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MicroMedicine, Inc. is using Microfluidics Technology to Revolutionize Cell Isolation with an Automated, Precise, and High-Performance Solution providing more Target Cells Available for the Downstream Clinical Diagnostic Tests and Cell Therapy

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"MicroMedicine's technology provides an automated, precise, and high-performance solution for cell isolation. The math is simple - the more cells isolated from whole blood with high purity, the more target cells available for the downstream clinical diagnostic tests and cell therapy. MicroMedicine alleviates the stress of cell isolation and maximizes the cells of interest."
- Ravi Kapur, PhD.

CEOCFO: ***Dr. Kapur, what is the idea behind MicroMedicine?***
Dr. Kapur: The company's roots began at Massachusetts General Hospital, where the three founders, Mehmet Toner, PhD, Ronald Tompkins, MD, ScD and I, focused on developing better tools to isolate cells from blood. Precise and reliable cell isolation from whole blood is critical for diagnostic testing and therapies. Furthermore, therapies that require the patient's own cells (autologous cells) to be manipulated in the laboratory prior to reinfusion for therapeutic or theranostics rely on precise and high-performing cell isolation for success. Unfortunately, the technologies available for sorting cells from blood are quite archaic. They are fifty to one hundred years-old and rely on centrifuges and reagents to isolate the cells of interest. The field was demanding a better tool.

CEOCFO: ***Is it for lack of trying that there are no new methods or did people just think what was going on was ok? Why has it not changed?***
Dr. Kapur: The traditional issue with clinical medicine is that practitioners want to use off-the-shelf tools because they're fast and easy. However, many of the cell separation technologies used today were developed for different applications and are not optimal for isolating large quantities of valuable cells while maintaining cell viability and functionality. While the field has heavily invested in innovation in downstream analysis, such as next gen-sequencing and other analytical technologies, few resources have focused on the upstream sample preparation to extract the target cells reliably.

CEOCFO: ***Was it a slow process or was there an epiphany one day about which way to go?***
Dr. Kapur: Never an epiphany! We have been working on this for the past 15 years. We focused on the challenge of cell isolation and were

completely agnostic about the 'how'. We started by conducting an extensive engineering analysis to determine the 'how'. What we have developed and what we have utilized over the past fifteen years is a technology platform called microfluidics. It is completely counterintuitive because microfluidics was conceived twenty years ago to enable processing of very small volumes of fluid (microliters to nanoliters) through microchannels with high precision to enable analytics. We did not invent microfluidics, but we leverage its exquisite ability to control particles (i.e., cells) flowing in a fluid (blood). The ability to affect and address every cell individually using the principles and physics of microfluidic flow was the differentiator from the existing bulk processing approach for cell separation. The challenge was the perceived limitation of processing small volumes with microfluidic channels. Our science, design, inventions, and innovation focused on transforming microfluidic devices to process very large volumes of clinically relevant material to enable precise, gentle and high quality cell separation.

CEOCFO: ***How do you do that today?***
Dr. Kapur: The technology uses something called inertial lift. Fundamentally, particles in laminar flow do not change streamlines but if you flow them fast enough and if the particles are just the right size for the channel that they are in, they will switch streamlines and get into a singular focus. We observed this phenomenon in microfluidic channels in the Massachusetts General Hospital laboratory about a decade ago and have since published extensively in peer-reviewed journals. We utilize the differential inertial lift force between the small particles (enucleated red blood cells and platelets) and the large particles (immune cells and other circulating non-hematopoietic nucleated cells) to separate the cells of interest. The trick here is to use microfluidic channels to isolate the millions of cells which are of interest for downstream diagnostics and therapy, from the billions of red blood cells and platelets in a continuous fashion from very large blood volumes. To give you a frame of reference, our device sorts particles at 200 million particles per second. If everybody on planet earth was a cell, 7.2 billion of us would be through that chip in thirty six seconds and those that are smaller would show up in one bin and those that are larger would show up in another bin.

CEOCFO: ***How many different cells are in the blood that you are looking at?***
Dr. Kapur: There are three key populations in blood. The largest population is the red blood cells which carry the oxygen. When you go to the hospital and give a tube of blood, there are 50 billion red blood cells in the 10 ml tube. Then you have another population called platelets and their job is to make your blood clot. For example, when you get a cut, the reason you do not bleed out is because platelets form a mesh to seal up the spot. There are about 3 billion platelets in a tube of blood. Finally, in that same tube of blood there are about 50 million immune cells of interest. We aim to isolate these 50 million cells from a background of >50 billion cells.

CEOCFO: ***Would you tell us about the cell isolator, the size and capacity?***
Dr. Kapur: We are currently in product development, but many of the features are set. The physical footprint for the product will be approximately 20" in all 3 dimensions, which means it can easily fit on a lab bench. 50 ml of whole blood is processed in only 20 minutes, a significant reduction to the 60+ minutes required today. Lastly, minimal

training is required to operate the device due to the high-level of automation and step-by-step guide on the user interface.

CEOCFO: ***Would this be applicable for any blood test?***
Dr. Kapur: This is upstream sample processing so anyone who sorts out populations of cells from blood is likely interested in our technology. Just remember that we are not developing a diagnostic test or a therapy, we are developing the front-end that enables people developing diagnostic tests and therapies to obtain their starting material. If you are looking for specific immune cells from blood and want to remove red blood cells and the platelets then this is the product for you.

CEOCFO: ***What has been the response from people in the medical community?***
Dr. Kapur: There is tremendous interest in our product! For decades, researchers have relied on a labor intensive, inconsistent, and time-consuming front-end cell isolation process because there was no alternative. MicroMedicine's technology provides an automated, precise, and high-performance solution for cell isolation. The math is simple - the more cells isolated from whole blood with high purity, the more target cells available for the downstream clinical diagnostic tests and cell therapy. MicroMedicine alleviates the stress of cell isolation and maximizes the cells of interest.

CEOCFO: ***Where are you in development? What is the timetable and what is your strategy as you go forward and look at eventual commercialization or are we a little early for that?***
Dr. Kapur: Our plan is to place systems in the hands of early access partners in the second half of 2018 and release for sale in early half of 2019. Prior to our first sale the product will be a Class 1 listed medical device. While our first product described above addresses issues in the blood processing field, similar challenges are felt in cell therapy manufacturing. We are excited to leverage our technology to address the issues with immune-oncology and CAR-T therapies.

CEOCFO: ***What have you learned from previous ventures in working with innovative products and ideas that you brought to the table that would put MicroMedicine ahead of the game?***
Dr. Kapur: The big learning from the first two ventures that we successfully exited with Fortune 500 companies, was that it is super important to de-risk the technology and fully understand the clinical need before you start a venture. While the technology was developing at Massachusetts General Hospital through funding from the NIH, NSF, and DoD, we also spent significant time and resources identifying meaningful clinical needs and demonstrating how the technology can fundamentally address those clinical needs. Because of that work at Massachusetts General Hospital, in just two short years, MicroMedicine is getting ready for a product launch in early 2019. With a strong technology underpinning, MicroMedicine is able to focus on building a team of professionals with a strong track record of developing and commercializing medical devices around novel technologies. We can focus solely on product development and commercial execution.

CEOCFO: ***Finally, what if anything might people misunderstand about MicroMedicine and revolutionizing cell isolation?***
Dr. Kapur: Microfluidics has been around for 20+ years, and when people think of microfluidics they think of small volumes (microliters) of

fluids moving inside microchannels. That is what microfluidics was developed for, as you could do a great many drug development assays with a small amount of materials. We have had to educate people that by leveraging the basic physics of microfluidics we can sort cells with precision from hundreds of ml of complex biological fluids.