Discovering and Diagnosing Neuropsychiatric Disorders
Caused by an Autoimmune Response

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Moleculera Labs
Iterative Business Model: Integrated Discovery and Development for Dx and Candidate Tx

Clinical Development Program

- Symptom-Categorized Annotated Clinical Specimens
- Interactive Patient Studies with Clinicians
- Discovery of Candidate Disease Targets
- Complementary/CDx Diagnostics

CLIA/COLA Laboratory focused on Neuropsychiatric Disorders
# Moleculera Labs – Overview

<table>
<thead>
<tr>
<th>Biotech Company</th>
<th>Having a CLIA/COLA accredited laboratory, blood-testing services for neuropsychiatric disorders caused by infection-triggered immune dysfunction, that are treatable</th>
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<tr>
<td>Cunningham Panel™</td>
<td>5-panel test aids in diagnosis of chronic neuropsychiatric disorders in children and adults. We are the sole laboratory in the world offering this patented test.</td>
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<td>Started with PANDAS/PANS</td>
<td>17 million children afflicted with neuropsychiatric symptoms, 60 million adults with neuropsychiatric disorders, ADD/ADHD, OCD, CDD, Chronic Fatigue Syndrome, Autism</td>
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<td>Strong reimbursement</td>
<td>Priced at $925. Patients pay $425 and company bills their insurance. Hospitals are billed 100% of list price. Moleculera averages ~$855/ test</td>
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<td>&gt;5,500 tests completed</td>
<td>Since 2013 launch, more than 6,000 tests processed from more than 950 physicians in the U.S. and 20% internationally</td>
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<td>&gt;$4.7 million of revenue</td>
<td>~$5 million invested, generated $4.7MM in revenue, reaching break-even. Raising market expansion and target validation Round of $8-10MM Series B</td>
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<td>Targets and Treatment Response</td>
<td>~4,000 annotated neuropsychiatric disorder clinical specimens and key relationships with practicing physicians. Additional Dx/Tx candidate targets for ADD/ADHD, Epilepsy, Schizophrenia, Bipolar, Chronic Depression and other disorders</td>
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PROBLEM: Patients Labeled into Symptom-Based Categories

Common Symptoms

- Sensory Abnormalities
- Obsessions
- Sleep Disturbance
- Tics
- Repetitive Behavior
- Hyperactivity
- Changes in Handwriting
- Difficulty in School
- Bedwetting
- Aggression/Rage
- Irritability
- Separation Anxiety

Diagnostic Categories

- **Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)**
- **Autism Spectrum Disorders**
- **Developmental & Behavioral Disorders**
- **Neuropsychiatric Disorders**
- **Asperger's Syndrome**
- **Tourette's Syndrome**
- **Attention Deficit Hyperactivity Disorder (ADD/ADHD)**
- **Chronic Depression**
- **Pervasive Developmental Delay (PDD)**
PROBLEM: Current Medical Practice Treats Symptoms Rather Than the Underlying Root Cause

Neuropsychiatric Symptoms, Anxiety, Aggression, Rage, OCD, Tics, Depression, Hyperactivity, Insomnia, Phobias
MECHANISM: Infection-Triggered Autoimmune Neurologic Conditions

Microbial, Viral, Fungal Infection Occurs

Body Produces Antibodies That Recognize Infectious Agent

Antibodies Cross-React With Neurologic Receptors (molecular mimicry)

Reaction Disrupts Brain Function (friendly fire)
MECHANISM: Infection-Triggered Autoimmune Response through Molecular Mimicry*

- Guillain-Barré Syndrome
  - Campylobacter jejuni
- Sydenham Chorea
  - Group A Streptococcus
- Cardiomyopathy (myocarditis)
  - Coxsackie virus, Group A Streptococcus
- Crohn’s Disease
  - Gram-positive bacterial peptidoglycans
- Diabetes Type 1
  - Coxsackie B virus, rubella, herpesvirus, rotavirus
- Systemic Lupus Erythematosus (Lupus)
  - Epstein-Barr virus (EBV nuclear antigen -1)
- Multiple Sclerosis
  - EBV, measles and HHV-6
- Psoriasis
  - Streptococcus pyogenes (Streptococcal M Protein)
- Myasthenia Gravis
  - Herpes Simplex Virus Type 1 (gpD)

Broad Market Opportunity for Precision Medicine in Neuropsychiatric Disorders

Companion diagnostic success is based upon targeting the same mechanism-of-action as the treatment.

Autoimmune Etiology of Neurologic and Neuropsychiatric Symptoms

- Autism
- OCD
- Tics
- PANDAS
- PANS
- ADHD
- ADD
- Epilepsy
- Chronic Fatigue Syndrome
- Chronic Depression

moleculera labs
Links Between Neurologic, Psychiatric Disorders and the Immune System and Infection, exogenous triggers

Brain Function
(Neurological and Neuropsychiatric symptoms)

GENETIC PREDISPOSITION

Infectious/Non-Infectious Triggers
(Enviromental, bacteria, viruses, parasites)

Axis

Immune System
(inflammation, microglia activation, cytokines, autoimmune antibodies)

IMMUNE SYSTEM DYSFUNCTION
The Cunningham Panel™ Test

1) Anti-Dopamine D1
   Correlates with psychiatric symptoms

2) Anti-Dopamine D2L receptor
   Correlates with movement disorders

3) Anti-Lysoganglioside GM1
   Correlates with neuropathic symptoms

4) Anti-Tubulin
   Correlates with cognitive complaints

5) CaM KII Activity
   Correlates with involuntary movements
Autoantibodies Follow Patient’s IMPROVEMENT in Symptoms Post Treatment

RECOVERED PATIENTS

Case study subjects (N = 37) during symptomatic episodes (symptomatic) and after symptoms improved or the subject recovered (Improved/Recovered)

**Anti-Dopamine D1 Receptor Titers**

**Anti-Dopamine D2 Receptor Titers**

**Anti-Lysoganglioside GM1 Titers**

**Anti-Tubulin Titers**
Autoantibodies Follow Patient’s NON-IMPROVEMENT in Symptoms Post Treatment

NON-RECOVERED PATIENTS

Case study subjects (N = 26) who did not improve/recover (Non-Recovered) symptomatic episodes (symptomatic)
Classes of Treatments Effectively Used

- Anti-microbials
- Steroids and NSAIDs
- Plasmapheresis (Plasma exchange)
- Intravenous Immunoglobulins (IVIG)
- Immune modulating medications
- Symptomatic Treatment
  - Cognitive Behavioral Therapy
  - SSRIs
Expansion of Testing Population by Prescribing Physicians

Neuropsychiatric Disorders in Children and Adults
- 60 million

Neuropsychiatric Disorders in Children
- 17 million

PANDAS & PANS Children
- 2-3 million

Neurological and Neuropsychiatric Disorders in Children and Adults
- 70-80 million

21% samples are adults

30% of samples autistic children (per ICD10 code)

Initial target market

Initial target market

30% of samples autistic children (per ICD10 code)

Initial target market
Completed research and patient studies ready for Laboratory Validation

Autoimmunity Against the Heart for Myocarditis, Afib and Heart Failure in Children and Adults

- 5 Autoantibodies directed against human cardiac proteins
- Causing Atrial Fibrillation and Heart Failure
- 25% of patients die or have heart transplantation by 3 years after diagnosis and only 60% attain normal echocardiograms during the same period.
- Tissue injury due to host immune system attack
Summary

Neuropsychiatric disorder and Cardiovascular focus in a large and expanding markets

Unique business model for discovery and development of Dx and candidate Tx targets

Thousands of annotated, symptom-based, Informed Consent specimens

Synergistic research and clinical development with practicing physicians

Ongoing source of increasing revenue from laboratory service model

Seeking strategic partnership for IVD Kit Platform Format and Next Kit development
Thank you!

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