

Invenio Medical, Inc.

2019: 1st Quarter - Operations Update

January 2019 started off with finalized in-house testing of lateral-flow strips on human biological specimens. We also had the opportunity to meet with, and commenced feasibility contract with a manufacturer of the “chemistry” component of our device. Simultaneously, we contacted, and had several discussions with a plastics manufacturer here in California who is currently producing a product that uses a delivery device very similar to our conceptual design. We have obtained some samples, created some prototypes, and have completed preliminary testing. As with all initial designs, our testing demonstrated a few minor barriers with the current configuration, which we are currently working on overcoming with the manufacturer in order to meet our needs.

Our proposed plastics manufacturer is still working out a way to incorporate necessary changes into the current device, with minimal cost, and in a manner that would not require retooling of the molding devices. As quarter-end we are still trying to come up with a suitable solution. We have also experienced difficulty in meeting with the manufacturer, due to their international travel schedules.

In early February we met with a second manufacturer who we expect will be our choice for the “chemistry” part of the manufacturing process. We have entered into a contract for a plan to first “de-risk” the lateral flow test strip that our Scientist had designed, thereby providing us with insurance that the strip itself is ready for scalable manufacturing. The Proposal also includes a roadmap to what we are also looking for, the integrated strip-in-a-tube device. The Proposal will deliver an Initial Risk Assessment for the strip, and incorporate training from our Scientists. This is currently being planned for between our Scientists and manufacturing entity.

In late February, we signed the above referenced agreement, in our effort to avoid any future delays, as well as preventing and unnecessary barriers due to lack of forethought and planning. The said company has a great deal of experience in bringing products like ours to market, and our chief scientist has worked with them in the past, with high recommendations.

We have provided all necessary requested information to the manufacturer, along with SOP’s electronically transferred, and received by their project manager for review and implementation.

Below is a brief summary of the project’s scope:

	Description of Work	Original Timing	New Timing
Approval of Stage 2a - Project Definition Proposal	Manufacturer to furnish written Proposal requiring approval and signature to commence work	February	March
Completion of Proposed Stage 2a Project Definition Phase	Manufacturer to furnish a written report to Invenio for mutual review	Mid-March	Mid-April
Technical Transfer Gap/Risk Review Meeting for Stage 2a	Manufacturer and Invenio stakeholder participation	Mid-March	Mid-April
Technical Transfer Agreement for LFI Test Strips only	Manufacturer to transfer the product as per a mutually agreed upon SOW.	April	May
Design planning for Stage 2b	Manufacturer and Invenio will collaborate on finalizing the design of the sample processing tube (SPT)	March	April
Approval of Stage 2b – Project Definition Proposal	Manufacturer to furnish written Proposal requiring approval and signature to commence work	TBD – dependent on above	same
Completion of Stage 2b Project Definition Phase	Manufacturer to furnish a written report to Invenio for mutual review	TBD – dependent on above	same
Technical Transfer Gap/Risk Review Meeting for Stage 2b	Manufacturer and Invenio stakeholder participation	TBD – dependent on above	same
Technical Transfer Agreement for SPT & LFI test strip integration	Manufacturer to transfer the product as per mutually agreed upon SOW	TBD – dependent on above	same

We acknowledge and sincerely thank all our Angel Investors for their continued support, and we look forward to sharing with you news on clinical and partnership progress in the coming months.

Yours Faithfully,

Victor R. Lange, PhD, JD, MSPH
CEO/President
Invenio Medical, Inc.