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Milestone Medical Inc. Provides Second Quarter 2015 Business Update

*Reports Continued Progress on U.S. FDA Marketing Clearance and Epidural Instrument Clinical Trials;
Distribution Agreement in Italy;
Commencement of First Epidural Shipments;
Memorandum of Understanding for Co-Development and Manufacture of Intra-Articular Drug Delivery
Instrument in Italy*

LIVINGSTON, NJ, September 3, 2015 -- Milestone Medical Inc. (WAR: MMD), today provided a business update for the second quarter ended June 30, 2015.

Leonard Osser, Chief Executive Officer of Milestone Medical, stated, “We remain focused on the commercial rollout of our epidural and intra-articular instruments as our top priority in 2015. Specifically, we are continuing our efforts to identify and meet with distributors in a number of countries in Europe and have made progress. In June, we entered into our second exclusive distribution agreement for the sale of our epidural instruments in Italy with Moss S.P.A, one of the leading distributors of diagnostic and specialty surgery equipment in Italy. The fact that this agreement includes 3 year guaranteed minimums reinforces their confidence in the market potential of our instrument. In June, we also commenced our first shipments and sales of the epidural instrument to Trimed Sp. Z.o.o, one of the largest distributors of diagnostic equipment in Poland, which purchased a small number of instruments for internal use and training purposes as it ramps up for a formal launch later this year. Introducing our instruments initially to key opinion leaders in Poland and other European markets provides important independent validation regarding the instrument’s efficacy and will help drive market adoption. In May, we signed a Memorandum of Understanding with Fidia Farmaceutici SpA, a specialty pharmaceutical company based in Italy, for the co-development and manufacture of a custom intra-articular drug delivery instrument for Fidia’s hyaluronic acid formulations. Fidia is one of the leading global manufacturers of hyaluronic acid formulations for joint pains.”

Mr. Osser commented, “We are also making progress advancing our medical instruments through the FDA regulatory process. We are moving forward with U.S clinical trials of our epidural instrument at several premier sites in the U.S. Recently, we announced successful results of the interim analysis of the COMPASS Study (CompuFlo® Assessment Study). The analysis demonstrated that the instrument correctly identified the epidural space location and clearly achieved the goal set by the FDA IDE Investigational Plan. To date, over 200 participants have completed the clinical trial procedures and our goal is to enroll up to 400 patients at five separate sites. We expect the clinical trial and accompanying statistical analysis to be completed this year, at which time we will return to the FDA for final marketing clearance. We anticipate that the additional validation from the U.S. clinical trials will also help accelerate the commercial launch of our medical instruments in Europe.”

“At the same time, we are broadening our U.S. distribution strategy beyond the current focus on labor and delivery markets to include a network of regional distribution partners whose strengths include hospitals, clinics and pain management centers. The U.S. epidural market is estimated at over \$7 billion annually and in Europe the addressable

market for epidurals is estimated to be even larger. Meanwhile, we continue to advance the intra-articular instrument through the FDA review process; however it is hard to accurately predict the exact timing as the regulatory process is outside of our control.”

Mr. Osser added, “We remain focused on uplisting from the NewConnect Market to the Main Market of the Warsaw Stock Exchange and the planned public offering of our shares. We believe transitioning to the Main Market will help increase awareness and expand the audience of potential investors in the company. We are in the final stages of regulatory approval of our Prospectus which funds will be used for the continued expansion of our sales and marketing initiatives, as well as additional working capital to accelerate the launch of our epidural and intra-articular instruments in Europe. At the same time, Milestone Medical is pursuing grants in Europe, which would help us to expand both our production as well as our R&D capabilities in Europe.”

Mr. Osser concluded, “Despite the fact that we reported first revenues, Milestone Medical is still in the development stage as we prepare for full commercial rollout of our medical instruments. We continue to carefully manage our expenses, which are mainly attributable to regulatory approval, pursuing new distribution partners and marketing of our medical instruments. We believe the \$2.0 million line of credit provided by Milestone Scientific reinforces the confidence in our strategy, and should provide us sufficient capital to finalize the FDA regulatory approval process.”

Conference Call

Milestone Medical’s executive management team will host a conference call at 3:00 p.m. Central European Time (9:00 a.m. Eastern Time), on Thursday, September 3, 2015. The conference call can be accessed via a live Internet webcast on the Company’s website at www.medicalmilestone.com. A webcast replay of the conference call will be accessible on the Company’s website at www.medicalmilestone.com for 90 days.

About Milestone Medical Inc.

Milestone Medical, Inc. has developed epidural and intra-articular drug delivery systems based on a patented, painless, computer-controlled injection and drug delivery technology originally developed by Milestone Scientific, Inc. Development of both the epidural and intra-articular instruments is now complete and the Company is currently pursuing regulatory approval for both instruments in the U.S. Milestone Medical received CE Mark approval to sell and market its intra-articular and epidural instruments across European Union. For more information please visit www.medicalmilestone.com.

Safe Harbor Statement

This press release contains forward-looking statements regarding the timing and financial impact of Milestone’s ability to implement its business plan, expected revenues and future success. These statements involve a number of risks and uncertainties and are based on assumptions involving judgments with respect to future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond Milestone’s control. Some of the important factors that could cause actual results to differ materially from those indicated by the forward-looking statements are general economic conditions, failure to achieve expected revenue growth, changes in our operating expenses, adverse patent rulings, FDA or legal developments, competitive pressures, changes in customer and market requirements and standards, and the risk factors detailed from time to time in Milestone’s periodic filings with the Securities and Exchange Commission. The forward looking-statements in this press release are based upon management’s reasonable belief as of the date hereof. Milestone undertakes no obligation to revise or update publicly any forward-looking statements for any reason.