ARTES MEDICAL INC Form DEFA14A September 12, 2008

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934 (Amendment No. 1)

Filed by the Registrant b Filed by a Party other than the Registrant o Check the appropriate box:

- o Preliminary Proxy Statement
- o Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
- o Definitive Proxy Statement
- o Definitive Additional Materials
- b Soliciting Material Pursuant to §240.14a-12

Artes Medical, Inc.

(Name of Registrant as Specified In Its Charter) (Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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ARTES MEDICAL ANNOUNCES AGENDA FOR ITS ANNUAL MEETING

SAN DIEGO, Calif., September 12, 2008 The Board of Directors of Artes Medical, Inc. (Nasdaq:ARTE), a medical aesthetics company, has made the following announcement regarding the Company s annual meeting of stockholders to be held on October 30, 2008.

Dear Stockholders of Artes Medical:

We are writing to (i) inform you regarding the action the Company is requesting its stockholders to consider and approve at the annual meeting of stockholders to be held on October 30, 2008 (the Annual Meeting), (ii) discuss and respond to a non-management preliminary proxy statement filed by H. Michael Shack, a stockholder who collectively with the other stockholders listed in his filing own approximately 1% of the Company's outstanding voting stock and to explain why the matters set forth in his filing are not eligible to be voted upon at the Annual Meeting and (iii) discuss the lawsuit the Company recently filed against two of its former officers and directors for, among other things, breach of their contractual obligations to the Company.

We remain firmly committed to promoting the Company s success and increasing the value of the Company to its stockholders. Our immediate goals are to (i) raise funds to support the Company s operations and product acquisition plans, (ii) accelerate the growth and acceptance of the Company s products among physicians and patients, (iii) expand the Company s current product portfolio to include additional new and innovative medical aesthetic products that can be cost-effectively marketed and sold through its national sales team and (iv) further leverage the Company s already established commercial infrastructure. We set forth our specific plans to achieve these goals in the Business Discussion section below.

As discussed in more detail below, we do not believe the current market value of the Company s stock reflects the true intrinsic value of the Company. We remain open and willing to consider any legitimate proposal for strategic alternatives that will maximize value for our stockholders, including potential alternatives involving a change of control or the sale of the Company. However, we believe the non-management preliminary proxy statement, apart from being legally deficient and contrary to the corporate safeguards previously approved by the Company s stockholders, has been supported by two former officers and directors of the Company, Stefan Lemperle and Gottfried Lemperle (collectively, the Lemperles), in an attempt to establish their control over the Company without paying the Company s stockholders an adequate and fair acquisition price or a control premium.

The Company s Annual Meeting

The Annual Meeting will be held on October 30, 2008 at 10:00 a.m. (Pacific Time) at the San Diego Marriott Del Mar, located at 11966 El Camino Real, San Diego, California 92130.

Election of Directors. At the Annual Meeting, the Company will ask its stockholders to consider and approve the election of Christopher J. Reinhard and John R. Costantino as Class II directors to serve for three (3) year terms until the annual meeting of stockholders in 2011 and until their successors are duly elected and qualified.

Mr. Reinhard has been the Company s Executive Chairman since June 2004. He was asked to join the Company by several of the Company s stockholders at a time when the Company was a private six employee company with no products approved by the FDA for marketing or sale and no manufacturing operations. Since December 2004, Mr. Reinhard has also served as Chairman of the Board and CEO of Cardium Therapeutics, Inc., a publicly-traded medical technology company. Prior to that (from July 2002 to December 2004), Mr. Reinhard served as Chief Executive Officer of Collateral Therapeutics, Inc., another publicly-traded biotechnology company. Mr. Reinhard worked for Collateral Therapeutics in a variety of roles (including Chief Financial Officer and President) from June 1995 to July 2002, when Collateral Therapeutics, Inc. was acquired by Schering AG. Mr. Reinhard holds a B.S. in finance and an M.B.A. from Babson College.

Mr. Costantino has been a director of Artes Medical since June 2006. Beginning in January 2006, Mr. Costantino has also served as Managing General Partner of NGN Capital LLC, a venture capital advisory firm focusing on the healthcare and biotechnology industries. In addition, Mr. Costantino has served as Vice President of Walden Capital Partners since 1994, and has been a Managing Director at Walden Partners Ltd., a merchant bank providing consulting and investing services, since 1992. Mr. Costantino also serves on the Board of Directors of GE Funds, GE Investment Funds, Inc., GE Institutional Funds and GE LifeStyle Funds, all management investment companies. Mr. Costantino holds a B.S. from Fordham University, a J.D. from Fordham Law School, and is a Certified Public Accountant.

Non-Management Proposals

On August 11, 2008, H. Michael Shack, who collectively with the other stockholders named in his filing own approximately 1% of the Company s outstanding voting stock, filed a preliminary proxy statement stating that, at the Company s Annual Meeting, he intends to submit proposals to: (i) amend the Company s Bylaws to fill vacancies on the Company s Board of Directors, (ii) remove for cause three (3) of the Company s current directors and (iii) elect five (5) of his nominees to the Board. As outlined in a recent lawsuit filed in San Diego Superior Court and discussed below, the Company is informed and believes that the Shack filing was instigated and is supported by the Lemperles in violation of, among other things, their contractual obligations to the Company.

The Investor Group s **Proposals are Legally Deficient.** The investor group s proposals are deficient in that they did not provide the Company with notice of the proposals as required by Article II, Section 2.1 of the Company s Bylaws. Further, the Company believes, and has received a written opinion from Abrams & Laster LLP, the Company s special Delaware counsel, that the investor group s proposals do not comply with the substantive and procedural requirements of Section 141(k) of the Delaware General Corporation Law.

The Claims Made in Investor Group s Preliminary Proxy Statement are Inaccurate. Apart from being legally deficient, most, if not all, of the assertions made in the investor group s preliminary proxy statement are inaccurate. The investor group s assertions distort the factual record of the Company s existing management as set forth in detail below.

Further, we do not believe that the investor group s proposals are in the best interests of the Company s stockholders, and for the reasons stated above, the Company does not intend to have the investor group s proposals brought before the Annual Meeting. In short, the investor group s proposals seeks to circumvent the orderly process required in the Company s stockholder-approved Bylaws and Certificate of Incorporation. We urge you to discard any proxy card that you may receive regarding the investor group s proposals. Nevertheless, we remain open to any proposal involving a strategic alternative that would maximize value for our stockholders, including a potential change of control transaction, and we encourage the investor group (and the Lemperles) to consider this course of action if they wish to obtain control over the direction of the Company.

The Lemperle Lawsuit

On August 29, 2008, the Company filed suit in San Diego Superior Court against Stefan Lemperle and Gottried Lemperle for, among other things, breach of contract, fraudulent inducement and intentional and negligent interference with prospective economic advantage relating to their attempts to interfere with the Company s management and operations. The lawsuit seeks both compensatory and punitive damages, as well as injunctive relief.

In sum, the lawsuit alleges that the Lemperles were separated from the Company in 2006, and were provided substantial severance packages in exchange for their complete disassociation from the Company, and their agreement to refrain from interfering with the Company s business. Stefan Lemperle s separation agreement specifically prohibits him from encouraging stockholders to challenge management or decisions of the Company s Board of Directors through November 2009 or from otherwise interfering with the Company's affairs. However, the Company believes that neither Stefan nor Gottfried Lemperle intended to comply with the terms of their separation agreements, and that despite their contractual obligations to the Company, the Lemperles conspired to undermine the Company s management and to take control of the Company as evidenced by investor group s proposals seeking to replace a majority of the Company s current directors with individuals hand-picked by the Lemperles (the Lemperle Nominees). For example, Terry Knapp and Charles A. Schliebs, both Lemperle Nominees, were recommended to be directors on the Company s Board by Stefan Lemperle in June 2006. Similarly, Barry Vogel and Robert Binkele (both Lemperle Nominees) have close ties with and were introduced to the Company by Stefan Lemperle and a former officer of the Company, respectively. Further, the lawsuit alleges that and the Company believes that the Lemperles shared confidential or proprietary information about the Company, and that they communicated this confidential or proprietary information to other stockholders of the Company, including Shack and/or the Lemperle Nominees in violation of the terms of their separation and confidentiality agreements with the Company.

Business Discussion

As stated in our recent Annual Report, 2007 was a year of accomplishment and challenge for the Company. The Company launched its flagship product, ArteFill®, into the United States aesthetics market, making it the first and only FDA-approved non-resorbable dermal filler for the treatment of smile lines. The Company also established a nationwide network of more than 1,200 dermatologists, plastic surgeons and cosmetic surgeons who have received training in the proper use of ArteFill so that it has become available to a growing number of patients throughout the United States.

On the other hand, the overall level of ArteFill product sales for 2007 did not measure up to our expectations and the product s inherent potential. We have taken a hard look at the Company s initial launch strategy and have initiated changes in the way we market ArteFill in order to capitalize more fully on ArteFill s competitive advantages.

Our immediate goals are to (i) raise funds to support the Company s operations and product acquisition plans, (ii) accelerate the growth and acceptance of the Company s products among physicians and patients, (iii) expand the Company s current product portfolio to include additional new and innovative medical aesthetic products that can be cost-effectively marketed and sold through its national sales team and (iv) further leverage the Company s already established commercial infrastructure.

Financing. As discussed in our public filings, we intend to raise additional funds to support the Company s operations and business plan discussed in more detail below. The Company recently received a notice from The Nasdaq Stock Market (Nasdaq) indicating that its stockholders equity at June 30, 2008 was less than the \$10 million in stockholders equity required for continued listing on The Nasdaq Global Market. The Company submitted a plan to Nasdaq addressing how it plans to achieve and sustain compliance with Nasdaq s continued listing requirements. A central part of this plan is to complete one or more financing transactions as soon as practical to raise funds to increase the Company s stockholders equity to the levels required to maintain its Nasdaq listing.

Commercial Experience. Our market research tells us that patients are searching for a safe, effective and long-lasting solution to wrinkle correction. Even as the industry continues to build around the use of temporary dermal filler products, the high patient attrition rate among temporary dermal filler patients due to credit card fatigue and injection fatigue is real and not going away anytime soon. Our market research further shows that today s women lead busy and active lives, and many want a safe and truly effective long-lasting wrinkle solution. We believe that ArteFill is uniquely positioned to address this opportunity as the only FDA-approved non-resorbable dermal filler.

We are receiving positive feedback from physicians and patients who have experienced ArteFill since launch in February 2007. Physicians continue to report strong results relating to smile line correction and patient satisfaction, with no serious adverse events reported. With over 10,000 patients now treated since ArteFill s launch, we have established an excellent safety and efficacy record that is further supported by a 5-year safety and efficacy study published in the peer-reviewed journal Dermatologic Surgery.

Physician Development Initiatives. Since market launch, the Company has trained more than 1,200 dermatologists, plastic surgeons, and cosmetic surgeons on the use of ArteFill, and it is the Company s goal to have 1,800 physicians trained by year-end 2008. We continue to focus on those physicians experienced in the field of aesthetic medicine. We are convinced that we need to continue to build this important base of physician acceptance so that, as our sales effort and consumer initiatives begin to converge, we can translate this into stockholder value.

During 2007, we built a robust practice development program designed to assist physicians in educating patients and treating them with ArteFill. We will also be initiating follow-on patient incentive programs operating in concert with physician-driven initiatives. We have seen strong interest among physicians to participate in our programs, which include other sales incentives, coupons and specialized discount programs. In addition, since FDA approval, ArteFill has been included in many leading dermatology and plastic surgery medical conferences showcasing the benefits of the product safety, long-term efficacy and differences among various dermal filler products.

Larger and More Experienced Direct Sales Force. Following our market launch last year, it became clear that even as we rapidly added physicians, the Company needed a larger and more experienced sales force to provide a persistent presence at the physician level. As a result, the Company has more than doubled the size of its sales force while substantially increasing its consumer awareness programs. The Company s sales team now includes 42 sales representatives, the majority of whom have extensive prior experience selling other competitive dermal fillers, medical device products and aesthetic products directly into our target market physician base.

Direct-to-Consumer Marketing Efforts. The Company has also accelerated its consumer outreach efforts, including national print advertising campaigns in major women s beauty magazines, robust Internet marketing programs and other consumer initiatives. Because of these activities, we have seen visits to the Company s websites more than double in first quarter 2008 compared to fourth quarter 2007. We believe that this demonstrates an accelerating consumer interest in ArteFill. Further, while the Company clearly must continue to focus on physician-centric marketing initiatives and education, direct-to-consumer marketing activities have become a way of life and physicians now expect all dermal filler companies to stimulate consumer interest through outreach programs.

Continuing Research and Safety Studies. As previously announced, the Company s 1,000-patient long-term safety study was initiated in late 2007. Patient interest has been extremely strong in this study, and enrollment has been rapid. The Company produces a highly purified and partially denatured collagen in its product, and we believe that this purity substantially reduces the risk of allergic reactions to the bovine gel component of ArteFill. The Company has initiated a skin test removal study, and during the first quarter of 2008, almost 500 patients were skin tested to participate in this study. In total, approximately 700 patients have now been recruited to participate in the study. When completed, we believe that this will represent another landmark study in the dermal filler field based on the number of patients participating and the length of the study period. We expect to have results by early 2009 and, with supporting clinical data, the Company intends to seek regulatory approval to eliminate the skin test requirement which we believe will further accelerate the market acceptance of ArteFill on a going forward basis.

Competitive Positioning. Over the past year, product offerings in the dermal filler market have increased and we expect a steady flow of non-differentiated hyaluronic acid-based and porcine-based temporary dermal filler products to enter the market this year and next. As a result, we anticipate continued price pressure in the temporary filler space. Based on information in FDA approved product labeling, virtually all of the current and planned temporary dermal filler products offer efficacy ranging from as little as three months to perhaps up to twelve months. As a result, we believe that ArteFill will remain highly differentiated from these competitor products as the first and only FDA-approved non-resorbable injectable wrinkle filler, and we expect to retain the Company s premium pricing and market positioning. We believe that there is no other dermal filler product like ArteFill that (i) offers physicians with a more significant revenue opportunity during a 30-minute procedure, and (ii) provides patients with such long-lasting results. These simple facts, coupled with our continuing effort and focus, are what keep all of us at the Company excited.

Recent Developments

Since the end of 2007, we have initiated a number of actions to improve the Company s operations and increase the Company s value to its stockholders.

Record Second Quarter Results. The Company reported record ArteFill revenues of \$3.2 million for the quarter ended June 30, 2008, an increase of \$1.1 million or 52% over ArteFill revenues of \$2.1 million from the quarter ended June 30, 2007 and a 91% increase in ArteFill revenues from the first quarter ended March 31, 2008. The growth in ArteFill sales in the second quarter of 2008 reflects the positive impact of the Company s expanded team of sales representatives and its new consumer outreach programs.

Elevess Distribution Agreement and Rapid Product Launch. Consistent with its business strategy, in July 2008, the Company announced a distribution agreement with Anika Therapeutics Inc. covering its marketing and sale of Elevess , a new FDA-approved hyaluronic acid based dermal filler. The Company initiated its Elevess product launch in September 2008. Elevess is ideal for patients seeking immediate, comfortable, temporary wrinkle correction lasting six months or more. ArteFill is the only FDA-approved, non-resorbable treatment of choice for patients desiring long-lasting results. In addition to the use of Elevess as a stand alone product, we believe both products are complementary, in that they may be bundled for sequential use that allows Elevess to be used as a temporary solution during the ArteFill skin test waiting period, followed by an ArteFill long-lasting treatment. Based on this, the Company has introduced marketing programs that provide favorable economic incentives for both physicians and patients who choose to purchase both ArteFill and Elevess for use in their medical practices. With these products in its portfolio, the Company is now uniquely positioned to deliver a full spectrum of wrinkle treatments for the growing facial aesthetics market.

Cost Reduction Plan. Earlier this year, the Company instituted a plan to significantly reduce certain administrative and operating costs in order to realign its overall cost structure to its current revenue projections. We believe that the cuts made will help streamline the business and reduce overall costs, resulting in a stronger business model (focusing more sharply on growing and developing the market for ArteFill) and increasing overall stockholder value.

Strengthened Board and Management Team. In an effort to establish a stronger Board and management team and to allow the Company to adjust to the ever-changing economic and competitive landscapes, we recently announced important changes to the Company s management team and the reorganization of management responsibilities. We are very pleased Michael Green has joined us as our Chief Financial Officer (CFO). Michael has extensive experience as a public company CFO, experience in capital raising and product and company acquisitions, was an auditor for Price Waterhouse for 13 years, and is a CPA. Michael is a great addition to our team and we are looking forward to his contributions as move forward. We have also added two new directors, Todd Davis and Douglas Abel. Todd has extensive healthcare operating experience, having worked in business development and general management at Elan Pharmaceuticals and in sales and marketing at Abbott Laboratories. Douglas brings extensive experience to the Company in the aesthetics and medical device fields. In addition, we are actively engaged in a search for a qualified Chief Executive Officer to lead the Company into the next phase of the commercialization of ArteFill. We believe these changes will enhance value to the Company s stockholders and support the Company s efforts to produce medical device products that benefit both patients and physicians.

Stockholders Rights Plan. We believe the current market value of the Company's stock does not reflect the Company's intrinsic economic value. As such, in May 2008, we adopted a stockholders' rights plan to help protect the Company and its stockholders from coercive takeover tactics. The adoption of the plan is intended to facilitate negotiations with potential third party acquirers, more fully ensure a fair and orderly process and guard against a takeover by a third party on terms that would not be fair to or in the best interests of the Company's stockholders by taking advantage of the Company's current, inadequate stock price. A committee of independent directors of the Board will assess whether the plan remains in the best interests of the Company and its stockholders at least every three years and may, at its discretion, make this assessment more frequently.

CHRP Financing. In February 2008, the Company completed a financing arrangement with Cowen Healthcare Royalty Partners, L.P. (CHRP) in which it raised \$21.5 million. The Company used the proceeds from this financing to expand its dedicated U.S. sales force and consumer outreach programs, as well as to repay its existing debt. As part of the financing, the Company granted CHRP a royalty interest in sales of its products, as well as a secured promissory note. The Company also issued CHRP two warrants, one to purchase 1,300,000 shares at \$5.00 per share and another to purchase 375,000 shares at \$3.13 per share. These warrant shares, if fully exercised, represent significantly less than 10% of the Company s outstanding capitalization. As a result, the Company used its tangible and intangible assets to secure \$21.5 million through this financing arrangement, and minimized the potential dilutive effect to its stockholders.

Conclusion

In closing, we remain firmly committed to promoting the Company s growth and overall progress. We, the Board of Directors, have taken direct action to systematically understand the issues that face the Company and have initiated positive and affirmative actions intended to successfully advance ArteFill and Elevess in the market and to enhance long-term stockholder value.

With our increased sales force, our balanced marketing and promotional consumer initiatives, our increased practice development activities and our clinical studies, we believe ArteFill has the potential to establish a very important market niche in which patient satisfaction supports our premium pricing and allows us to generate an attractive revenue stream with a relatively modest niche market share. Although we feel that our successes are not yet represented in the Company s stock price, we firmly believe that the decisions we have made will move the Company forward and are in the best interests of the Company and its stockholders.

For the reasons set forth above, we do not believe that the assertions or the requested actions contained in the investor group s preliminary proxy statement are serious, justified or necessary. Further, we believe that the investor group s proposals seek to circumvent the orderly process required in the Company s stockholder-approved Bylaws and Certificate of Incorporation. We remain open to any proposal involving a strategic alternative that would maximize value for our stockholders, including a potential change of control transaction, and we encourage Shack, the Lemperles and others to consider this course of action if they wish to obtain control over the direction of the Company.

We encourage you to participate in the Company s Annual Meeting and vote your proxy in accordance with the recommendations of the Company s Board of Directors and management. Thank you again for your continued support of the Company.

Most sincerely,

Christopher J. Reinhard

Executive Chairman of the Board of Directors

Forward-Looking Statements

This letter to stockholders contains forward-looking statements that are based on the Company s current beliefs and assumptions and on information currently available to its management and Board of Directors. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. As a result of these risks, uncertainties and other factors, which include the Company s history of net losses, its ability to timely raise additional funds to support its operations and future product acquisition plans, its ability to manage its operating expenses, its reliance on sales of ArteFill and Elevess, its future receipt of FDA approval to extend the efficacy period of ArteFill beyond six months and eliminate the skin test requirement, and the risk that the Company s revenue projections may prove incorrect because of unexpected difficulty in generating sales and market acceptance of ArteFill and Elevess, readers are cautioned not to place undue reliance on any forward-looking statements included in this letter to stockholders. A more extensive set of risks and uncertainties is set forth in the Company s SEC filings available at www.sec.gov. These forward-looking statements represent beliefs and assumptions only as of the date of this letter, and the Company assumes no obligation to update these forward-looking statements publicly, even if new information becomes available in the future.

Important Additional Information

On September 12, 2008, the Company filed an amended preliminary proxy statement with the Securities and Exchange Commission (the SEC) in connection with the solicitation of proxies for its 2008 annual meeting of stockholders and will mail the definitive proxy statement (the Proxy Statement) to stockholders prior to the annual stockholders meeting. The Proxy Statement contains important information about the Company and the annual meeting. The Company s stockholders are urged to read the Proxy Statement carefully. Stockholders will be able to obtain copies of the Company s 2008 Proxy Statement and other documents filed by the Company with the SEC in connection with its 2008 annual meeting of stockholders at the SEC s website at www.sec.go or at the Investor Relations section of the Company s website at www.sec.go or at the Investor Relations section of the Company s website at www.sec.go or at the Investor Relations section of the Company s website at www.sec.go or at the Investor Relations section of the Company s website at www.sec.go or at the Investor Relations section of the Company s website at www.sec.go or at the Investor Relations section of the Company s website at www.sec.go or at the Investor Relations section of the Company s website at www.sec.go or at the Investor Relations section of the Company s website at www.sec.go or at the Investor Relations section of the Company s website at www.sec.go or at the Investor Relations and its executive officers are deemed participants in the solicitation of proxies from stockholders in connection with the Company s websites referenced above are not deemed to be incorporated by reference into the Proxy Statement.

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