

# Executive Summary

## May 3, 2016

*“A Disruptive Drug Delivery Solution”*

### Our Product

Microdermics, Inc. is a Vancouver based start-up focused on commercializing a novel hollow microneedle platform for efficient and targeted delivery of state-of-the art vaccines and therapeutics in the multi billion-dollar biopharmaceutics market.



Microdermics will design, build, test, and manufacture proprietary hollow metal microneedles to replace 160 year-old, one-size-fits-all needle technology for the delivery of biologics and vaccines. Hollow microneedles provide a superior alternative by eliminating pain and fear, as well as improving dosage efficiency—intradermal injections result in a greater immune response, up to 80% less dosage translates into significant economic gains, which can improve the profitability and extend the life-cycle of these vaccines and therapeutics.

Our technology has disruptive effects on healthcare systems by reducing pain-associated barriers to compliance, reducing the risk of needle-stick injuries and eliminating the need for healthcare professionals through self-administration. *Imagine a healthcare system benefitting from self-administered vaccinations and therapeutics--made possible by eliminating the risk of a needle-stick injury.*

### Our Value Proposition

- **Market differentiation.** Companies are proactively seeking innovative methods of attracting patients to their products in highly competitive segments, such as insulin injector pens. Currently, there are at least 10 different insulin pens; however, the one shared feature among all of them is: **NEEDLES.**
- **Optimized Product Performance.** Unlike a standard intramuscular injection with a hypodermic needle, Microdermics has the ability to efficiently alter our microneedles along five separate dimensions—allowing us to identify the ideal target area, dosage, and convenience factor for each product and patient profile:
  1. Number of microneedles on an array
  2. Length of microneedles (.3 - .8mm)
  3. Lumen opening of each microneedle (.04 - .1 mm)
  4. Space between microneedles on the array
  5. Material coating: Nickel, Silver, or Gold

- **Improved Health Economics.** There are two methods by which Microdermics can have a profound impact on the costs of healthcare (1) transform the focus of patient care from the hospital to consumers via self administration of a vaccine or therapeutic and (2) transdermal delivery of vaccines via our microneedles targets an abundance of highly responsive cells in the upper dermis that translates into a “dose-sparing” effect wherein a fraction of the standard dose yields the same level of protection—introducing entirely new economics to a low-margin business.
- **Product Life-Cycle Extensions.** Many of the world’s largest biopharmaceutical companies have been suffering from a decline in R&D productivity over the past decade, which has resulted in serious business consequences for many of these publicly traded companies, combined with extreme pressure to increase sales. The simplest approach to expanding sales from commercial products in addition to products about to lose patent protection is to combine the product with a new proprietary delivery system, such as Microdermics’ hollow microneedle platform.

## Our Competitive Advantage

- **Low-Cost Manufacturing Process:** The Microdermics manufacturing process for hollow microneedles does not require a cleanroom environment or expensive microfabrication equipment as silicon-based microneedles. The mold for the Microdermics microneedles is made in a cleanroom environment, but this mold can be reused many times during the microneedle fabrication process.
- **Scalable Manufacturing Process:** Our manufacturing process for hollow microneedles allows manufacturing of many needle arrays simultaneously on the same substrate. We have demonstrated the manufacturing of 50 arrays simultaneously at a yield of up to 95% in a research lab environment, and we envision transition to pilot scale with 200 arrays per substrate at a yield above 99%. Unlike silicon-based devices that can also be manufactured at scale, our process does not require expensive equipment facilitating the multiplication of equipment for increased throughput.
- **Customizable Microneedle Arrays:** It takes relatively little effort to change the geometry of our microneedle arrays. The arrangement of needles in an array is defined through the design of the photolithography mask that is used to make the mold, and the needle length is defined by a single step during the mold making process. The needle manufacturing process then only requires small adjustments to its process parameters. This allows customizing needle arrays for particular applications.
- **Manufacturing Materials:** Metal vs Silicon vs Stainless Steel: Metal is ductile while silicon is brittle and therefore risks breaking more easily. We have not been able to achieve failure (breakage) of our needles in response to shear forces. Conventional needles made from stainless steel are individually drawn, and mounting them into arrays is challenging, while our technology directly enables the manufacturing of arrays of microneedles.

- **Hollow vs Solid Microneedles:** Solid microneedles are either coated with a drug contained in a dissolvable matrix or the entire microneedle is made from a drug-laden dissolvable material. Solid Microneedle delivery methods and the needle structures are very simple, but these methods require new drug formulations that need to follow full regulatory approval processes for new drugs and new devices. Hollow microneedles, however, permit drug delivery without reformulation and there is flexibility over the dose of drug administered; the latter is a consideration for the delivery of drugs like insulin. In addition to drug delivery, hollow microneedles can also be applied to sensing. *The greatest challenge for fabricating hollow microneedles is the creation of the needle lumen, a problem that we have solved through our molding process.*

## Our Regulatory Pathway

Microdermics is developing its medical device platform in accordance with the US FDA and foreign equivalents as a Class II medical device requiring appropriate regulatory clearances prior to commercialization.

We are pursuing a strategy that will enable Microdermics to obtain the necessary regulatory clearances in the most efficient means available, the 510(k) process. Premarket Notification (510(k)) submissions for medical devices are reviewed by FDA's Center for Devices and Radiological Health (CDRH), specifically, by the Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostics and Radiological Health (OIR).

We are planning on securing our 510(k) by the 4th quarter of 2017 following our planned clinical trials and continued bench testing.

## Contacts

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