moleculera labs

Overview– A Precision Medicine Diagnostics Company

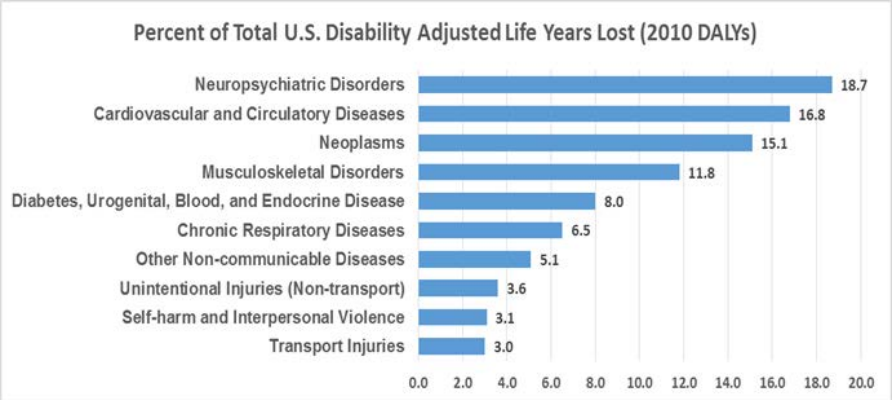
Moleculera Labs, Inc. is a revenue-generating biotechnology company focused on diagnosing neuropsychiatric disorders in children and adults. Moleculera's COLA/CLIA accredited clinical laboratory performs tests that direct specialized treatment for neuropsychiatric disorders ***caused by an infection-triggered immune system dysfunction***. This infection-triggered immune dysfunction mechanism, is an emerging area of medicine that may prove to account for a whole host of chronic and debilitating disorders that have been previously unresponsive to symptomatic medical treatments.

Moleculera's first-in-class test, the **Cunningham Panel™** is comprised of five assays that aid in the diagnosis of autoimmune-induced neuropsychiatric disorders that are treatable. Common symptoms include ***obsessive compulsive disorders (OCD), repetitive behavioral disorders, motor or vocal tics, verbal and non-verbal communication problems, and deteriorating social skills.*** A portion of these patients, especially children, may have been clinically diagnosed with Autism Spectrum Disorder, ADD/ADHD, Tourette's, Pediatric Autoimmune Neuropsychiatric Disorder Associated with Strep infection (PANDAS), Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)[1], and many other neuropsychiatric syndromes. Typically these patients have been treated with a wide variety of psychotropic drugs with little to no improvement. Patients that test positive, typically respond to anti-infective and immune therapy as the underlying immune system dysfunction is treatable. However, it is challenging for physicians to identify these patients who would respond without a laboratory test.

This panel was developed by Dr. Madeleine Cunningham at The University of Oklahoma, in collaboration with the National Institutes of Mental Health (NIMH). Her work and the science behind the panel have been described in multiple top peer-reviewed journals.[2] Moleculera is the only clinical laboratory in the world performing this panel, with a U.S. Patent that will be issued this year. Launched in 2013, ***over 6,100 test panels have been performed and over 980 doctors have prescribed the panel***. The Company's target market specialists include neurology, psychiatry, immunology, rheumatology, integrative medicine, and autism specialists.

Unmet Market Need and Large Opportunity

The NIH published that the total U.S. disease burden for neuropsychiatric disorders in 2010, exceeded heart disease and cancer. According to NIMH, over 20 percent of children in the United States, at some point during their life, have had a seriously debilitating neuropsychiatric or mental condition[3]. These disorders can be intensely difficult as parents watch their children suffering and pleading for help. The Child Mind Institute estimates over 17 million U.S. children are suffering from some form of mental or neuropsychiatric condition[4]. The Center for Disease Control (CDC) estimates that ***over 60 million children and adults*** suffer from some neuropsychiatric condition. Physicians, especially those familiar with neuropsychiatric conditions, are reluctant to treat neuropsychiatric symptoms with immune modulators without laboratory evidence to direct and support these changes in treatment decisions.



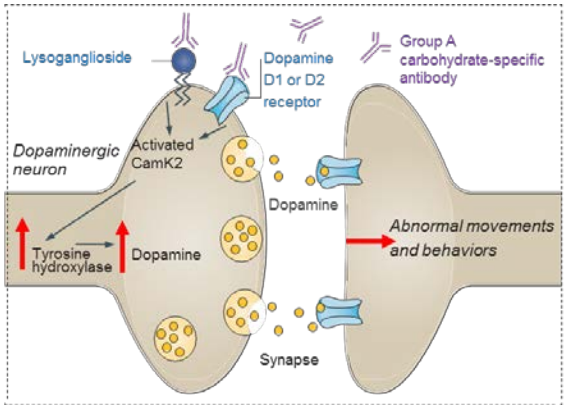
[1] The *Journal of Child and Adolescent Psychopharmacology*, February 2015, featuring the latest research on PANS PANDAS.
[2] Including a recent review by Dr. Cunningham published in *International Reviews of Immunology*, Volume 33, Issue 4 (2014).
[3] http://www.nimh.nih.gov/health/statistics/prevalence/any-disorder-among-children.shtml
[4] http://www.speakupforkids.org/report.html and Merikangas et. al, J Am Acad Child Adolesc Psychiatry. 2010 October; 49(10): 980–989.

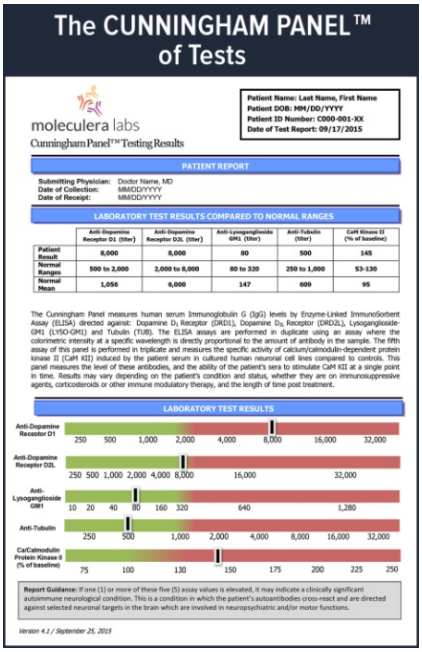
moleculera labs

Moleculera's First Commercial Solution

The **Cunningham Panel™** identifies common neuropsychiatric disorders that may have been triggered by an underlying immune system dysfunction in which antibodies cross-react and attack certain neurologic receptors producing these symptoms. The panel consists of five tests. Four tests measure circulating levels of autoantibodies directed against specific neuronal targets, including Dopamine D1 receptor (DRD1), Dopamine D2L receptor (DRD2L), Lysoganglioside GM1, and Tubulin. Autoimmune antibodies that bind to these targets can interfere or block normal neurologic activity in the brain. The fifth test targets CaM Kinase II, a key enzyme that is involved in the production of neurotransmitters dopamine, epinephrine and norepinephrine. The collective results provide an autoimmune neuropsychiatric assessment to aid the physician in a proper diagnosis and direct therapy. Moleculera estimates a market opportunity of greater than $500 million in the U.S. alone for its first commercialized test. In addition to individual physicians, the company is currently serving marquee medical institution customers including Stanford Hospital, Cincinnati Children's, and Kaiser Permanente, with international partner laboratories in Sweden and Denmark.

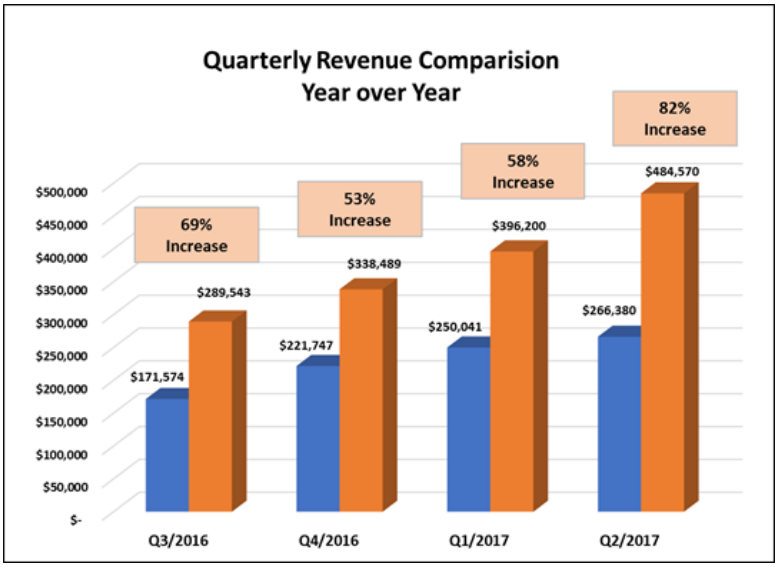
Antibody interference with brain activity





Moleculera Revenue Model and Reimbursement

Moleculera analyzes blood samples sent to its CLIA laboratory in Oklahoma City, OK. ***The Panel's list price is $925 with an average realized revenue of approximately $850.*** Once a physician places an electronic order, an e-mail is generated to their patient who pays a deposit of $425 in advance and the company bills their insurance under existing CPT codes with good reimbursement. ***The Company expects to reach profitability by December 2017*** and has generated to date, more than $4.9 million in revenue on $5 million in capital raised. Revenues for 2016 were ~$1.2 million, with 69% growth over the same quarter last year with a ***2017 run rate of about $2.0MM***. Moleculera Labs is the only laboratory performing this panel of tests, with about 20% of orders coming from out of the country.



moleculera labs

Leadership

Dr. Madeleine Cunningham is an internationally recognized leader in research on infection-induced autoimmune neuropsychiatric disorders, and is a tenured professor at the University of Oklahoma with over 130 authored publications in leading scientific and medical journals. In 2013, the **Cunningham Panel™** was made commercially available through Moleculera, co-founded by Dr. Cunningham and Dr. Craig Shimasaki. Shimasaki is a serial entrepreneur with over 33 years of biotechnology experience, starting his career at Genentech. Shimasaki has co-founded three companies, taken 5 laboratory tests through the FDA approval process, and directed two CLIA labs, raising over $60 million for these companies and taking one company public.

Growth Initiatives and Investment Opportunity

Moleculera is developing additional test panels for neurologic and neuropsychiatric disorders including schizophrenia, bipolar disorder, chronic depression and Parkinson's disease. The Company has over 3,000 annotated clinical specimens for development of algorithms for treatment, and R&D for additional conditions that resolve with immune treatment modalities. We are preparing for a ***future Series B Preferred capital raise of $5MM - $8MM*** within the next 6 months. The use of proceeds is to expand our U.S. and International sales and marketing and to increase our market share into hospital and institutional accounts, complete additional clinical studies in collateral neurologic and neuropsychiatric adult disorders, and expand our testing menu.

Exit and Return for Investors

The anticipated exit is either through an acquisition by a large publically-traded corporation in a related or collateral industry, or an IPO within 3-5 years. Between 2015 and 2016, similar companies in the same medical sector such as ours have been acquired at an average of 3.6x, to as high as 7.9x revenue.

For more information contact:

Craig Shimasaki, PhD, MBA
President & CEO
Moleculera Labs
www.moleculera.com
shimasakic@moleculera.com
(405) 239-5250