## MetastaticPrecision - Rapid Diagnostic Test for Canine Lymphoma

Kelsey Collins<sup>1</sup>, Scott Taylor<sup>2</sup>, Karen J.L. Burg<sup>1</sup>

<sup>1</sup>Department of Small Animal Medicine & Surgery, University of Georgia and <sup>2</sup>Poly-Med, Inc.

Team Name: Team MetastaticPrecision (MP) comprises CEO Kelsey Collins, Scientific Advisor Karen Burg, and Industry Mentor Scott Taylor. Kelsey is a Small Animal Medicine and Surgery (SAMS) researcher at the University of Georgia (UGA) with a bachelor's degree in Animal Science. Kelsey's background includes animal health and wellness; she worked as a veterinary assistant in both clinical and research settings for 7 years. Karen is a UGA faculty member and SAMS tissue engineer, with 7 years administrative experience in facilitating university technology translation. Scott is the Chief Technology Officer at Poly-Med, Inc. and has over 19 years of small business experience in medical device technology development, product development, and commercialization, with particular expertise in fiber-based technologies and novel medical devices.

The Technology: The MP technology provides a rapid inoffice cancer diagnosis (lymphoma) to veterinary staff, with minimal training. This is accomplished with a novel, patented test kit and cell cytometer and reduces diagnosis time from days to minutes using only a biological sample collected from a minimally invasive fine-needle aspirate of a lymph node or mass. The cell cytometer is a benchtop device that is used externally to the patient. The technology is based on unique fibers that have non-circular crosssections, creating channels along their lengths. The fibers' enhanced wicking capabilities allow a heterogeneous cell sample to move and self-distribute along its lengths. This amounts to a chromatography-like approach to the classification of cells. Since malignant cells have different physical characteristics from those of benign cells, cells will self-distribute at specific distances along the fibers or in the end cap, according to cell size, cell compliance, presence of adhesion molecules, and surface charge.<sup>4</sup> This results in the isolation of cancer cells at specific points on the fibers. Based on the distance the cells travel along the fiber, any veterinary technical staff member will be able to quickly look at the device and know a definitive answer of whether there is cancer present-regardless of their level of expertise. The immediate advancement potential is in disease monitoring; however, the long-term goal is to provide an earlier diagnostic for disease prevention. The technology is captured in US Patent 9,849,452 B2 (to the University of Georgia).

The Market: Lymphoma, a cancer of the lymph nodes accounting for 15-20% of cancer diagnosis in dogs, is the most common form of cancer in dogs. Dogs are 2-5 times more likely to develop lymphoma than are humans. Hemangiosarcoma is the second most common form of cancer in dogs and often goes unnoticed until very late stage. After conducting over one hundred interviews with various target customers and assessing demand and clientele, we have concluded that the target market for this product is small animal veterinarians in both urban and suburban regions of the US. The Total Available Market (TAM) for animal diagnostics is \$47.9 billion dollars and the

Serviceable Available Market (SAM) for cancer diagnostics for animals is \$3.1 billion dollars. The market size for cancer diagnostics for all companion animals is about \$875 million, and the market for canine diagnostics (Target Market) is approximately \$184 million.<sup>6</sup> While these numbers are based on cancer as a whole, we intend to focus on lymphoma and potentially hemangiosarcoma. Cancer diagnostics and research is a rapidly growing area among veterinary diagnostic manufacturers, and it is predicted that the future for this market will grow at an annual rate of 6.4%.<sup>7</sup>

Commercialization Strategy: Since veterinary diagnostics of this type do not require approval or clearance by the US Food and Drug Administration, we will thoroughly test the product through a soft launch of the minimum viable product in the next 1-2 years. Veterinarians will have the chance to use the product and provide their feedback; we will thus gather information on the specificity and effectiveness of the cytometer. Once the product has been validated for accuracy and specificity, e.g. in the next 4-5 years, we will seek partnership with a private veterinary manufacturing company. The cytometer will be sold as a testing kit, through a distributor. We estimate the product will be packaged in a box of 10 for \$250. The cost to market this product at conferences (~\$30,000), in journals (~\$11,000), veterinary newsletters (~\$3,000), as well as customer education with experts in this area (~\$8,000) is estimated to be around \$52,000 for the first year. An estimated 55,000 out of 75,000 US veterinarians work solely with small animals, if 55,000 veterinarians adopt our product and run an average of three tests per week, at \$25 per test (sold in a box of 10 for a price of \$250), each veterinarian will spend about \$6,000 a year on our product. The value for this product in the first five years will be ~\$1.65 billion dollars.

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