# 2019

# ANNUAL REPORT


27671 AQUAMARINE
MISSION VIEJO, CA 92691

# Contents

# CEO's Letter

DEAR INVESTOR

2019 has been a challenging, and sad year for Invenio Medical, Inc. As you may all know, we unexpectedly lost Jay Haischer, our Chief Operations Officer in October, 2019. Jay had been a member of our Executive team over the past several years, and will be missed. Jay's contributions to Invenio Medical Inc. will live on through the ages, improving healthcare throughout the World.

On behalf of Invenio Medical, Inc., I would also like to apologize for the delayed update summary to our Investors. I have personally responded to numerous individual investor queries over the last few months; however I had soon come to the realization that this communication method was ineffective. Please rest assured that we have never missed development deadlines, nor have we placed less priority on this project**.**

We have been finalizing our test strip testing with the cooperation of 2 separate hospitals, validating the sensitivity of our Aptamer formulation. This also involved the adjustments of various chemical formulations, based on the result line on the lateral flow-strip being much more faint than anticipated. It is extremely important to realize that this device must be easy to read, otherwise it fails.

As you may recall, 2018 truly did demonstrate rapid progress in the Research & Development of our device. At that point in time, we completed of Phase 1 of our project. This included creation of a buffer solution and test strips (Proof of Concept). This was all completed far ahead of anticipated schedule which was very exciting. Phase 2 was contracted a month later, in April 2018, to further optimize the solution in order to identify our specific MRSA target.

Our next goal was to identify a single manufacturer who could injection mold, and produce the polymer device, create the test strips, and consolidate them into a final product. At that point in time, we began conversation with Web Industries, a manufacturer who would provide us with project timelines, ROM Unit & Transfer Cost, as well as conducting a Risk Summary.

As we continued our efforts of diligently testing our device, we continued collecting required data to submit for an accurate representation of potential manufacturer costs. Several tasks of the project plan had already been accomplished during Phase 1 & 2 of product development. We also received preliminary timelines from the Manufacturer, which would be tentative based on our completion of strip testing.

In November, 2019, we were granted official U.S. Trademark (SN 88215343). Simultaneously, we have been working with our Intellectual Property Attorney to finalize the patent process, due to multiple modifications to the design and functionality of our device. The initial patent submission was invalid, as we had to modify our design on several occasions throughout the testing process.

As we continue finalizing the clinical studies of the test strips further enhancing sensitivity, our mutual goal is to ensure that the test can be read adequately by the end user. If this step is rushed or omitted, our device development would not pass FDA clearance. This is precisely why we have already tested over 12,000 human specimens, in order to compile data points and documentation for FDA 510K clearance. Simultaneously, our goal would be to also submit for CE clearance for sale in European Nations.

The initial Transfer cost of $196,400 as proposed by Web Industries will be a part of our second round of investor funding. This will also produce initial batch sizes of 75,000 strips, equating to a cost of $0.86 - $0.57 per strip. We are currently finalizing our strip studies, prior to commencing with full transfer to Web Industries.

We understand that you may have anticipated that we would be market-ready by now, however as communicated in prior updates, the development of a point-of-care rapid test must be completed and executed with extreme caution, as the results of the test impact patient care. Therefore, we can currently state with certainty, that we have made substantial progress with the most challenging part of reaching product manufacturing. The testing and validation piece is often the most arduous and frustrating task, and with our available patient population, as well as available samples, we having been moving steadfast in the right direction.

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

Yours Faithfully,

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

# PROJECT SUMMARY / TIMELINE

## SCOPE SUMMARY

### PROJECT TIMELINE, ROM UNIT & TRANSFER COST, RISK SUMMARY

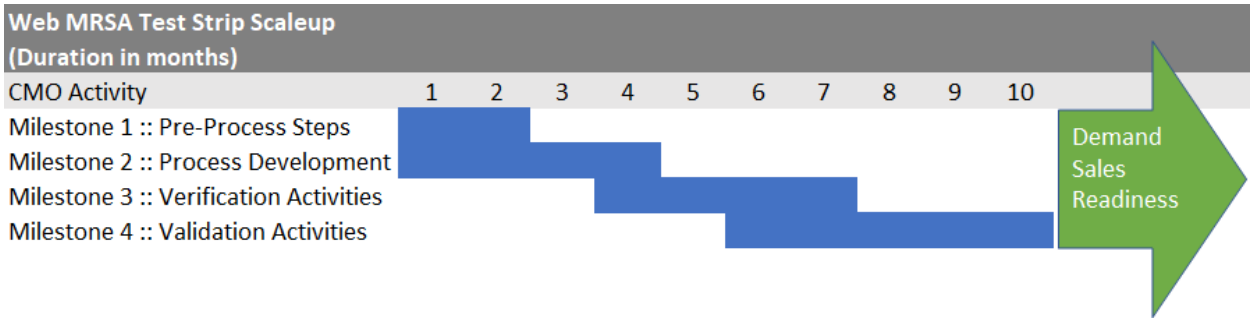
Over the past 7 months, Invenio Medical Inc. has been working with several manufacturers, assessing abilities of our required test development volumes, as well as evaluating their ability to procure essential test components in a timely manner. Upon selecting our Manufacturer of Choice, the output of project definition aims to provide a thorough assessment of the manufacturing process proposed by Web Industries ("Web") to manufacture the Invenio MRSA AptaSure™ device. In this document, we are providing our Investors with pricing and assumptions to perform Stage 3 Technical Transfer activities for the test strip component of the assay.

In the following pages, you will find transfer cost and unit cost pricing estimates followed by a pricing assumption summary page. Accompanying this document, as reference documents, are the Project Plan and the Initial Risk Assessment for the project. This is a crucial component to minimize potential

### TECHNICAL TRANSFER TIMELINE

Below is an illustration of the sequencing and concentration of technical resources described in Invenio Medical Inc.'s technical transfer scope of work. The scope of work reflects an approximate 10-month timeline and summarizes the milestone activities in the Project Plan.

The duration of the technical transfer has been dependent on the success of trails run during the process development, verification and validation stages of the project. Invenio and the CDO of the assay, Cataloid, have been involved in the approval of the process development studies as well as verification and validation studies.



This timeline began according to an agreed upon start date between Web and Invenio, of July 1st, 2019. This scaleup represents our goal timelines, based on concurrent validation studies on the aptamer/strips on live MRSA specimens.

## PRELIMINARY PRICING SUMMARY

Below is a pricing model with cost estimates as discussed with Web Industries. This model represents a scope of work inclusive of production of cut test strips, for use for analytical testing by Invenio/Catalloid.

The unit cost is presented per test strip and dependent on order quantity. The transfer cost is inclusive of all necessary process development steps to produce cut test strips. Assumptions for the transfer cost and unit cost are provided in the section below.

**Project Definition Scope 2A. Scope of Work – Test Strip Commercialization Pricing**

| TRANSFER COST | UNIT COST (per test strip) |
|---|---|
| $196,400<br>(10 month timeline) | Initial Batch sizes of 25,000 – 75,000<br>Equivalent of 1st Year Production volumes of > 250,000 strips<br>$0.86 - $0.57 per strip |

## CRITICAL PRICING ASSUMPTIONS

1. Technical Transfer Assumptions
   a. Includes materials for all verification and validation activities.
2. Unit Pricing Assumptions
   b. All unit prices include supplier management and all materials.
   c. All raw material costs are good faith estimates based on current test design and available supplier information.
   d. There is potential for a decrease in unit cost if further raw material cost savings occur during the technical transfer.

The table below represents the various activities that have transpired as related to the development of the AptaSure MRSA test.

| Task Name | Duration | Start | Finish |
|---|---|---|---|
| **Milestone 1: Pre-Process Activities** | **115 days** | **Mon 7/1/19** | **Fri 12/13/19** |
| **Quality** | **7 days** | **Mon 7/1/19** | **Thu 7/11/19** |
| Finalized Invenio Documents Sent to Web | 5 days | Mon 7/1/19 | Tue 7/9/19 |
| **DHF Initiation** | **1 day** | **Wed 7/10/19** | **Wed 7/10/19** |
| **Supplier Assessment** | **1 day** | **Thu 7/11/19** | **Thu 7/11/19** |

| | | | |
|---|---|---|---|
| **Documentation** | **20 days** | **Thu 7/11/19** | **Wed 8/7/19** |
| **Bill of Materials** | **8 days** | **Thu 7/11/19** | **Mon 7/22/19** |
| **Raw Material Specifications Drafts** | **20 days** | **Thu 7/11/19** | **Wed 8/7/19** |
| **Procurememt** | **40 days** | **Thu 7/11/19** | **Thu 9/5/19** |
| Ahlstrom 222 - Absorbent Pad | 4 wks | Thu 7/11/19 | Wed 8/7/19 |
| Ahlstrom 8964 - Conjugate Pad | 4 wks | Thu 7/11/19 | Wed 8/7/19 |
| Lohmann - Over-label | 4 wks | Thu 7/11/19 | Wed 8/7/19 |
| Lohmann 15 mil - Backing Card | 4 wks | Thu 7/11/19 | Wed 8/7/19 |
| Sartorius CN150 - NCM | 8 wks | Thu 7/11/19 | Thu 9/5/19 |
| 40nm - Gold Particles | 2 wks | Thu 7/11/19 | Wed 7/24/19 |
| Control Antibody | 2 wks | Thu 7/11/19 | Wed 7/24/19 |
| Conjugate Antibody | 2 wks | Thu 7/11/19 | Wed 7/24/19 |
| Test Antibody | 2 wks | Thu 7/11/19 | Wed 7/24/19 |
| Aptamer | 2 wks | Thu 7/11/19 | Wed 7/24/19 |
| PBP2A Recombinant antibody | 2 wks | Thu 7/11/19 | Wed 7/24/19 |
| **Milestone 2: Process Development** | **212 days** | **Tue 1/22/19** | **Tue 11/19/19** |
| **Biochemistry Documents** | **42 days** | **Thu 8/8/19** | **Mon 10/7/19** |
| **Conjugate Solutions** | **17 days** | **Thu 8/8/19** | **Fri 8/30/19** |
| **NCM Solutions** | **13 days** | **Tue 8/20/19** | **Fri 9/6/19** |
| **General Buffers** | **17 days** | **Tue 8/27/19** | **Thu 9/19/19** |
| **QC Control Manufacture** | **15 days** | **Mon 9/9/19** | **Fri 9/27/19** |
| **Assay Procedure** | **15 days** | **Tue 9/17/19** | **Mon 10/7/19** |
| **Engineering Studies** | **70 days** | **Thu 8/8/19** | **Thu 11/14/19** |
| **Deposition** | **64 days** | **Thu 8/8/19** | **Wed 11/6/19** |
| **Lamination** | **67 days** | **Thu 8/8/19** | **Mon 11/11/19** |
| **Cutting** | **40 days** | **Fri 9/20/19** | **Thu 11/14/19** |
| **Documentation** | **206 days** | **Tue 1/22/19** | **Mon 11/11/19** |
| **Deposition** | **16 days** | **Wed 9/18/19** | **Wed 10/9/19** |
| **Lamination** | **11 days** | **Mon 9/30/19** | **Mon 10/14/19** |
| **Cutting/Vialing (if applicable)** | **9 days** | **Wed 10/30/19** | **Mon 11/11/19** |
| **QC Testing** | **191 days** | **Tue 1/22/19** | **Mon 10/21/19** |
| **DHF Update** | **3 days** | **Fri 11/15/19** | **Tue 11/19/19** |
| Engineering Studies | 3 days | Fri 11/15/19 | Tue 11/19/19 |
| MRSA Catalloid - Manufacturing Documents | 3 days | Fri 11/15/19 | Tue 11/19/19 |
| **Milestone 3: Verification** | **76 days** | **Thu 11/7/19** | **Wed 3/4/20** |
| **Material Inspection** | **5 days** | **Tue 11/12/19** | **Mon 11/18/19** |
| Ahlstrom 222 - Absorbent Pad | 3 days | Tue 11/12/19 | Thu 11/14/19 |
| Ahlstrom 8964 - Conjugate Pad | 3 days | Tue 11/12/19 | Thu 11/14/19 |
| Lohmann - Over-label | 3 days | Tue 11/12/19 | Thu 11/14/19 |
| Lohmann 15 mil - Backing Card | 3 days | Tue 11/12/19 | Thu 11/14/19 |
| Sartorius CN150 - NCM | 3 days | Tue 11/12/19 | Thu 11/14/19 |
| 40nm - Gold Particles | 3 days | Tue 11/12/19 | Thu 11/14/19 |
| Control Antibody | 1 wk | Tue 11/12/19 | Mon 11/18/19 |
| Conjugate Antibody | 1 wk | Tue 11/12/19 | Mon 11/18/19 |
| Test Antibody | 1 wk | Tue 11/12/19 | Mon 11/18/19 |
| Aptamer | 3 days | Tue 11/12/19 | Thu 11/14/19 |
| PBP2A Recombinant antibody | 3 days | Tue 11/12/19 | Thu 11/14/19 |
| **Raw Material Specifications Approval** | **7 days** | **Fri 11/15/19** | **Mon 11/25/19** |
| **Ahlstrom 222 - Absorbent Pad** | **5 days** | **Fri 11/15/19** | **Thu 11/21/19** |
| **Ahlstrom 8964 - Conjugate Pad** | **5 days** | **Fri 11/15/19** | **Thu 11/21/19** |
| **Lohmann - Over-label** | **5 days** | **Fri 11/15/19** | **Thu 11/21/19** |
| **Lohmann 15 mil - Backing Card** | **5 days** | **Fri 11/15/19** | **Thu 11/21/19** |

| | | | |
|---|---|---|---|
| Sartorius CN150 - NCM | 5 days | Fri 11/15/19 | Thu 11/21/19 |
| 40nm - Gold Particles | 5 days | Fri 11/15/19 | Thu 11/21/19 |
| Control Antibody | 5 days | Tue 11/19/19 | Mon 11/25/19 |
| Conjugate Antibody | 5 days | Tue 11/19/19 | Mon 11/25/19 |
| Test Antibody | 5 days | Tue 11/19/19 | Mon 11/25/19 |
| Aptamer | 5 days | Fri 11/15/19 | Thu 11/21/19 |
| PBP2A Recombinant antibody | 5 days | Fri 11/15/19 | Thu 11/21/19 |
| Quality Control Plan | 10 days | Wed 11/20/19 | Thu 12/5/19 |
| Draft Quality Control Plan | 2 wks | Wed 11/20/19 | Thu 12/5/19 |
| Draft PFMEA/DFMEA | 2 wks | Wed 11/20/19 | Thu 12/5/19 |
| Verification Trial #1 | 40 days | Thu 11/7/19 | Tue 1/14/20 |
| Deposition | 23 days | Thu 11/7/19 | Wed 12/11/19 |
| Lamination | 21 days | Tue 11/12/19 | Thu 12/12/19 |
| Cutting | 19 days | Fri 11/15/19 | Fri 12/13/19 |
| Verification Trial #1 Report | 15 days | Mon 12/16/19 | Tue 1/14/20 |
| Update Manufacturing Documents | 5 days | Thu 12/12/19 | Wed 12/18/19 |
| Verification Trial #2 | 31 days | Thu 12/12/19 | Mon 2/3/20 |
| Deposition | 15 days | Thu 12/12/19 | Fri 1/10/20 |
| Lamination | 15 days | Fri 12/13/19 | Mon 1/13/20 |
| Cutting | 11 days | Mon 12/16/19 | Wed 1/8/20 |
| Verification Trial #2 Report | 15 days | Tue 1/14/20 | Mon 2/3/20 |
| Update Manufacturing Documents | 4 days | Thu 1/9/20 | Tue 1/14/20 |
| Verification Trial #3 | 37 days | Thu 1/9/20 | Fri 2/28/20 |
| Deposition | 15 days | Mon 1/13/20 | Fri 1/31/20 |
| Lamination | 17 days | Tue 1/14/20 | Wed 2/5/20 |
| Cutting | 22 days | Thu 1/9/20 | Fri 2/7/20 |
| Verification Trial #3 Report | 15 days | Mon 2/10/20 | Fri 2/28/20 |
| Update Manufacturing Documents | 6 days | Mon 2/3/20 | Mon 2/10/20 |
| Manufacturing Documents Finalized | 19 days | Tue 2/4/20 | Fri 2/28/20 |
| Deposition | 9 days | Tue 2/4/20 | Fri 2/14/20 |
| Lamination | 9 days | Fri 2/7/20 | Wed 2/19/20 |
| Cutting | 9 days | Tue 2/11/20 | Fri 2/21/20 |
| Procedure training | 1 wk | Mon 2/24/20 | Fri 2/28/20 |
| Milestone Report Reviewed and Approved by Invenio | 3 days | Mon 3/2/20 | Wed 3/4/20 |
| Milestone 4: Validation | 63 days | Tue 2/11/20 | Thu 5/7/20 |
| Material Inspection | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| Ahlstrom 222 - Absorbent Pad | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| Ahlstrom 8964 - Conjugate Pad | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| Lohmann - Over-label | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| Lohmann 15 mil - Backing Card | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| Sartorius CN150 - NCM | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| 40nm - Gold Particles | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| Control Antibody | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| Conjugate Antibody | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| Test Antibody | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| Aptamer | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| PBP2A Recombinant antibody | 3 days | Tue 2/11/20 | Thu 2/13/20 |
| Quality Control Plan | 10 days | Thu 3/5/20 | Wed 3/18/20 |
| Finalize Quality Control Plan | 2 wks | Thu 3/5/20 | Wed 3/18/20 |
| Finalize PFMEA/DFMEA | 2 wks | Thu 3/5/20 | Wed 3/18/20 |
| PQ Protocol | 15 days | Fri 2/21/20 | Thu 3/12/20 |
| Draft | 3 days | Fri 2/21/20 | Tue 2/25/20 |

| | | | |
|---|---|---|---|
| **Peer review** | **3 days** | **Wed 2/26/20** | **Fri 2/28/20** |
| **Review in Veeva** | **3 days** | **Mon 3/2/20** | **Wed 3/4/20** |
| **Address Comments** | **3 days** | **Thu 3/5/20** | **Mon 3/9/20** |
| **Effective in Veeva** | **3 days** | **Tue 3/10/20** | **Thu 3/12/20** |
| **Execute PQ Protocol** | **26 days** | **Thu 3/5/20** | **Thu 4/9/20** |
| **PQ Trial #1** | **19 days** | **Thu 3/5/20** | **Tue 3/31/20** |
| **PQ Trial #2** | **26 days** | **Thu 3/5/20** | **Thu 4/9/20** |
| **PQ Trial #3** | **25 days** | **Thu 3/5/20** | **Wed 4/8/20** |
| **PQ Report** | **15 days** | **Fri 4/10/20** | **Thu 4/30/20** |
| **Draft** | **3 days** | **Fri 4/10/20** | **Tue 4/14/20** |
| **Peer Review** | **3 days** | **Wed 4/15/20** | **Fri 4/17/20** |
| **Review in Veeva** | **3 days** | **Mon 4/20/20** | **Wed 4/22/20** |
| **Address Comments** | **3 days** | **Thu 4/23/20** | **Mon 4/27/20** |
| **Effective in Veeva** | **3 days** | **Tue 4/28/20** | **Thu 4/30/20** |
| **Finalize DHF** | **2 days** | **Fri 5/1/20** | **Mon 5/4/20** |
| **Milestone Report Reviewed and Approved By Invenio** | **1 wk** | **Fri 5/1/20** | **Thu 5/7/20** |

## IDENTIFICATION AND DE-RISKING MANUFRACTURING:

### A. RAW MATERIALS

Currently, Invenio has been responsible for maintaining materials supply for the critical aptamer that is used in the assay. Catalloid currently manufactures the gold particles used in the assay using a proprietary method. Web has trained on the Catalloid gold particle procedure, and will also procure gold particles from a third party based on availability by Catalloid.

Web Industries is responsible for the procurement of the web materials and other critical reagents. Invenio or Catalloid, has provided 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/Catalloid identified suppliers.

The execution of supplier audits has been the responsibility of Invenio. Web Industries will require supplier approval (per Web's internal procedures) prior to material procurement.

**The table below represents Critical Suppliers and the raw material(s) they supply at this time:**

| SUPPLIER | RAW MATERIAL |
|---|---|
| Lohmann | Backing card (60mm)<br>Over label (30mm) |
| Ahlstrom | Sample/Conjugate Pad (8964, 22mm)<br>Absorbent Pad (222, 20mm) |
| Sartorius | Nitrocellulose Membrane (CN150, 25mm) |
| NA | Control antibody (Goat anti-mouse) |
| Invenio | Aptamer |

| | |
|---|---|
| NA | Test Line Antibody |
| NA | QC Controls (PBP2A Recombinant Protein) |

**RISK**: Sustainable supply of all critical raw materials.

**MITIGATION:** Invenio Medical Inc., has provided Web with documented quality requirements (including: a supplier survey and proof of sufficient quality certification) to ensure sustainable supply of these materials. Non-critical material suppliers have also been contacted in order to produce a Notification of Change agreement, though it is believed that these materials have had minimal impact on product performance. The greatest risks associated with the raw materials provided by those suppliers is generally associated with availability at this stage.

## A. INCOMING INSPECTION

Web has been responsible for performing incoming inspection on all critical raw materials. Web has included procedures for each material and accept/reject criteria to adequately control the quality of incoming products. In the absence of existing procedures, Web had developed adequate testing and acceptance criteria for the raw materials and critical reagents.

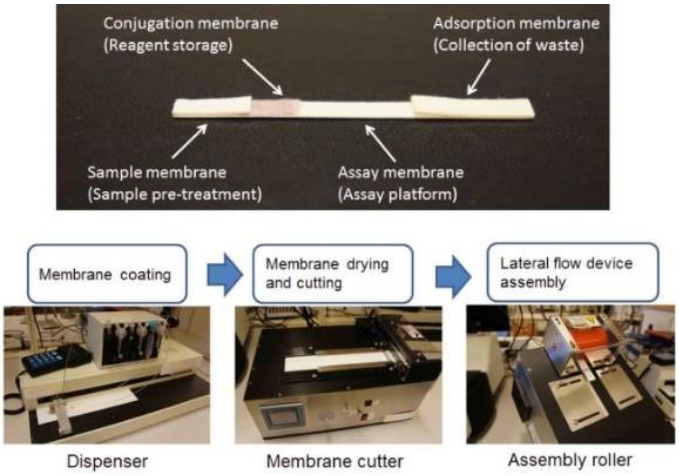
There are no formal inspection procedures, beyond Certificate of Analysis verification, being used at Catalloid.

**RISK**: Inadequate quality control of all incoming critical raw materials

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

## B. BIOCHEMISTRY OPERATIONS

Web's 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 Catalloid. 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 Catalloid need to be revised to capture specific details and methods of manufacture that are not explicated stated. Web has obtained the missing information in the form of a written response from Catalloid. 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.

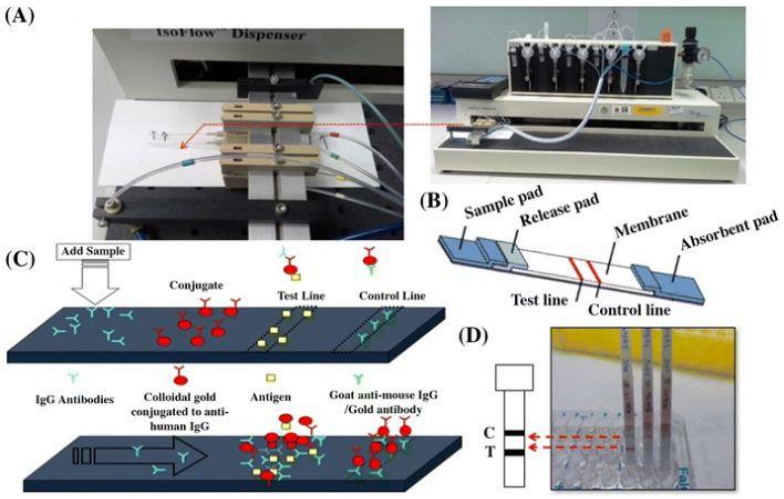
**MITIGATION:** Complete and detailed Standard Operating Procedures (SOPs) have been supplied by Catalloid and translated to WIB SOP format. The appropriate training from the Catalloid team to members of the WEB Biochemistry Operations has taken place. The risk is present in the context of human error or inadequate training, which Invenio has been monitoring throughout the development process.

## C. NCM DEPOSITION

Web uses 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, Catalloid 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. The current dispensing conditions for the NCM solutions are in the table below. After deposition is complete, the cards are then dried at 45°C-50°C for 24-72 hours.

| Parameter | Dispensing Condition |
|---|---|
| **Dispense Rate** | 0.075uL/mm |
| **Nozzle Speed** | 50mm/sec |
| **Spray Location (Test line, control line)** | 27mm, 35mm (±0.5mm) from bottom of card |




Preparation and schematic of lateral flow dipstick. a Jetting it linearly onto a membrane card using IsoFlow™ Dispenser, b a lateral flow device in the dipstick format, c operation principle of a lateral flow dipstick, and d expected results of a lateral flow dipstick

Web deposits NCM solution directly to the NCM web materials 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 Web and materials prepared by Catalloid is underway 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.

## D. CONJUGATE DEPOSITION

Web 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 conjugate material with the BioDot AirJet dispensing tips, a pressure spray nozzle.

Currently, Catalloid utilizes an Imagene IsoFlow benchtop dispenser to deposit solution onto the conjugate pad material through the IsoFlow atomizing nozzle (a pressure spray nozzle). The current dispensing conditions for the conjugate pad are in the table below. After deposition of conjugate solution is complete, the pad is then dried at 37°C-50°C for 1-2 hours.

| Parameter | Dispensing Condition |
|---|---|
| **Dispense Rate** | 0.5uL/mm (titer testing 0.4, 0.5, 0.6uL/mm) |

| | |
|---|---|
| **Dispenser Height** | 5mm from pad |
| **Dispenser Pressure** | 3-4 PSI |
| **Nozzle Speed** | 20mm/second |
| **Spray Location** | 7mm from edge of pad |

Web will be depositing the conjugate solution directly to the Ahlstrom 8964 pads (unsupported) in a reel format. Web will attempt to deposit with an AirJet dispensing tip, which is also 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 Catalloid 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.

## E. NCM/SAMPLE PAD BLOCKING

This product does not require NCM or sample pad blocking.

## F. LAMINATION PROCESS

Web 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".

Catalloid currently laminates cards by hand. The overlap targets and tolerances for the different pad materials are not known.

See table below for the provided overlap targets.

| Overlap Position | Target |
|---|---|
| Conjugate pad – NCM | NA |
| Absorbent pad - NCM | NA |
| Overlabel – Conjugate pad and Absorbent Pad | 5mm |

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

**MITIGATION**: With limited lamination specifications Web will perform an initial feasibility study to determine the overlaps of the pads to the NCM based on the placement target described in the Catalloid document. The determined overlaps and overlap tolerances held by the Web 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.

## G. CUTTING PROCESS

Web 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 Catalloid 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 Web's equipment.

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

## H. IN-PROCESS TESTING

Web defines testing that is required at each manufactured step as a Control Plan. This overall plan will include in-process testing and quality testing. Web 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.

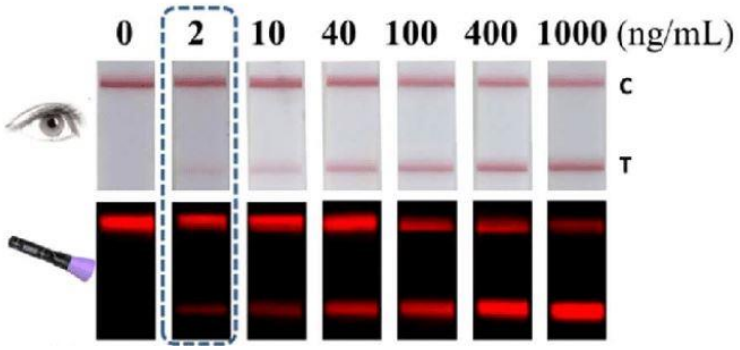
Catalloid currently tests the conjugate pad prior to final build as well as the final built cards using the following sample method:

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.

Currently, no testing is being performed to ensure the appropriate function of all of the major components individually (i.e. MRSA-NAG conjugate and Conjugated Gold). Rather Catalloid is currently testing the components as the final mixed conjugate used for deposition. Web will need to develop appropriate independent testing for each of these conjugates. This may require retains of past Catalloid conjugate materials. This hurdle is currently being evaluated, with simultaneous testing of individual strips.

The following figure demonstrates the current strip testing, incorporating fluorescence. Applying specialized wavelength of lighting may enhance the visibility of the control and test lines.




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

**MITIGATION:** Conservative sampling plans will be created by WIB, 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 Web according to the information provided by Catalloid regarding the current testing procedures used in development. In lieu of having certain testing procedures, Web will work with Catalloid to develop these processes.

**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 Catalloid. If the reader is intended to be used to release materials, the reader output needs to be attributed to each respective control level. Catalloid will need to provide data to show what ranges of reader values are acceptable for each control level.

## I. 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.

## J. FINAL PACKAGING

The final packaging for the MRSA AptaSure test strips will be determined by Invenio. Several design models have been selected, however final dimensions will be known by mid-2020, when testing/validation of final strips has concluded.

## K. QUALITY CONTROL MANUFACTURE

Web will be responsible for the sustainable manufacture and tracking/trending of Quality Controls used in the testing of the device. Currently, Catalloid 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 Catalloid. 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 Web's IRB procedures. This process will occur in mid-2020, once strips have undergone complete review.

**RISK:** Inequivalent performance of quality controls manufactured by Web.

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

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

**MITIGATION:** Web and Catalloid are reviewing e 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:** Clinical matrix samples do not exhibit same performance in comparison to QC control panel.

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

## L. QUALITY TESTING

Web has performed quality control testing based on an overall Control Plan that incorporates testing at each stage of manufacture as a gated process (see table below). The full definition of the Control

Plan will need to be developed to be statistically relevant to the manufacturing process and in accordance with any regulatory needs of Invenio.

| TESTING STAGE | MANUFACTURING STAGE |
|---|---|
| Batch Match (Pilot Testing) | Post solution manufacture, prior to batch solution manufacture |
| Deposition | Post deposition of NCM/Conjugate |
| Final Lamination | Post lamination |
| Cutting | Post-cutting |
| Final QC | TBD (product and lot size based) |

## M. FACILITIES

Web 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. Web will produce general buffers and solutions using water that meets or exceeds ASTM Type I specifications.

These facility standards meet requirements set by Catalloid/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.

## N. REGULATORY

Web 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 Web's 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. Web Industries has been capable of meeting the regulatory requirements for this product.

# ANNUAL CONSOLIDATED FINANCIAL STATEMENTS

10:09 AM
02/25/20
Cash Basis

## Invenio Medical, Inc.
## Profit & Loss
### January through December 2019

| | Jan - Dec 19 | Jan - Dec 18 |
|---|---|---|
| Ordinary Income/Expense | | |
| Expense | | |
| Business Licenses and Permits | 0.00 | 519.86 |
| Computer and Internet Expenses | | |
| Hardware | 1,129.10 | 1,603.04 |
| Services & Subscriptions | 1,987.84 | 4,296.34 |
| Software | 0.00 | 488.72 |
| Total Computer and Internet Expen... | 3,116.94 | 6,388.10 |
| Dues and Subscriptions | 935.27 | 359.88 |
| Legal Services | 468.00 | 2,223.00 |
| Marketing | 0.00 | 1,500.00 |
| Meals and Entertainment | 0.00 | 424.91 |
| Office Supplies | 0.00 | 182.41 |
| Postage and Delivery | 31.55 | 85.02 |
| Processing Fees | 25.00 | 250.00 |
| Professional Fees | 509.90 | 125.00 |
| Research and Development | 28,498.17 | 99,700.00 |
| Supplies | | |
| Lab Supplies | 0.00 | 1,243.31 |
| Supplies - Other | 0.00 | 80.00 |
| Total Supplies | 0.00 | 1,323.31 |
| Taxes | | |
| California Franchise tax | 800.00 | 823.00 |
| Delaware taxes | 549.00 | 0.00 |
| Penalties and fees | 92.32 | 0.00 |
| Taxes - Other | 0.00 | -823.00 |
| Total Taxes | 1,441.32 | 0.00 |
| Telephone Expense | 0.00 | 1,615.35 |
| Travel Expense | 2,795.61 | 7.00 |
| Total Expense | 37,821.76 | 114,703.84 |
| Net Ordinary Income | -37,821.76 | -114,703.84 |
| Net Income | **-37,821.76** | **-114,703.84** |

10:13 AM
02/25/20
Accrual Basis

**Invenio Medical, Inc.**
**Balance Sheet**
**As of December 31, 2019**

| | Dec 31, 19 | Dec 31, 18 |
|---|---|---|
| ASSETS | | |
| Current Assets | | |
| Checking/Savings | | |
| Chase Business | 64,922.19 | 102,743.95 |
| Total Checking/Savings | 64,922.19 | 102,743.95 |
| Total Current Assets | 64,922.19 | 102,743.95 |
| TOTAL ASSETS | 64,922.19 | 102,743.95 |
| LIABILITIES & EQUITY | | |
| Liabilities | | |
| Current Liabilities | | |
| Accounts Payable | | |
| Accounts Payable | 699.53 | 699.53 |
| Total Accounts Payable | 699.53 | 699.53 |
| Total Current Liabilities | 699.53 | 699.53 |
| Total Liabilities | 699.53 | 699.53 |
| Equity | | |
| Capital Stock-Class A | 2,000.00 | 2,000.00 |
| Capital Stock-Class C | 3,282.85 | 3,282.85 |
| Paid In Capital | | |
| Founder 1 | 3,811.69 | 3,811.69 |
| Founder 2 | 2,346.90 | 2,346.90 |
| Founder 3 | 1,523.67 | 1,523.67 |
| Founder 4 | 800.00 | 800.00 |
| Investor Capital-In excess ... | 275,917.15 | 275,917.15 |
| Total Paid In Capital | 284,399.41 | 284,399.41 |
| Retained Earnings | -187,637.84 | -72,934.00 |
| Net Income | -37,821.76 | -114,703.84 |
| Total Equity | 64,222.66 | 102,044.42 |
| TOTAL LIABILITIES & EQUITY | 64,922.19 | 102,743.95 |

Telephone- Service and monthly cost for '800' number including voicemail system.

\Legal – Retainer for legal services & Application of Aptasure trademark.

Marketing (2018) - Creation of Aptasure video animation demonstration.

Research and Development- Phase I & II of Aptasure optimization, development of our own Aptamer for future availability assurance and testing.