

Business Plan Summary

Water risk threatens the health of global communities and the bottom line of numerous global corporations. Water system managers are challenged to meet the demands for quickly detecting an expanding list of waterborne pathogens. Emerging and chlorine resistant pathogens threaten the drinking water infrastructure and water treatment systems in developed countries while millions die in resource poor environments because test systems are too complex and expensive. Safe-H2O has a unique rapid detection technology for water pathogens that will shift the paradigm and improve how water managers and suppliers better protect their customers and better secure our valuable resource - water.

Products and Services

Safe-H2O's Rapid Pathogen Detection (RPD) System consists of an Analyzer (The RPD Pro) and consumables (reagents and sample membranes). The system is easy to use, portable, delivers rapid results and is cost effective. Our system will automate waterborne pathogen detection while reducing the cycle time for results. Currently, the fastest 'gold standard' water pathogen test (E coli) takes 18 hours; tests for difficult pathogens (everything other than E coli) take up to 2-14 days. Safe-H2O's water pathogen test system will deliver results in less than 4 hours. The RPD Pro Analyzer will also store results in a secure cloud based portal for easy data management. The cloud based data management system will be an additional service for our customers. This unique and powerful approach to water pathogen detection and data management will improve the effectiveness and efficiency of the pathogen testing market; positioning the RPD System to be the premier multi-pathogen detection system on the global market. We will also expand our offering to include an inline analyzer to detect and report pathogen contamination.

Company

Safe-H2O is a water bio-detection company based in San Jose, CA. The company's co-founders are: Dan Morrow, CEO; and Michael Jones, President. Dan has 20 years' experience in medical devices and life sciences, and has lead successful startups for the last 10 years. Michael has 20 years' business management experience in the US and global water safety markets, with direct and

distributor sales expertise. Along with Microbiologists, Bio-medical engineers and consultants, Safe H2O has utilized patented technology, making it significantly easier to detect waterborne pathogens.

Market

The total global water testing equipment and consumables market today is \$3+B with the pathogen testing segment at \$800 million; \$360 million in US. Annual market growth in the Asia-Pacific region is projected to be 12-18% while growth in the developed countries is expected to be in the 5-7% range. The pathogen testing sector is forecasted to grow ~ 10% annually over the next 5 years due to two key drivers: more pathogen testing in the Asia-Pacific market and an expanding list of pathogens of concern being monitored by the regulators like the EPA and the World Health Organization (WHO). It is expected that the total global rapid pathogen testing market will exceed \$1.6B in 2020. The market is a mix of regulated water (primarily global potable water and some commercial water – Legionella in the EU) and unregulated segments. Global water utilities are required to test potable water for Total Coliform and/or E coli as indicators of biological contamination. This segment accounts for more than 65% of the market. The total coliform test is more of a surrogate however it is the most extensively used bacterial contamination test because it is fairly 'rapid'. Testing frequency is usually based on the size of the population served by the water utility, with U.S. utilities serving greater than 1M having to test their water more than 300 times per month. Legionella testing is required on a quarterly basis in the EU and NY State recently legislated the same for cooling towers as a result of the Legionella incident in the Summer of 2016. All other pathogen testing falls into the unregulated segment.

Customers

In the US there are approximately 9,000 large drinking water facilities which are required to test approx. 500,000 water samples per month for pathogens. Our initial customers are 4,000 of these facilities that are required to conduct the vast majority of the testing. We will also target the 1,200 commercial test labs servicing the drinking and wastewater facilities in the US. Key drivers for change are: overhead costs; direct cost per test; staff training for new pathogens; and data management. Customers in the global market's developed countries are structured in a similar manner. Customers in developing countries will come from a broader array of organizations: public and private labs and many entities concerned with potable water supplies and industrial water issues.

Market Strategy/Launch

Safe-H2O has identified 3 groups of key pathogens: *Legionella*, the combination of *Cryptosporidium Giardia (C/G)* and *E coli*, as the best initial assays for our product offering. Legionella outbreaks are increasing in the US and globally, C/G is one of the most expensive and difficult tests for water utilities using surface water and *E coli* is one of the recognized global indicators of waterborne pathogen contamination. After launching our system with these 3 assays we will quickly follow up with an *E coli O157:H7* assay to assist US water facilities in meeting the requirements of the Revised Total Coliform Rule (RTCR) which went into effect in April 2016. We will then bring to market assays to address the EPA's and WHO's full water pathogen list, along with assays for related water contaminants like microcystins. There are also emerging opportunistic pathogens like *P. aeruginosa* and the brain-eating amoeba *Naegleria fowleri* that we will target in the near future.

We will partner with commercial water treatment providers currently focused on the Legionella segment. This market segment, current size estimated at \$400M, has been a strategic focus of Safe H2O since inception and we have formed and cultivated strong relationships with key market segment leaders. Our goal is to select the best strategic partner to facilitate global penetration of this lucrative and growing market. We have developed similar relationships with water utilities who analyze for C/G and E coli and we will convert trials into sustainable revenue streams while building global awareness and preference for our offering.

Safe-H2O will have a direct sales force for the US, potentially augmented by manufacturing reps. We will utilize distribution partners in Europe and Asia through already established networks. We will also participate in key global water conferences.

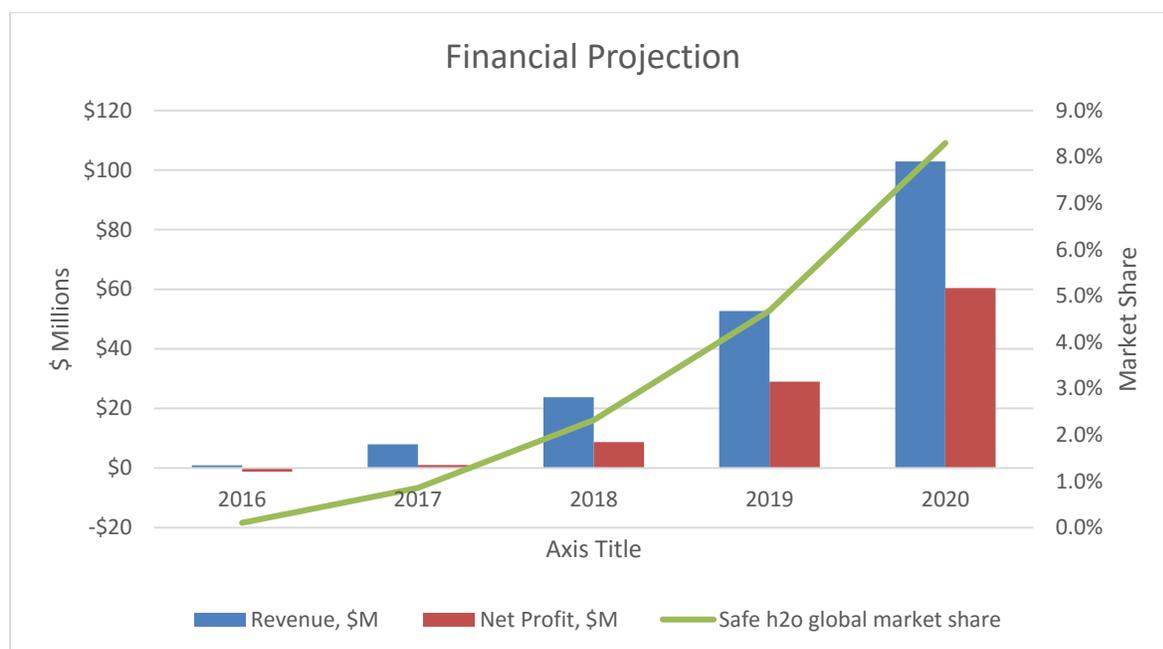
Business Model

Safe-h2o will sell Analyzers together with the consumables, a recurring revenue program similar to the printer & ink cartridge model. We will capture customers because our system will save the labs time and money. Introduction of new assays for pathogens will help the labs quickly scale to changing customer needs while allowing Safe-H2O to further penetrate the water utility segment and branch into additional commercial water (like food wash and prep water) and tangential water markets (like recreational water for microcystins and cholera, etc.).

Tests for difficult pathogens will be priced competitively, while the Analyzer price is within most water organizations annual budgets for a relatively short sales cycle time.

By providing a portal with both sales support and data tools, the Company will build customer loyalty and the library of assays expands to address new opportunistic pathogens.

Financial Projection



Technology

The RPD System utilizes unique fluorescence scanning spatial cytometry technology to automate complex pathogen assays. The technology was developed by ReaMetrix Labs. The RPD Pro analyzer consists of 4 primary modules: optics; laser; electronics; and mechanical. Enriched water samples are mixed with reagents and pipetted onto a membrane Disk. The Disk is placed in the analyzer and the system does the rest. Fluorescent sensors measure the amount of captured analyte on the membrane; providing a direct total count for the targeted viable organisms. The technology supports a broad assay menu. The technology is protected by a broad portfolio of patents and licensed to Safe-H2O for waterborne pathogen tests.

Competition and Competitive Advantage

The competitive technology is dominated by large analytical suppliers providing the slow, media based detection systems that have been the standard water pathogen test for over 50 years. Some newer competitors offer qPCR for it's rapid results however this technology has limitations that the Safe H2O approach readily overcomes. No competitor has a rapid, cost effective, multi-pathogen detection system.

Competitive Method Comparison:

1. DNA (qPCR RT-PCR) tests
 - a. Determines the amount of the targeted DNA in a sample, but cannot estimate cell count.
 - b. PCR inhibitors in tap water introduce additional inaccuracies.
 - c. Cannot differentiate between live and dead cells
2. Lateral Flow Tests
 - a. Qualitative, go-no go
 - b. No differentiation between live and dead cells, thus no CFU count / volume.
3. Safe-H2O RPD Lg Test
 - a. Immuno-magnetic beads with fluorescent labeling – compatible with all types of water.
 - b. Reader utilizes live / dead assay capability to only count live cells.

Our competitive advantage is an easy to use system, with lower cost of acquisition, lower cost per test and significantly lower time to results than competing alternatives. We will save the end user both time and money while providing the results they need to make actionable decisions.

Operations Plan

During our first 18 months, we used incubator wet lab space at QB3 to optimize our first waterborne pathogen tests. We then relocated to ReaMetrix@San Jose to build production prototype Analyzers and set up our supply chain. Utilizing a bench top assembly line we built Prototypes and reagent kits. Using data from these initial systems got early trials set up with potential customers and will soon initiate the test approval cycle for C/G with the EPA. The Legionella market in the US is currently not regulated so there are fewer barriers to going to market. We do intend to pursue *Legionella* test certification via AOAC/AFNOR. The next milestone will be full commercial launch with a successful A Round. We will build a US sales

and marketing team while expanding the development team and setting up operations to support sales. Key to the in-house team will be a world class assay development group focused on expanding our menu of pathogen disks to support customer requirements. US sales will drive the Company to profitability in 2017, simultaneous with sales expansion to Europe and Asia-Pacific via a network of global distributors.

Team

The initial Safe-h2o team is the two co-founders in addition to a microbiologist and a biomedical engineer. The team is augmented by content experts in sample preparation; assay development; and end user experience. With the production prototype systems validating product performance, Safe-h2o will then carry our mission to significantly improve water pathogen detection forward with an operational team focused on customer requirements and improvements. Our engineers and biologists will develop the instruments, kits and software. The R&D team will also manage co-development work with our consultants and strategic partners. Our operations team will manage the supply chain, inventory, and quality and maintain a strong relationship with regulatory agencies.

Research and development is tasked with delivering new products to the operations team. The team covers four technical areas: Instrument, Disk, Assays, Sample preparation and Software/Web. Instrument group both develops the instrument and integrates the Disk, Assay, Prep and Software/Web components.

Investment

Pitching to Angel groups, followed by positive due diligence reports has brought the company initial Seed funding. The \$700K Seed Round, based on a \$2M pre-money valuation, was completed early Q3'15. With customer validation in progress, Safe H2O also initiated a Pre A Round of \$700K to accelerate the launch of the Rapid Legionella assay. A \$3M A Round is scheduled for Oct'16. The Due Diligence Report (available on GUST) forecasts 100% IRR or 14 X ROI. There are M&A opportunities for water diagnostic companies with disruptive technology. In 2013 a competitor was purchased for 6.5X revenue.