DiscoveryDX

Building the Leading Infectious Disease @HOME Diagnostics Company

Business Plan

For more information:

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Please watch our investor video: https://vimeo.com/434812663/23be9ef6a3

As Things Stand Today

At the end of 2019, few people knew much about viral infectious-disease testing, and even less cared. It has since become a major topic in households around the world because of COVID-19. In the past, the slow, bureaucratic, and expensive testing methods were tolerated. Today fast, simple, and low-cost diagnostics are demanded.

Introduction

DiscoveryDX (Diagnostics) will disrupt the market in Point-of-Care Testing (POCT) for infectious diseases by developing an array of low-cost, easy-to-use diagnostic kits—utilizing patented molecular switch technology—to produce rapid, reliable, and highly accurate test results for consumers, patients, medical practitioners, and a vast commercial customer base. The first two tests being developed are for detecting the presence of active influenza and SARS-CoV-2 (COVID-19).

The Market

As of April 4, 2020, in the most recent 2019 – 2020 U.S. flu season, there were 39 – 56 million cases of flu leading to 410,000 hospitalizations and 24,000 – 56,000 flu deaths, according to the Centers for Disease Control.

To date, a confirmed 41 million people worldwide have been infected with the coronavirus, leaving 1.1 million dead. The COVID-19 diagnostic market is being created even as you read this business plan. Servicing the testing needs of the world is a multibillion-dollar international market.

The Problem

While the world's attention is focused on the novel coronavirus, another equally deadly contagion has long made its home in society. Annually in Europe between 40–110 million people are infected by the influenza virus, resulting in an estimated 150,000 deaths (in the 2018–2019 season). In the U.S. *every year* between 30 and 50 million people are infected, with 15–20 million requiring medical attention. 180,000–400,000 are hospitalized and between 10,000–60,000 perish—mostly the young, old, and immune compromised. Worldwide, seasonal influenza epidemics kill up to 650,000 people a year, according to the World Health Organization.

Yet with modern antiviral medications like **Tamiflu**® (*oseltamivir*) and its generics, influenza is thankfully a treatable illness—if detected early enough. However, current at-home consumer flu tests lack sensitivity, resulting in high rates of false negatives, i.e., the test says you don't have the flu virus when you really do. This delays treatment and the carrier unknowingly infects more people, often family members, friends and coworkers.

Typically, the way to be accurately diagnosed for an influenza infection is to visit a doctor's office and have a specimen taken and sent out to the lab for a sample-to-answer test (or cultured) which significantly delays the diagnosis. The test result usually comes back well after the doctor visit. This system is inconvenient, expensive, contributes to the spread of the virus and gives up some degree of personal privacy.

The situation for currently available coronavirus tests is that they are typically processed in laboratories in batches, with results being returned anywhere from 1 to 10 days later. Several dozen new POC rapid diagnostic tests for the coronavirus for use at a doctor's office have recently received FDA Emergency Use Authorization. Their performance and accuracy are not presently well-documented. A rapid, low-cost, easy to use, and accurate, (fully at home) test kit for COVID-19 does not currently exist.

What is urgently required in addressing both contagions is a very low-cost, simple to use, yet highly accurate *consumer* flu and COVID-19 diagnostic test for at-home use.

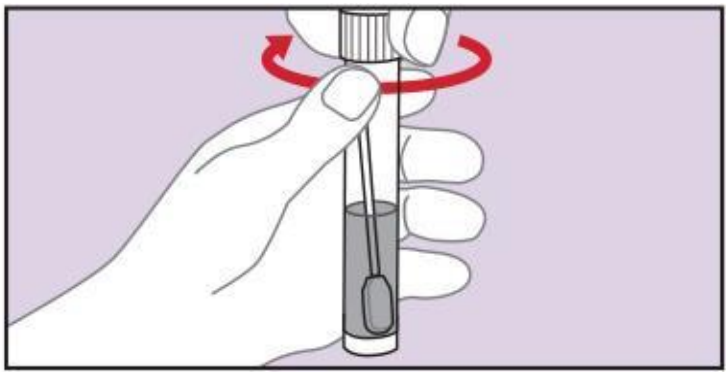
The novel **hinged peptide molecular switch** is the technology platform that could potentially provide this commercial solution.

The Solution

Based on groundbreaking university research, DiscoveryDX is developing early detection kits, one for coronavirus and another for influenza.

In both cases, a flu or coronavirus test will be run by obtaining a microbe sample from saliva, or by swabbing inside the mouth or nose and then placing the sample in a small receptacle of testing liquid.

If virus is present the testing liquid will change to a unique color specific to the type of virus being tested. (Blue for flu and yellow for COVID-19)



Prototype Mock-up
For Demonstration Purposes

This diagnostic product will be a significant breakthrough in the early detection of these dangerous infections, rapidly informing the patient's treatment choices.

For example, after a suspected exposure, and even before the first sign of symptoms of a cold, flu or coronavirus, the consumer could test themselves or a loved one and within minutes know if the person being tested (child, spouse, parent, grandparent) has a flu virus, the COVID-19 virus, or is free of either and just has a common cold, or nothing at all. If it is the flu, then the patient can take immediate action by consuming an antiviral product which can greatly reduce the severity of an influenza infection. If the result is positive for COVID-19, then isolation and early medical intervention can begin. In the case of young, elderly, and immunocompromised patients *knowing this result can mean a lifesaving decision*. Conversely, if the patient just has a common cold, then it's only a matter of relieving symptoms. If no virus is present, then the fortunate person can get on with their normal life.

These simple but accurate diagnostic tests will be possible thanks to a new biotechnology development: the synthetic molecular switch.

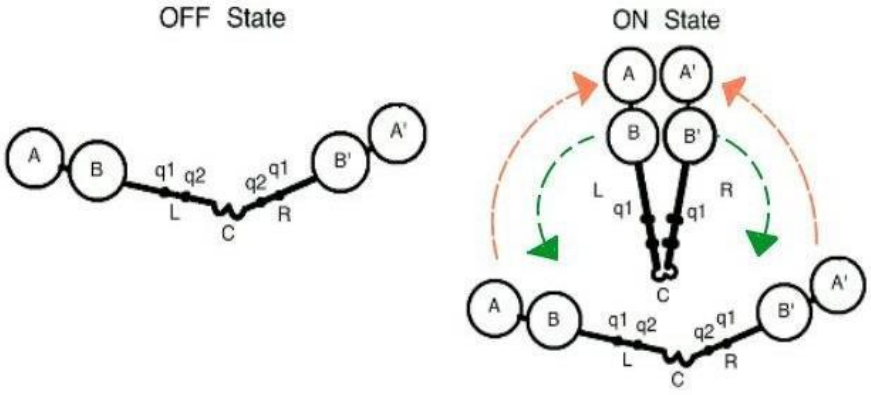
The Technology – The Molecular Switch

In its operation, a molecular switch resembles an electronic switch, much like what we use to turn on and off lights. However, a molecular switch is much, much smaller—it is a nanoscale "device." Molecular switches occur in nature; for instance, your retina uses photosensitive molecular switches for vision. (In a fraction of a second, they change and send an electrical pulse to your brain.). Natural switches either involve adding two molecules together or rearranging the structure of a molecule.

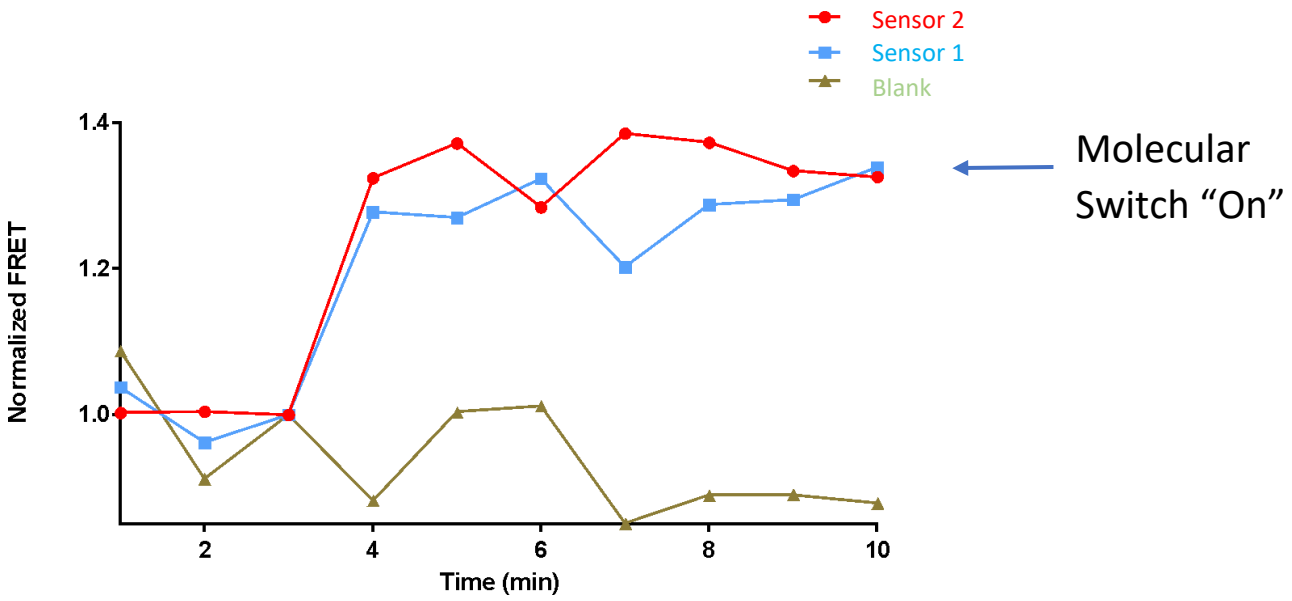
To increase the versatility and robustness of molecular switches for commercial use, researchers over the last two decades have been trying to synthesize new types, an effort which now has produced promising results.

Scientists at the University College Dublin (UCD) in Ireland have developed a novel molecular switch, called a hinged peptide, which offers a potential breakthrough for more accurate chemical assays (tests) than has previously been possible. Due to the hinged peptide's unique design, recent results show this molecular switch outperforming previous technology in sensitivity, stability, and robustness.

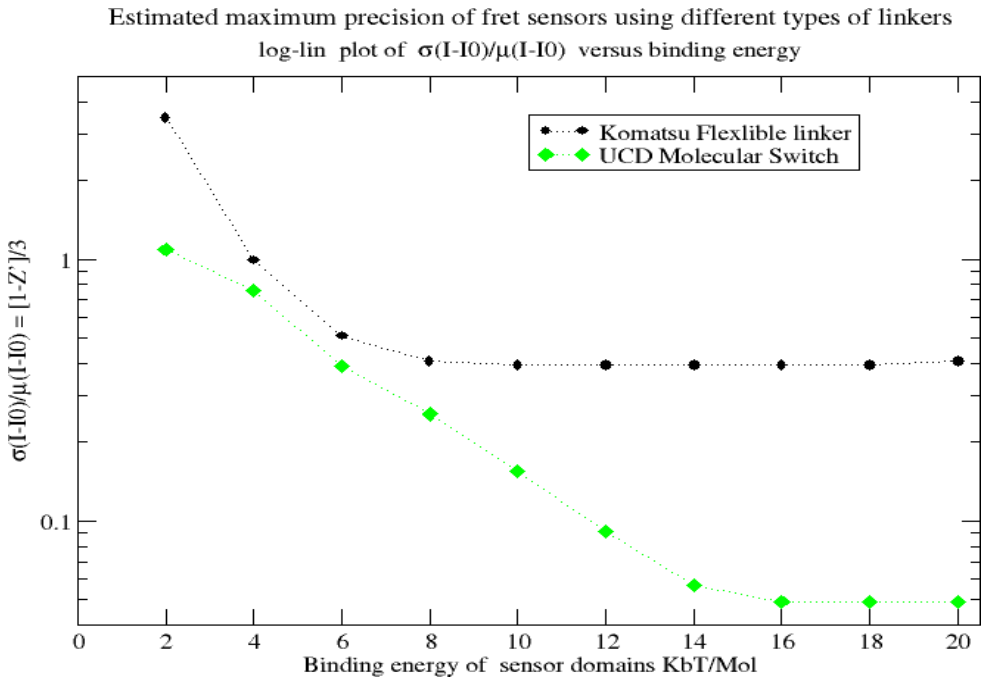
Hinged Peptide



The hinged peptide resembles a butterfly or a Venus flytrap. In the Open position it is "off" and in the Closed position it is "on."



The simplicity of the design is the secret to its accuracy and robustness over previous technical attempts.



The innovative UCD hinged peptide molecular switch has a superior signal-to-noise ratio at higher binding energies than the earlier Komatsu Flexible Linker (developed in 2011).

Market Strategy

The flu and COVID-19 test kits are being developed to have the following features:

- Very early detection (potentially 3 to 7 days before symptoms)
- Low false negatives (highly sensitive)
- Simple and easy to use
- Lowest cost (less than $1.00 manufacturing cost at scale)

The company will use a blended marketing approach of traditional advertising and heavy social media to drive direct sales, combined with frequent blog postings and interaction with key opinion leaders, to acquire mass market customers for in-home testing of COVID-19 and influenza. In parallel the company will pursue distribution through U.S. national retail chains like Rite-Aid, CVS, Walgreens and Walmart. Similar distribution partners will be teamed with for Europe, Asia and South America.

Three Markets, Three Divisions

There are three distinct markets to consider: 1) the Laboratory market, 2) the Commercial Market, and 3) the Consumer Market. The company has created three divisions to serve these markets.

The company's first product release will be to the Laboratory market in Q1 2021. There are 260,000 CLIA laboratories in the U.S. The company will provide these laboratories with a simple diagnostic protocol for detecting COVID-19 using the DiscoveryDX molecular switch technology. This test product will be suitable for very high-volume lab testing.

The company's second product will be targeted for release at the beginning of Q2 2021. Addressing the Commercial market, it will be able to test people 1, 3 or conceivably 5 days before symptoms. The classic example is screening passengers at an airport gate before they board a plane. Other applications include testing first responders, the military, schools, at border crossings, and anyone wanting to get into an NBA basketball game. This screening system will utilize a test-result reading instrument to maximize precision and testing rate. This is a business-to-business market; doctors' offices and clinics, corporate offices and hotels — anywhere there is POC serviceability.

The company's third product, for the Consumer market, is intended for use in the home. It is scheduled for release in the Q2 2021. This will become for the public at large what the classic pregnancy test became for women, a self-test product which will be simple-to-use, give accurate results in just 4 minutes, and cost only $20 on the shelf at Rite Aid, CVS, Walgreens and Walmart. Also sold online (See above).

Intellectual Property

UCD has had two worldwide patents issued on the key technology used in its design and development of the hinged peptide molecular switch. DiscoveryDX has an agreement with the university for **exclusive worldwide rights to the technology** for use in influenza and COVID-19 diagnostics, and as part of a biotech development program at UCD which the company is funding.

Competition

While there are many rapid influenza diagnostic tests available it is notable that all suffer from limitations in specificity, sensitivity, ease of use, cost and time to result. For instance, the BD Veritor™ Flu A+B POC, one of the leading tests, is approximately 80% sensitive (~20% false negative rate). The BD Veritor machine, sold only to doctors and healthcare professionals, sells for around $350 and the test sticks (slides) cost $10 for each one-time use.

The other 15 FDA approved RIDT tests to detect viral flu vary substantially in their sensitivity, from 40–69% (60% to 31% false negative rate).

The FDA is using emergency authorization to speed approvals for new COVID-19 diagnostic tests. All the COVID-19 diagnostic products in the market today need to be completed at a laboratory or doctor's office. A dozen companies are looking toward entering the coronavirus consumer/home testing market with COVID-19 diagnostic products. No fully-at-home COVID-19 consumer diagnostic test has been approved to date.

Management Team

Phillips W. Smith, Ph.D. — Chief Executive Officer and Chairman
A decisive leader with a 40-year track record as a team builder, mentor, and value creator with extensive experience with hi-tech start-up companies. He is a successful entrepreneur and prudent risk taker with extensive international experience in sales, service, and operations, most notably as Chairman of the Board at Taser International, where investors received a 50X payout in three years. He is a graduate of the U.S. Military Academy at West Point. He received an MBA at Michigan State University and a Ph.D. in Finance from St. Louis University.

Tony Materna — President and Chief Operating Officer
Mr. Materna has enjoyed a 25-year career in high technology and is the veteran of seven previous start-ups, two of which have gone on to be $100 million successes. He has held marketing, sales, senior management, and CEO positions with companies in electronics, computers, AI, test equipment, biotech, consumer products and digital outdoor signage. He is a graduate of the University of California, Berkeley with a B.S. in Mechanical Engineering.

Sarina Mohanty, Ph.D. — Chief Scientist
Dr. Mohanty was the Founder, CEO and Lead Scientist of Aptrix Biosystems, LLC, in 2008, where she developed an aptamer-based diagnostic platform for rapid, point-of-care detection of the infectious prion protein. As lead scientist, she raised seed-stage funding, conducted in-house platform development, and coordinated duties of CROs with in-house development to achieve R&D milestones. Dr. Mohanty is an inventor on the patent (2015) for the composition and use of the platform. Her work on transcription factor regulation elucidated the interactions between the HSF-mediated heat stress and the Akt/FOXO cell growth and survival pathways in *Drosophila*. She received her B.A. in Biology from the University of Virginia and received her Ph.D. and M.S. in Biochemistry and Molecular Biophysics from the California Institute of Technology in 2008.

Financing

The company is currently conducting a $15 million Mezzanine round at a $100 million valuation to fund productization and FDA clearance for market introduction in Q1 2021.

DiscoveryDX will be conducting an IPO to raise $50 million to drive sales growth at a $1 billion valuation after FDA clearance in Q1 2021.

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