February 25, 2014

Subject: Action to ensure sustainability and continuity of supply of MAA and DTPA

Dear Healthcare Professional and Nuclear Medicine Partner,

Jubilant DraxImage has determined that a onetime market price adjustment on MAA and DTPA is required. This market–wide pricing adjustment will take effect on March 1st 2014 to support ongoing sustainability and continuity of these critical products in the US.

As you are aware, in recent years, the entire nuclear medicine industry has faced ongoing supply issues for radiopharmaceuticals and ancillary medications. A number of manufacturers have left the market or ceased to manufacture some products. The challenge of maintaining a sustained and reliable supply of these critically important products has had an adverse impact on both healthcare providers and their patients, while innovation is no longer at the past high levels.

Jubilant DraxImage (JDI) is committed to the field of nuclear medicine and recognizes its role and responsibility in supplying critical products to healthcare providers even if in many instances all other manufacturers have abandoned such critical products.

We will invest significantly in our manufacturing facility and process improvement. We plan to qualify and maintain a second API supplier and a second manufacturing site to ensure the long-term supply of MAA and DTPA kits in the United States and to help educate, with your help, the medical community on the value of V/Q scans. We have undertaken a major manufacturing process improvement initiative and have begun discussions with the SNMMI Leadership on the best clinical research approach to support improved management of patients with lung disease or pulmonary embolism. We are committed to supporting medical education and clinical research in this area and will allocate dedicated corporate resources to support the clinical development of these products.
This onetime market adjustment will enable JDI to continue to supply and to fulfill its investment promise. The historically low prices did not cover the costs of manufacture - a manufacturing process that is complex and difficult in the past has become even more costly with process and automation improvements. Furthermore, increasing regulatory requirements have continued and these increased regulatory requirements impact our production of our MAA and DTPA kits, which in time result in further, dramatically increased costs.

As you and your members understand, MAA is a critical component of the hundreds of thousands of lung imaging procedures performed across the United States every year. Due to the clinical utility and overall effectiveness of this important product, MAA is unique and essential for V/Q imaging. As you know, in a V/Q scan, the ventilation portion is also essential. Xe-133, the current US approved gold standard for ventilation imaging, represents 20% of the CMS reimbursement for V/Q scan compared to MAA representing only 1%. At a minimum, we believe that MAA reimbursement value is at least comparable to Xe-133. Although both perfusion and ventilation information is optimally required, perfusion is at the center of the V/Q's evaluation of pulmonary embolus detection.

At current utilization levels, the value received by JDI for the MAA represents an extremely small portion of the reimbursement for a lung perfusion and ventilation procedure. The total Medicare HOPPS reimbursement to a hospital in 2014 is $430.87. At current vial utilization and pricing levels in the US, the value JDI receives for the MAA is approximately $4.00, less than 1% of the total reimbursement for the procedure.

The ongoing manufacture of MAA and DTPA kits continue to be the highest priority in our production schedule and our operational teams at JDI have been working diligently toward the goal of a stable, commercial supply. We are committed to making significant investment to assure product sustainability including qualifying and maintaining a second API supplier and manufacturing site. We are also interested in educating the medical community about the advantages of V/Q scanning over CT and support the appropriate use of both CT and V/Q scans.

As an important resource for the nuclear medicine community, we wanted to inform you of this decision to allow you to ask any questions important to your membership.

Please don’t hesitate to contact me to discuss further at sbissonnette@jdi.jubl.com.

Sincerely,

Suzanne Bissonnette, Director, Marketing