, 2006 and 2007, respectively. The income tax benefit arose from the amortization of the deferred tax liability attributable to the intangible asset acquired in the purchase of our wholly-owned German-based manufacturing subsidiary. A deferred tax liability was created on the date of purchase as there was no allocation of the purchase price to the intangible asset for tax purposes, and the foreign subsidiary s tax basis in the intangible asset remained zero. EITF 98-11 requires the recognition of the deferred tax impact of acquiring an asset in a transaction that is not a business combination when the amount paid exceeds the tax basis of the asset on the acquisition date. Further, EITF 98-11 requires the use of simultaneous equations to determine the assigned value of an asset and the related deferred tax liability.

Table of Contents

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 1999, our operations have never been profitable and we have an accumulated deficit of approximately $86.0 million.

We have financed our operations through sales of our preferred stock and common stock, options and warrants exercisable for our preferred and common stock, convertible and nonconvertible debt and through the initial public offering of our common stock. Since inception, we have raised $61.7 million through private equity financings, $1.5 million through the exercise of options and warrants, $28.1 million through convertible and nonconvertible debt, and $25.3 million through the initial public offering of our common stock. In November 2006, we entered into a loan and security agreement with Comerica Bank consisting of a revolving line of credit for up to $5,000,000 and a term loan for up to $5,000,000. At March 31, 2007, $9.6 million was outstanding under the loan and security agreement. As of March 31, 2007, our cash and cash equivalents were $38.3 million.

Cash Flow

Net cash used in operating activities. During the three months ended March 31, 2007, our operating activities used cash of approximately $7.7 million, compared to approximately $7.0 million for the three months ended March 31, 2006, an increase of $0.7 million. The increase in cash used was due primarily to an decrease in the net loss of approximately $1.4 million, primarily attributable to the launch of our product in the first quarter 2007, offset by $1.4 million decrease in adjustments for non-cash expenses, primarily related to non-cash interest expense and $0.7 million net increase in operating assets and liabilities primarily due to an increase in inventory and accounts receivable offset by decreased payments on accounts payable and accrued expenses.

Net cash used in investing activities. Our investing activities used cash of approximately $0.3 million during the three months ended March 31, 2007, compared to $0.8 million for the three months ended March 31, 2006. Investing activities during the three months ended March 31, 2007 and 2006 were comprised of $0.3 million and $0.7 million, respectively, of purchases of plant and production equipment and tenant improvements. During the three months ended March 31, 2006, we used cash of $0.1 million, for long-term deposits and other assets, primarily capitalized initial public offering costs.

Net cash provided by financing activities. Cash provided by financing activities was approximately $0.1 million for the three months ended March 31, 2007, compared to approximately $25.4 million for the three months ended March 31, 2006. Financing activities during the three months ended March 31, 2007 resulted in $0.4 million in proceeds from the exercise of stock options and warrants, $0.3 million in repayments on our Comerica Bank loan and security agreement, and $0.1 million in repayments on capital lease obligations and other equity related offering costs. During the three months ended March 31, 2006, our financing activities resulted in $31.8 million in proceeds from the issuance of preferred stock, $0.1 million in proceeds from the exercise of stock options, offset by $6.5 million in repayments of convertible promissory notes and repayments of our capital lease obligations.

We believe that our cash and cash equivalents at March 31, 2007, together with the interest thereon, proceeds from sales of ArteFill, and the funds available under our credit facility, will be sufficient to meet our anticipated cash requirements with respect to the commercial launch of ArteFill, the automation and scale-up of our manufacturing capabilities and our research and development activities and to meet our other anticipated cash needs through at least the first quarter of 2008. Changes in our operating plan, lower than anticipated sales, increased expenses, or other events and uncertainties, including those described in Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2006, may cause us to seek additional debt or equity financing on an accelerated basis. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could negatively impact our growth plans and our financial condition.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our exposure to interest rate risk is primarily the result of borrowings under our existing credit facility. At March 31, 2007, $9.6 million was outstanding under our credit facility.

Borrowings under our credit facility are secured by first priority security interests in substantially all of our tangible and intangible assets. Our results of operations are not materially affected by changes in market interest rates on these borrowings.

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 March 31, 2007, 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, cash equivalents and investment securities, a 1% movement in market interest rates would not have a significant impact on the total value of our cash, cash equivalents and investment securities. We do not have any holdings of derivative financial or commodity instruments, or any foreign currency denominated transactions.

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.

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 Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed in the reports that we file or furnish under the Exchange Act and were effective in ensuring that information required to be disclosed by us in the reports that we file or furnish under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting:

During the quarter ended March 31, 2007, 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.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

Sandor Litigation

In August 2005, Elizabeth Sandor, an individual residing in San Diego, California, filed a complaint against us, Drs. Gottfried Lemperle, Stefan Lemperle and Steven Cohen in the Superior Court of the State of California for the County of San Diego. The complaint, as amended, set forth various causes of action against us, including product liability, fraud, negligence and negligent misrepresentation, and alleged that Dr. Gottfried Lemperle, our co-founder, former Chief Scientific Officer and a former director, treated Ms. Sandor with Artecoll and/or ArteFill in violation of medical licensure laws, that the product was defective and unsafe because it had not received FDA approval at the time it was administered to Ms. Sandor, and that Ms. Sandor suffered adverse reactions as a result of the injections.

In addition, the complaint alleged that Dr. Gottfried Lemperle and his son, Dr. Stefan Lemperle, our co-founder, former Chief Executive Officer and a former director, falsely represented to her that the product had received an approvability letter from the FDA and was safe and without the potential for adverse reactions.

The complaint also alleged medical malpractice against Dr. Cohen, the lead investigator in our U.S. clinical trial, for negligence in treating Ms. Sandor for the adverse side effects she experienced. Ms. Sandor sought damages in an unspecified amount for pain and suffering, medical and incidental expenses, loss of earnings and earning capacity, punitive and exemplary damages, reasonable attorneys fees and costs of litigation. On June 1, 2006, the parties filed a stipulation to dismiss the case without prejudice and to toll the statute of limitations. The court dismissed the case on June 5, 2006 as stipulated by the parties, and Ms. Sandor is allowed to refile her case at any time within 18 months from that date. We have has no information with respect to whether or not Ms. Sandor will refile her case prior to that time.

FDA Investigation

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

To our knowledge, prior to, or following this inquiry, none of our current or former officers or directors had been contacted by the FDA in connection with an FDA investigation. As a result, we have no direct information from the FDA regarding the subject matter of this investigation. We believe that the investigation may relate to the facts alleged in the Sandor litigation and the matters identified in the following correspondence from the FDA. In July 2004, we received a letter from the FDA s Office of Compliance indicating that the FDA had received information suggesting that we may have improperly marketed and promoted ArteFill prior to obtaining final FDA approval. We also received a letter from the FDA s MedWatch program, the FDA s safety information and adverse event reporting program, on April 21, 2005, which included a Manufacturer and User Facility Device Experience Database, or MAUDE, report. The text of the MAUDE report contained facts similar to those alleged by the plaintiff in the Sandor litigation. In May 2006, we received the FDA s EIR for its investigation of our San Diego manufacturing facility. The EIR referenced two anonymous consumer complaints received by the FDA. The first complaint, received by the FDA in December 2003, alleges that Dr. Stefan Lemperle promoted the unapproved use of ArteFill, providing, upon request, a list of local doctors who could perform injections of ArteFill. The second complaint, received by the FDA in June 2004, alleges complications experienced by an individual who had been injected with ArteFill by Dr. Gottfried Lemperle in his home. The second complaint further alleges that Dr. Stefan Lemperle marketed unapproved use of ArteFill.

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

United States in 2004 by his father, Dr. Gottfried Lemperle.

Table of Contents

We intend to cooperate fully with any inquiries by the FDA or any other authorities regarding these and any other matters. Since initiating a call in November 2006, we have not received any communications from the FDA s Office of Criminal Investigation regarding the investigation.

As a result, we have no information regarding when any investigation may be concluded, and we are unable to predict the outcome of the foregoing matters or any other inquiry by the FDA or any other authorities. In May 2006, we terminated our consulting relationship with Dr. Gottfried Lemperle, and in November 2006, Dr. Stefan Lemperle resigned as a director and employee. Neither Dr. Stefan Lemperle nor Dr. Gottfried Lemperle provide services to us in any capacity.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described under Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2006, which we filed with the SEC on March 30, 2007, together with all other information contained or incorporated by reference in this report before you decide to invest in our common stock. The risks described in our annual report have not materially changed other than as set forth below. If any of the risks described in this report or in our annual report actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment.

On April 10, 2007, we announced that we entered into a settlement agreement with Melvin Ehrlich, who served as our president and chief operating officer from January 15, 2004 through April 5, 2004. In November 2006, we filed a demand for arbitration with the American Arbitration Association against Mr. Ehrlich seeking declaratory relief regarding the number of shares of common stock Mr. Ehrlich was entitled to purchase under a warrant he received in connection with his employment agreement. Under the settlement agreement, which became effective on April 6, 2006, we paid $250,000 in cash and issued 26,710 shares of common stock and a warrant to purchase 25,000 shares of common stock, at an exercise price of $8.07 per share. The settlement agreement contains a mutual release of claims and a mutual covenant not to sue. The shares of common stock, the warrant and the shares of common stock issuable upon exercise of the warrant are subject to lock-up restrictions that do not expire until June 17, 2007. As announced in our Annual Report on Form 10-K for the year ended December 31, 2006, we made an accrual in the fourth quarter of fiscal year 2006 based on the terms of the then proposed settlement agreement.

Based on our settlement agreement with Mr. Ehrlich, we are deleting the risk factor titled Legal proceedings with a former officer and employee could be costly and could divert our management team s attention from our business and operations contained in our Annual Report on Form 10-K for the year ended December 31, 2006.

Item 5. Other Information.

None.

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.
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.

Table of Contents

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.

4.18 (1) Warrant to purchase 28,235 shares of Series E preferred stock issued to Comerica Bank on November 27, 2006.

10.33 Settlement and Release Agreement, dated April 2, 2007, between us and Melvin Ehrlich.

31.1 Certification of Chief 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 Chief 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.

(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.

* 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.

Table of Contents

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: May 8, 2007

By: \s\ Diane S. Goostree
Diane S. Goostree
Chief Executive Officer and President

Date: May 8, 2007

By: \s\ Peter C. Wulff

Peter C. Wulff
Executive Vice President and Chief Financial Officer

23