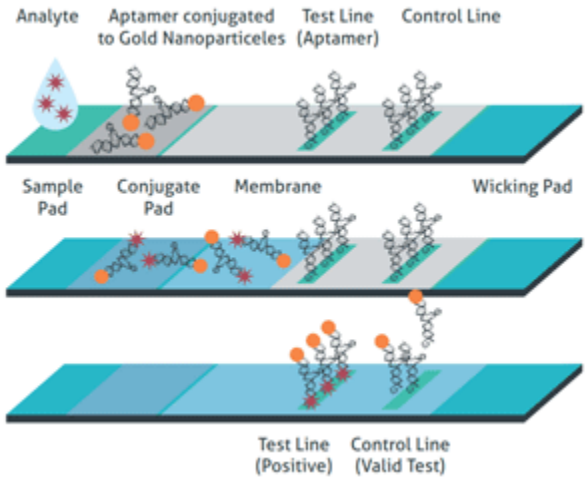
Invenio Medical, Inc.

2019: 2nd Quarter - Operations Update

Since the release of our last update, Invenio Medical, Inc. has made much progress in the development of our revolutionary AptaSure™ MRSA product. As you may recall, we had much success in the development of the validated lateral flow strips, with several hundred tested units, on human specimens.

Preliminary test results on the lateral flow strips were remarkable, demonstrating full functionality, including a high level of sensitivity and specificity of the test strips. The development of our lateral flow test strips has been the most important factor in our device development. As indicated in our introductory material, the lateral flow strips are what makes our device work. This is the "brain" of the device. These strips, contain nitrocellulose membranes, with engineered Gold Nanoparticles (or labels), and antibodies/aptamers, to produce test results (**Figure 1**). When a sample is collected on the swab, it is inserted into the holding tube, and a solution washes over the collection surface of the swab. Should any cells be present on the swab, they cells are lysed (killed, with cell wall broken open. The genetic components and proteins associated with the killed cell are then identified through chemical processes, all while at the bottom of the tube. This is when we see the markers, binding to these specified indicators, providing us with a positive or negative result

Figure 1.



Once our strips had been determined to work properly, with optimal specificity and sensitivity in detection of the MRSA pathogen, our next developmental hurdles pertained to the development of an all-inclusive holder/tube. This tube would need to facilitate the appropriate buffer/lysing agent containment, along with the swab and associated test strip.

Various configurations have been developed, with the first version working properly, however there was initial concern over the "tightness" of the swab upon insertion into the collection tube (**Figure 2**). This smaller diameter tube was an "off-the-shelf," tube, already being manufactured by one of our selected vendors. This would allow for us to skip several months, as well as tens of thousands of dollars, as we would use a product that already has a proper injection-mold already made, and would not require new

tooling, etc.. However, in order to accommodate the lateral flow strip, the strip would need to be contained within a separate isolation tube in order to prevent premature exposure on the incorrect location of the strip. This caused the inner tube diameter to become more "tight," which would not be adequate, as this would lead to possible device and/or testing failure (**Figure 3**).

Figure 2.

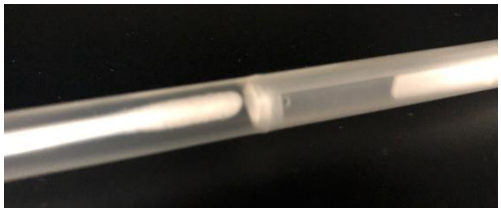
Figure 3.

At this same time, we explored possibly elongating the collection tube (**Figure 4**), rather than simply increasing the inner diameter. We could reduce the overall swab length, to accommodate the bottom portion for the "test chamber" (**Figure 5**). We speculated that we could place the lateral flow test strip in a bottom "test chamber" of the tube, thereby preserving the original design theory, as well as associated tube diameter, once again, saving us valuable time, and limited financial resources.

In either design, we ran several hundred samples through both tube iterations, and also noticed that a concern was encountered with the faintness of the test line on the lateral flow strip. Please recall that the lateral flow-strip has 2 lines that appear when the test is positive. One line is the control, indicating that the strip has appropriate fluid flow. If this line is not present on the strip, this indicates for a possibly defective strip and/or not enough fluid reaching the sample pad.

Figure 4.

Figure 5.



<u>Tube Configuration Dependent – Testing Results</u>

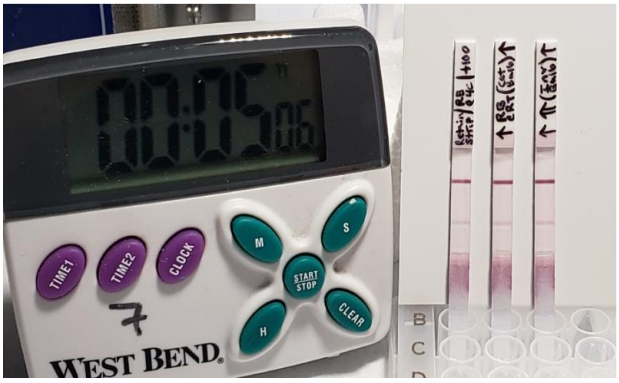
Once the validated lateral flow strips had been inserted into the various models, we began testing the overall functionality of the tubes with varying levels of sensitivity. This was also influenced by the source of bacteria collected. If the MRSA was grabbed from inoculation, the colony count of bacteria present was much higher, therefore leading to a darker red line. In some cases, depending on whether or not the specimen was freshly obtained from human nares, the number of pathogens present would be very

low, thereby being difficult to detect. This would indicate that we would need to adjust the sensitivity of the Aptamer conjugated to the Gold Nanoparticles, or adjust the lysing agent/buffer to be stronger in order to wash out/lyse more of the cells in the collected specimen.

Our Research & Development team in Indiana, also helped us re-test the current lateral flow strips (**Figure 6**), and validated that strong signals were still present in our strips. This ruled-out defect in the strips, and possibly pointed towards the obtained specimens as being insufficient. As evident in **Figure 6**, the Lateral Flow Test strip was tested at 2 minutes 20 seconds; 5 minutes 6 seconds, and 15 minutes 3 seconds. The testing demonstrated that our lysing/buffer, as well as strip was fully functional, with faint positive indicator evident at 2 minutes 20 seconds, and darkest control line at 15 minutes 3 seconds.

Figure 6.

Test Results at 2 min. 20sec.



Test Results at 5 min. 6 sec.

Test Results at 15 min. 3 sec.

Throughout the development of our tube configuration and associated lateral flow strip adjustments, we have been doing everything possible to maintain a rapid timeline, along with looking at our next

steps in bringing the AptaSure™ MRSA to market. This includes the requirement of complying with the Food and Drug Administration's (FDA) stringent requirements.

In order to utilize the AptaSure™ MRSA as a diagnostic tool for the detection of MRSA in human subjects, we need to complete a submission of documentation to the FDA, also known as 510K. A 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Therefore, the AptaSure™ MRSA needs to demonstrate substantial equivalence. This means that our device is at least as safe and effective as the predicate (other similar technologies).

A device is substantially equivalent if, in comparison to a predicate it:

- has the same intended use as the predicate; **and**
- has the same technological characteristics as the predicate;
  or
- has the same intended use as the predicate; **and**
- has different technological characteristics and does not raise different questions of safety and effectiveness; **and**
- the information submitted to FDA demonstrates that the device is at least as safe and effective as the legally marketed device.

Based on these factors, our AptaSure™ MRSA device is very unique, as it is far superior to any predicate technologies that had been developed. A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

Furthermore, The Food and Drug Administration (FDA) has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are:

Device Class and Regulatory Controls

1. Class I General Controls

    With Exemptions
    Without Exemptions

2. Class II General Controls and Special Controls

    With Exemptions
    Without Exemptions

3. Class III General Controls and Premarket Approval

The class to which our device is assigned, determines, among other things, the type of premarketing submission/application required for FDA clearance to market. Due to the nature of our device, and

intended use, the AptaSure™ MRSA falls into the Class II General Control Category, based on the fact that the AptaSure™ MRSA is a Point-of-Care Invitro Diagnostic device.

Invitro Diagnostics

In vitro diagnostics are tests done on samples such as blood or tissue that have been taken from the human body. In vitro diagnostics can detect diseases or other conditions, and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

In vitro diagnostics may also be used in precision medicine to identify patients who are likely to benefit from specific treatments or therapies. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

Risk Analysis

In order to further improve our chances of a swift FDA 510K approval, it was essential to evaluate any obstacles or risks inherent in the production of the AptaSure™ MRSA. These risks include any potential error that may be present in manufacturing, which could potentially lead to the misidentification of the target pathogen, based on an incorrectly manufactured device.

As such, Invenio Medical Inc. partnered with one of our selected manufacturers, to conduct the said Risk Analysis. Below, we have provided the Risk Analysis, which will also be part of our course of action in avoiding any obstacles with our 510K submission to the FDA.

Risk Analysis – 05/06/2019

Background:

The Invenio MRSA AptaSure™ device is a lateral flow device designed to detect and quantify the presence of MRSA (methicillin-resistant staphylococcus aureus) in a patient's nasopharynx. The test strip consists of a multi-layered laminate strip construct with functional chemistry and biology dried onto solid materials. The test strip is intended to be integrated with a sample collection device that will allow for minimal sample extraction and processing steps to run the assay. The device is intended for use by point-of-care professionals and hospitals to screen patients for infection and to limit exposure of other patients to infection. This product is intended for FDA 510K approval.

Invenio and xxxx have entered into an agreement to define the scope of a possible transfer of manufacture of this device to xxxx from the contract CDO, xxxx. This assessment will be limited to the scope of work associated with manufacturing of the test strip. The swab collection device development will be underway during the technical transfer of the test strip.

The project definition includes an analysis of the design, manufacturing and regulatory compliance of the product to identify potential areas of risk to a sustainable manufacturing process. In the event that aspects of the product design or manufacture change, the contents of this assessment may change.

Below is a table summarizing the ranking system used to develop this assessment. The lower the ranking the less of a need to provide focus on a mitigation solution because one may already exist or is deemed to be easily implemented. A higher ranking indicates the need to provide sharper focus and higher prioritization to develop a mitigation solution that currently does not exist or needs to be evaluated further. The risk ranks are NOT representative of probability of occurrence of events or of failure of technical transfer.

RISK RANK	DEFINITION
LOW	Failure to mitigate risk has minimal impact on manufacturing. Mitigation can be accomplished with high confidence and minimal change.
MODERATE	Failure to mitigate risk may halt or delay manufacturing. Mitigation may require creation and/or implementation of new systems.
HIGH	Failure to mitigate risk would directly impact performance of test and/or manufacturing. Mitigation steps require a higher level of attention and must reach resolution during the product transfer phase.

Identification of Initial Risks:

A. RAW MATERIALS

Currently, Invenio will be responsible for maintaining materials supply for the critical aptamer that is used in the assay. Xxxx currently manufactures the gold particles used in the assay using a proprietary method. Xxxx will either train on the xxxx gold particle procedure or procure gold particles from a third party. It is the responsibility of Invenio and xxxx to come to an agreement on which scope is to be followed by xxxx.

Xxxx will be responsible for the procurement of the web materials and other critical reagents.
Invenio or xxxx, will provide specifications identifying what material supplier and material characteristics are required for this project and any other additional materials that are not included in the scope of this document. Web will purchase directly through Invenio/xxxx identified suppliers.

The execution of supplier audits will be the responsibility of Invenio, unless otherwise agreed upon. Xxxx will require supplier approval (per xxxx internal procedures) prior to material procurement.

RISK: Sustainable supply of all critical raw materials.

MITIGATION: Xxxx will need a documented quality requirement (in some cases, a supplier survey and proof of sufficient quality certification) to ensure sustainable supply of these materials. Non-critical material suppliers will be contacted to produce a Notification of Change agreement though it is believed that these materials will be of minimal impact on product performance. Prior knowledge does indicate that for most of the major suppliers (xxxx, xxxx, xxxx) a survey and certificate are suitable. The greatest risks associated with the raw materials provided by those suppliers is generally associated with availability at this stage.

RISK LEVEL: **LOW**

B. INCOMING INSPECTION

Xxxx will be responsible for performing incoming inspection on all critical raw materials. Xxxx will require procedures for each material and accept/reject criteria to adequately control the quality of incoming products. In the absence of existing procedures, xxxx will develop adequate testing and acceptance criteria for the raw materials and critical reagents.

There are no formal inspection procedures, beyond a Certificate of Analysis verification, being used at xxxx.

RISK: Inadequate quality control of all incoming critical raw materials

MITIGATION: For all critical raw materials, xxxx will require an incoming inspection procedure with accept/reject criteria that adequately controls the quality of the incoming product. Xxxx will need samples of critical reagents from xxxx to create baseline acceptance criteria for biologicals. Xxxx will work with web material suppliers to create acceptance criteria for specifications that are critical to product.

RISK LEVEL: LOW

C. BIOCHEMISTRY OPERATIONS

Xxxx Biochemistry Operations lab will be responsible for the manufacture of all reactive solutions (test line, control line, conjugate solution, etc.) and intermediate solutions according to the current manufacturing SOPs provided by xxxx. In addition, the Biochemistry Operations group will perform all required in-process testing and titration of membranes and conjugates to ensure acceptable functional response (see section I. In-Process Testing).

The documents currently supplied by xxxx need to be revised to capture specific details and methods of manufacture that are not explicated stated. Xxxx has obtained the missing information in the form of a written response from xxxx. However, the information will need to be integrated into the SOPs for the product prior to technical transfer.

RISK: Incorrect manufacture of solutions and intermediate components.

MITIGATION: Complete and detailed Standard Operating Procedures (SOPs) will be supplied by xxxx and translated to xxxx SOP format. The appropriate training from the xxxx team to members of the xxxx Biochemistry Operations lab will take place. The risk is present in the context of human error or inadequate training, which could also be attributed due to lack of clear SOPs.

RISK LEVEL: MODERATE

D. NCM DEPOSITION

Xxxx will use a BioDot RR120 reel-to-reel dispenser with two vertical drying tunnels, an inline bad part vision detection system, and a desiccated rewind box. Web preferentially deposits solutions onto NCM with the BioDot frontline dispensing tips, which are contact dispensers.

Currently, xxxx utilizes an Imagene IsoFlow benchtop dispenser to deposit the test line and control line solutions onto backing cards laminated with NCM through contact dispensing tips.

Xxxx will be depositing NCM solution directly to the NCM web materials (backed, but unsupported) in reel format. The major manufacturing differences will be in the drying of the materials in the drying tunnels rather than in an oven. The temperature specification for drying can be met, but equivalency studies will need to be performed to determine if any performance impact exists in the drying time difference. If adequate drying is not achieved through the tunnels, additional drying with a convection oven can be achieved. This will require additional studies to be performed during technical transfer.

RISK: Inequivalent product performance due to transfer of deposition process from tabletop system to reel-to-reel system.

MITIGATION: Equivalency testing of reel-to-reel materials at xxxx and materials prepared by xxxx will be conducted to evaluate any change in performance. There could potentially be a performance risk linked to the different drying characteristics of material rewound after deposition. Beginning, middle and end (BME) testing will be performed to show that all parts of the roll have equal performance.

RISK LEVEL: HIGH

E. CONJUGATE DEPOSITION

Xxxx will use a BioDot RR120 reel-to-reel dispenser with two vertical drying tunnels, an inline bad part vision detection system, and a desiccated rewind box. Xxxx preferentially deposits conjugate material with the BioDot AirJet dispensing tips, a pressure spray nozzle.

The major manufacturing difference will be in the initial drying of the materials in the drying tunnels rather than in an oven. The materials drying cycle will be occur in the drying tunnels. The temperature specification for drying can be met, but equivalency studies will need to be performed to determine if any performance impact exists in the drying time difference. If adequate drying is not achieved through the tunnels, additional drying with a convection oven can be achieved. This will require additional studies to be performed during technical transfer.

RISK: Transferring deposition process from tabletop system to reel-to-reel system will produce inequivalent results.

MITIGATION: Equivalency testing of reel to reel materials and materials prepared by xxxx will be conducted to evaluate any change in performance. There could potentially be a performance risk linked to the different drying characteristics of material rewound after deposition. Beginning, middle and end (BME) testing will be performed to show that all parts of the roll have equal performance.

RISK LEVEL: HIGH

F. NCM/SAMPLE PAD BLOCKING

This product does not require NCM or sample pad blocking.

G. LAMINATION PROCESS

Xxxx will use a BioDot LM9000 laminator to create the multi-layered laminate construct. The laminator will first supply backing material and remove the adhesive liner, then, with the use of micrometer adjustable roller guides, it will place the striped NCM onto the adhesive. The laminated NCM will then pass underneath a nip roller. The conjugate pad will then be adhered followed by the absorbent pad before passing under another nip roller. The laminated card will pass through another roller prior to the addition of the over label. The fully laminated card will pass through a final nip roller. The critical overlap for this product will be the overlap of the conjugate pad to the NCM. All other overlap measurements will be driven from this overlap placement.

The laminated material will pass beneath an inline vision system to mark any bad parts carried over from the deposition step or any misalignment defects from the lamination process. The guides will keep the various layers of laminate in a registered location and maintain design specifications for overlaps and lamination distances. The inline vision system will measure distances from a datum edge to confirm correct placement of materials and mark any “bad parts”.
Xxxx currently laminates cards by hand. The overlap targets and tolerances for the different pad materials are not known.

RISK: Lamination of product from reel-to-reel system does not fall within specifications determined by developer.

MITIGATION: With limited lamination specifications xxxx will perform an initial feasibility study to determine the overlaps of the pads to the NCM based on the placement target described in the xxxx document. The determined overlaps and overlap tolerances held by the xxxx laminator will be used to develop acceptance criteria for the lamination of the product. These studies will aim to ensure the process produces test strips that are consistent and have adequate performance.

RISK LEVEL: **MODERATE**

H. CUTTING PROCESS

Xxxx will use a cutting asset to cut the multi-layered laminate into test strips. This piece of equipment has manufacturing capabilities of maintaining a strip cut tolerance of ±0.1mm. The cutting mechanism used is a guillotine system that is similar to that of other commercially available cutting systems. The cutting mechanism currently used at xxxx is a guillotine cutter. Currently, this product has a strip width of 4.0mm with no associated tolerances.

RISK: Tolerance of card or strip width is outside of the tolerance of xxxx equipment.

MITIGATION: The equipment at xxxx will use the same cutting mechanics as the equipment currently used at xxxx and therefore should have similar tolerances. Xxxx will test this procedure during process development to determine the tolerance of the xxxx asset and to ensure the test strips produce perform adequately.

RISK LEVEL: LOW

I. IN-PROCESS TESTING

Xxxx defines testing that is required at each manufactured step as a Control Plan. This overall plan will include in-process testing and quality testing. Xxxx will be providing in-process testing services in order to monitor and maintain optimal test performance. Identification of all QC controls, replicates, sampling

rates, as well as target acceptance criteria for each control and statistical characteristic are required and sufficient to adequately assess performance.

Xxxx currently tests the conjugate pad prior to final build as well as the final built cards using the following sample method:

1. 3 cards (or pads for titer testing) from each "lot" – 20 strips from each
2. Triplicates of each control
3. MRSA-RB (running buffer) spiked with the MRSA recombinant protein (PBP2A) @ 0, 2.5, 5.0, 10ng/mL
4. Results recorded at 30 minutes a. Results recorded as a visual read (-, +, ++, +++, ++++, +++++)
b. Results verified by PBMC reader (below 200 is determined to be "-") – the reader is used as an informative tool only. It is currently used to ensure there is no more than a 25% difference in signal intensity from the "gold standard" card lot to the current in-process lot.

Xxxx is currently testing the components as the final mixed conjugate used for deposition. Xxxx will need to develop appropriate independent testing for each of these conjugates. This may require retains of past xxxx conjugate materials.

RISK: Incorrect or insufficient in-process and titration testing.

MITIGATION: Conservative sampling plans will be created by xxxx, dependent on lot size, to ensure that a statistically relevant number of samples is tested to determine proper function of all major components prior to further manufacturing. The testing plans and methods will be defined by xxxx according to the information provided by xxxx regarding the current testing procedures used in development. In lieu of having certain testing procedures, xxxx will work with xxxx to develop these processes.

RISK LEVEL: MODERATE

RISK: Scoring system allows for release of unacceptable tests.

MITIGATION: The scoring system used in development needs to be clarified. If a visual read is intended to be used in the manufacturing process, a scorecard needs to be developed that is representative of the signal intensities associated with "-", "+", "++", "+++", "++++", "+++++" at xxxx. If the reader is intended to be used to release materials, the reader output needs to be attributed to each respective control level. Xxxx will need to provide data to show what ranges of reader values are acceptable for each control level.

RISK LEVEL: HIGH

J. VIALING/POUCHING PROCESS

This product does not require vialing or pouching currently. The test strips will ultimately be housed with a sample collector unit for the final commercial product. The development and manufacture of strips within the sample collector unit are outside of the scope of this document.

K. FINAL PACKAGING

The final packaging for the MRSA AptaSure test strips will be determined by Invenio, depending on their intended use.

L. QUALITY CONTROL MANUFACTURE

Xxxx will be responsible for the sustainable manufacture and tracking/trending of Quality Controls used in the testing of the device. The control antigens will be procured by xxxx and are a standard off the shelf item. Currently, xxxx dilutes recombinant PBP2A (MRSA) protein into prepared running buffer at various levels.
Currently, no clinical matrix samples are being tested as part of the QC control panel at xxxx. In order to ensure appropriate clinical performance Web will be performing "presumed negative testing" on clinical samples as part of the QC testing procedures. The samples will either be procured through a third party or collected in-house through xxxx IRB procedures.

RISK: Inequivalent performance of quality controls manufactured by xxxx.

MITIGATION: Xxxx personnel will undergo training by xxxx employees on the manufacture of the quality controls for the different stages of testing. Xxxx will also adopt the same dilution and storage practices as outlined in xxxx documents. Xxxx would request that xxxx provide documentation of their testing and control manufacturing procedures currently used to release test materials.

RISK LEVEL: HIGH

RISK: Performance of devices using recombinant antigen in QC controls is not comparable to behavior of native antigen in the field.

MITIGATION: Web is requesting xxxx provide data to support the use of recombinant protein in the assay versus a native antigen. In order to have confidence that the QC controls being used to release product are indicative of clinical sample performance Web will need this information to move forward with the technical transfer.

RISK LEVEL: HIGH

RISK: Clinical matrix samples do not exhibit same performance in comparison to QC control panel.

MITIGATION: Xxxx is requesting xxxx/Invenio provide data on clinical matrix testing in order for xxxx to determine the appropriate acceptance criteria for "presumed negative samples."

RISK LEVEL: HIGH

N. FACILITIES

Xxxx will perform various manufacturing processes in different environments depending on the requirements of the product. Deposition processes will be performed in a controlled environment of 35-50%RH and 70ºF ± 2ºF. Lamination, cutting, and vialing processes will be performed in a controlled environment of ≤10%RH and 70ºF ± 2ºF. Xxxx will produce general buffers and solutions using water that meets or exceeds ASTM Type I specifications.

These facility standards meet requirements set by xxxx/Invenio for the manufacturing of this product. In the event that any environmental conditions change prior to transfer, this area will be reevaluated to identify any risks.

O. REGULATORY

Xxxx is an ISO 13485:2016 certified facility that is currently developing systems to meet FDA 21 CFR 820 regulations, and more specifically developing systems to effectively control and manage the established processes in xxxx LFI business unit. Certain systems may not be approved and effective prior to execution of the Scope of Work for this program, but will be effective prior to product launch.

The Invenio MRSA Aptasure™ test strip requires compliance to the aforementioned ISO regulations as well as the FDA regulations. Xxxx is capable of meeting the regulatory requirements for this product.

RISK ASSESSMENT SUMMARY

The referenced Risk Assessment has been produced as a need of our initial evaluation of the AptaSure™ MRSA manufacturing process. We have been working on evaluating all aspects of the manufacturing process, with a goal of minimizing all risks. This will allow us to have a shorter 510K submittal/approval.

Status of AptaSure™ MRSA Development

As indicated in the information provided herein, we have successfully developed our Lateral Flow Test strip, with associated Aptamer/Antibody configuration. The lysis/buffer has also been developed, along with various preliminary tubing configurations (elongated vs. short). Our concern was initially expressed with the "tightness" of the first "off-the-shelf" configuration. However, with additional engineering, we had the tube elongated to accommodate our goal.

We also had a detailed Risk Analysis completed, with identified Risk levels. These levels specify areas that need to be strengthened in order to minimize risk in our manufacturing process. This information will also be part of our document package, submitted to the FDA for our 510K approval.

As we work to minimize the Risks in future manufacturing, we are also concurrently working on increasing sensitivity of the MRSA aptamer/gold nanoparticle concentrations as placed onto our strips. Our goals are to ultimately ensure that the AptaSure™ MRSA is able to identify low colony forming units (CFUs) of MRSA in our tested patients.

Frequently Asked Questions (*FAQs*)

Since the release of our Q1 Update, we have received various questions from our valued Investors. We wish to share these Questions, as well as our responses to the questions. We are advocates of transparency, as well as hopeful that this information is beneficial to you.

Question 1
The 2019 Quarter 1 - Operations Update indicates Invenio is working with a proposed plastics manufacturer to incorporate necessary changes to the current device. Has Invenio and/or the plastics manufacturer come up with a suitable solution? In conjunction with the proposed plastics manufacturer, has Invenio established a timetable for finalizing a preliminary device design?

Answer 1
We have tried 3 different device modifications and we believe the most recent will suit our needs. There is an added filter for particulates that needed to be tested and adjusted so that it would not impact the

results of the test. Testing is ongoing. We need to obtain more devices and test strips, as well as finding additional patient(s) who have active MRSA colonization/infection of their nares.

Question 2

Since the current device is undergoing a design change, will a revised patent application for our device need to be resubmitted? If so, what is the "anticipated" timeframe for patent approval once Invenio has submitted a revised patent application?

Answer 2

We are working with a manufacturer who already has a tube configuration that will work to our advantage. With the incorporation of our Lateral Flow strip technology, proprietary buffer/reagent solution, we are in the process of working with our patent attorney to see what the best options may be. It may not be possible to patent some portions of our AptaSure device, as portions of the device will be patented products, which will simultaneously save us on manufacturing costs.

Question 3

Once the plastics manufacturer provides Invenio with a revised device design, who will be conducting the in-house testing on human biological specimens to determine if we have a functional device? What are the next steps if Invenio does not get the results anticipated?

Answer 3

Dr. Lange, our President and Chief Scientific Officer has, and will be running, and overseeing the testing of the AptaSure™ technology. Dr. Lange is also working with healthcare facilities to obtain human subject samples. Initially, there were some negative test strip results in June, 2019, which caused us to go back to our developer, inquiring and retesting some of the samples. In mid-July, we confirmed that the test strips were functioning properly, and the cause appeared to be in with the initial samples and the low colony forming units (CFUs) of the MRSA pathogen.

Question 4

Assuming we have a functional device after final in-house testing, when does Invenio "anticipate" clinical trials will start? How many hospitals have been selected to conduct clinical trials? We assume that you will be overseeing the clinical trials, correct?

Answer 4

Clinical trials will start after we have tech transfer and can produce a suitable number of testing units to meet the FDA requirements. That will occur after the next round of funding.

Question 5

When does Invenio "anticipate" submission of clinical trial data/studies/information to the FDA will be completed? What is the "anticipated" timeline for FDA approval after clinical trial data has been submitted to them?

Answer 5

There are too many steps before this in order to provide a reasonable estimate of this timeline. The trial would need to be created and approved by an IRB, and then testing would need to be completed. The FDA process is out of our control, and can take anywhere from 6 months to 2 years for approval

depending upon the data and their review. However, we are hopeful that the process would be closer to the 6 months' timeframe.

Question 6

We have assumed the Invenio Board has finished interviewing/evaluating manufacturers that are qualified and have the knowledge/expertise to produce our device.

a. Has Invenio selected a manufacturer and executed a performance contract with them?

Answer

We have a preferred manufacturer who has giving us a handful of devices that we are using to evaluate with our strips. This took place in Q2, and we anticipate that the final selection will be in Q3, as long as the device is functioning properly.

b. Has the selected manufacturer provided Invenio with an "anticipated" production schedule? How long will it take the selected manufacturer to gear up production of our device ready for sell to our initial customers?

Answer

We are not at this stage yet, although preliminary discussions have taken place as "What- If" scenarios.

Question 7

The business plan I received in June 2017 indicates that Invenio Medical is expected to raise seed capital of approximately $250,000 to obtain proof of concept and the venture capital to commence business operations. Additional working capital is anticipated.

a. How does the Invenio Medical Board intend to finance final device design, clinical studies related costs, FDA application and approval related costs, reagent and strip production, manufacturing costs for initial devices needed, etc.?

Answer

Our plan is to seek a second round of funding when a functional prototype has been solidified.

b. Approximately how much additional capital has the Invenio Medical Board determined will be needed to take our device to market?

Answer

We currently estimate a minimum of $500,000 to get us to a point where we would have everything in place to begin the manufacturing process. (i.e.: device design, tech transfer, first installment of license agreement for aptamer, and FDA approval).

c. Who will manage and oversee the raising of capital needed?

Answer

Jay and Kevin will be, and have been, working on planning stages of raising added capital with qualified parties. This round will be through venture capital investors, as opposed to Angel Investors in the first round.

Question 8
Regarding protection of our device from competition, has the Invenio Medical Board obtained the Intellectual Property Rights for the aptamer that is exclusive to our device?

a. Is there a cost to obtain these rights? If so, do we have enough funds in the bank to pay for these rights or do we need to raise additional capital?

   Answer
   We have submitted the necessary documentation through our patent attorney for the trademark and when will apply for any and all IP once the design is final. It does not make sense to file before that, since any change results in requirement of a new application.

b. If we have not yet obtained these rights, what is the Invenio Medical Board's plan to obtain the Intellectual Property Rights to the aptamer as quickly as possible?

   Answer
   Yes, we have our patent attorney with healthcare device experience involved with the process and as soon as we have a product suitable for IP we will apply for the appropriate type of patent.

c. We have assumed that the exclusive rights to the aptamer must be obtained before we go to market. Is this a correct assumption?

   Answer
   This is not a necessity but it is in the plan to purchase the exclusive right to the aptamer to prevent duplication with the specific strand of Aptamer which we believe is the most accurate for our purposes. Other strands can be developed but then cannot be within a specific sequence without infringement. Those would not have the sensitivity or specificity as ours for the specific disease.

Question 9
We have assumed that the Invenio Medical Board has prepared a strategic plan (2019, 2020 and thereafter) including milestones for getting our device to market in the shortest amount of time possible. Will you share this plan with us to alleviate our concerns that Invenio Medical is falling further behind in getting our device to market?

Answer 9
We have been very transparent in not only our plans, but in our achievements and through these quarterly updates with our progress and next steps. We are reluctant to publish a timeline, because in the past if those timelines are not reachable due to unforeseen problems, as most new products encounter, then we find that we have had to devote our time to unproductive tasks, rather than focusing on the job at hand.

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.