**Artemis Biomedical Technologies, Inc.** **July 2016**

## Background to Novel PDS Technology

- Prior attempts to measure blood glucose noninvasively have not met FDA standards for accuracy because the devices have been limited to measurement of glucose in the interstitial fluid of the skin, the levels of which are time-delayed vs blood glucose.
- Artemis scientists resolved this issue with the invention of Pulse Differential Spectroscopy (PDS) to filter the glucose measurement data due to blood and eliminate data due to interstitial fluid glucose.
- Our first device clearly demonstrated spectroscopic measurement of interstitial fluid glucose in clinical trials conducted as part of a PMA submission to FDA. Integrating PDS with the innovative technology of our first device will enable measurement of blood glucose and resolve the adverse effect of interstitial fluid glucose on accuracy.
- Artemis has designed a plan for a relatively inexpensive Brassboard Prototype to integrate PDS and demonstrate measurement of **blood** glucose meeting FDA standards for accuracy.
- The phased development of the marketed version of the Artemis PDS will be achieved in four progressive stages beginning with the integration of PDS technology and a continuous laser source in a Brassboard Prototype that will demonstrate accurate measurement of blood glucose.

## Development of the Brassboard Prototype (Phase 1) to demonstrate accurate noninvasive measurement of blood glucose concentration using Pulse Differential Spectroscopy (PDS)

### Brassboard Design

- PDS is a further innovation to our glucose measurement technology. Application requires modification of the basic systems architecture of the original device, and a laser-based light source to increase signal to noise ratio and eliminate the need for a spectrometer.
- To demonstrate the PDS technology, a low cost continuous laser source configured to meet Artemis specifications for the laser diode array (LDA) light source will be used for the Brassboard Prototype and proof of concept.
- The re-engineered electrical systems and software for the Brassboard will be functionally equivalent to the final consumer device and a laptop will be used for signal processing and the user interface.

### Brassboard Objectives:

- Validate PDS for accurate measurement of blood glucose, within FDA standards for accuracy.
- Validate engineering of critical systems to be used in the final prototype.
    - Test system architecture
    - Build and test electronics, printed circuit board
    - Test and verify performance of component substitution
- Validate Software Engineering
    - Boot code startup and scheduler
    - ADC Driver / Detector interface
    - Laser source sequencing and timing
- Prove the PDS filters spectral data due to blood to apply POC to other blood constituents

### Costs & Manufacture

- Completion: 3 months
- Cost: $750,000 ($500,000 net). The broadband laser is a standard production unit modified to our specifications and will be resold by the supplier to recover $300k of cost.

**Phased Alpha Prototype Development Strategy:**
In Phase 1, a Brassboard Prototype will be completed as detailed above using a continuous laser source and engineered to be functionally equivalent to the final consumer device.

Phases 2 and 3 will include a stepwise addition of wavelengths to the laser-based light source ultimately replacing the continuous laser source as the device is miniaturized.

- Phase 2, the preliminary Alpha Prototype will be completed with a user interface approaching the marketed version in look, feel and function. Optics, signal processing and electronic systems will be fully functional. At this stage the laser-based light source will have over 50% of the distinct center wavelengths of the final configuration.

- Phase 3, the fully-configured laser-based light source will be completed and the Alpha Prototype will be a fully functional hand held device that accurately measures blood glucose noninvasively. We expect to make substantial progress or complete the Market Version of the Artemis PDS during this third phase, which will be the device used in clinical trials.

- Phase 4, final modifications will be made to achieve a version that will be acceptable to FDA for pivotal trials.

| Phase | Version | Function | Form | Timeline to Completion |
|---|---|---|---|---|
| 1 | Brassboard as detailed above | Electrical engineering, laser based light source substitution and signal processing functions complete | Not specified | Months 1 - 3 |
| 2 | Preliminary Alpha Prototype | Fully functional electronics, signal processing and user interface in final form factor. | Approaching marketed version to user in appearance and operation | Months 4 - 8 |
| 3 | Alpha Prototype | Fully configured laser-based light source. Measures blood glucose | Near-identical to marketed version. Suitable for human factor testing. | Months 9 - 12 |
| 4 | Market Version Artemis PDS | Ready for pivotal clinical trials, | Final version for regulatory and manufacturing purposes | Months 13 - 18 |