prevacus

PresolMD, LLC

PresolMD, LLC is new joint venture in partnership with Prevacus, Inc. PresolMD, LLC has formulated and will bring to market the world's first brain injury prophylactic demulcent, branded **PreVPro™**. Prevacus is a neuropharmaceutical company focusing on new treatments for concussions, Niemann-Pick Disease, ALS and Chronic Traumatic Encephalopathy (CTE). **PreVPro™** is a natural proprietary formulation designed for the protection of cerebral extracellular matrix tissue from destabilization from active events resulting in concussion. While Prevacus treatment requires FDA approval for use after a concussion is sustained, **PreVPro™** is a nutraceutical that can be given prior to engaging in contact sports or any high-risk contact events and be onboard in the brain, ready to halt the pathological cascade associated with concussion.

PresolMD, LLC Formed:
July 2019

Company:
Consumer Products

Markets:
Health & Wellness
Organized Sports
Integrative Medicine
Sport
Medicine
Injury
Prevention
Military
Geriatrics

Initial Product Suite:
PreVPro™

Capital Sought:
$2,000,000 Equity

Pre-Market Valuation:
$20,000,000

Experienced Team:

Jake VanLandingham, Ph.D.
CEO, Prevacus, Inc.

Mike Lewandowski,

Chief Scientific Officer,
Prevacus, Inc.

David Lee, MD

Chief Medical Officer

Neurologist

Product Launch:

4th Quarter 2019

The Problem

Concussions causing Traumatic Brain Injury (TBI) are not preventable and are caused by motor vehicle accidents, falls, sports injuries, military duty and other at-risk work environments. Among children, most concussions happen on the playground, bike riding, skateboarding, or playing football, basketball, or soccer.

Each year, TBI causes a substantial number of deaths and leads to life-long disability for many Americans. In fact, TBI's contribute to about 30% of all injury deaths in the United States. Annually there are:

- Approximately 5 million concussion-related physician visits
- Approximately 288,000 hospitalizations from TBI
- Nearly 57,000 deaths related to TBI, and
- Lifetime economic cost of TBI's in the US is over $76.5 Billion a year

The exact short-term and long-term effects of concussion are still evolving. Data shows concussions are cumulative, and repetitive head trauma from participation in contact sports and military service can lead to permanent decrease in brain function. Long-term effects include vision problems, memory deterioration, impaired balance, loss of coordination, and persistent headaches. Concussions lead to disorders such as early Alzheimer's disease, Dementia, Parkinson's disease, PTSD, and anxiety disorders.

Currently there exists no means of preventing traumatic brain injury resulting from concussion.

PreVPro™

Our Solution

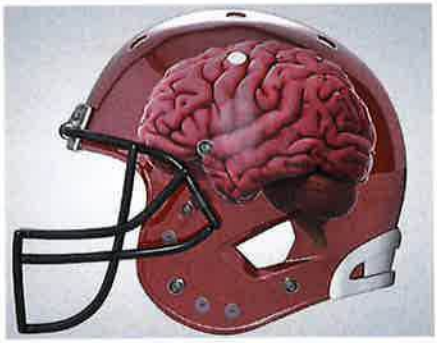
Protection by **PreVPro™**. transdermal application may be the most important deterrent to post-concussion syndrome, PTSD, ALS and CTE.

Presence of **PreVPro™**. active ingredients prior to a concussive event can protect the brain's delicate wiring against the resultant neuro-inflammatory cascade that causes damage to the delicate structural integrity.

- Breakthrough Support for Concussions
- The Only Choice in Prevention & Protection
- Clinically Tested for Safety
- No Steroids, No Opioids, No Banned Substance

PreVPro™ and Traumatic Brain Injuries

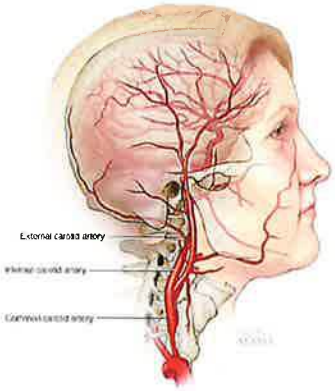
Increasing concern has been directed toward traumatic brain injury (TBI) especially that which occurs during contact driven sports (NFL football). In particular, post-concussion syndrome, PTSD and Chronic Traumatic Encephalopathy (CTE) are three TBI attributed conditions which have gained notoriety. Trauma induced injury to the brain involves a complex series of events divided into two major components: 1) primary injury which occurs at the time of impact and 2) secondary injury which involves delayed cell damage.



Delayed cell damage results from a cascade of inflammatory processes which promote overcorrections by the body's repair mechanism. They include but are not limited to COX, nFkappaB, and resultant cytokines which are activated and released into the brain's extracellular matrix (ECM) providing a feed forward destructive process of neurons and axons. Additionally, the blood brain barrier (BBB) can be compromised resulting in a "leaky" brain scenario leading to further damage of neural function

The microenvironment of the brain's extra-cellular matrix (ECM) concerned with maintaining homeostasis, immune response and repair involves both astrocytes and glial cells. These cells are involved in amyloid /Tau protein over production which adversely effects the ECM. In a similar fashion, we can further extrapolate from the patent that concussions and sub concussive blows (CTE) impact the delicate structural integrity and electrical wiring of the brain by disturbing the ECM. A remedy to this problem requires restoration or stabilization of the ECM allowing for repair and interruption of overcompensating repair mechanisms. Preliminary studies indicate that natural compounds contained in **PreVPro™**. such as EGCG, resveratrol, curcumin, and sulforaphane can stabilize the brain's ECM. Ideally, using **PreVPro™**. transdermal preparation should be accomplished beforehand in order to limit immediate and delayed cell damage.

PreVPro™. cream has a distinct advantage in delivery of these natural ingredients by providing physiologically active micromolar dosing as opposed to the lower nano/pico molar oral levels. Applying the transdermal preparation to the neck at the anatomical site of the carotid artery permits a direct conduit to the brain especially with a compromised or "at risk" BBB. Consideration as to the timing of application would suggest that if the compounds were onboard prior to the occurrence of a concussive event, they would be most beneficial. Since sub-concussive events are thought to play a role in pathological conditions such as post-concussion syndrome, PTSD, ALS and CTE, applying the **PreVPro™**. cream should be prior to contact events (military duty, sports, and leisure activities) in an effort to prevent resultant neuro-inflammatory cascades. Prevention by **PreVPro™**. transdermal application stands to be one of the most important deterrents to poor outcomes following concussion.



Executive Leadership Experience

Dr. Jake Vanlandingham, Founder & CEO. Prevacus, Inc.

Founder and President of Prevacus, Inc., to develop the world's first FDA-approved pos-concussion treatment as a nasal-inhalant neurosteroid (24M valuation.) Jake has a B.S. in Physical Therapy and spent 3- years working with neurologically impaired children with brain injuries in and around the time of birth. His Ph. D is in Neuroscience from Florida State University with a molecular biology focus on disease. His Post-doctoral work was in translational research and neurobehavioral aspects of diseases at Emory University. At Emory he also oversaw the clinical biomarker study for the ProTECT clinical trial using progesterone for acute treatment of severe to moderate TBI as the Assistant Director of the Brain Research Laboratory the largest laboratory in the Emergency Medicine Department. Jake has an excellent teaching record and has won multiple awards with both graduate and undergraduate students. He was a Year One Director of the Florida State University Medical School for 8 years before devoting all his' time to Prevacus, Inc. starting in 2015.

Michael Lewandowski - Chief Scientific Officer

Mike Lewandowski is a toxicologist turned entrepreneur with over 38 years of pharmaceutical development experience working with pharmaceutical companies and clinical research organizations to develop small and large molecule drugs. He is currently the Founding Principal and President of Global BioDevelopment, a consulting firm that specializes in pharmaceutical and medical device development services through strategic partnerships in the areas of manufacturing, formulation development, analytical and bio-analytical chemistry, pharmacology and toxicology, pharmacokinetics and drug metabolism, histopathology, experimental veterinary surgery, clinical pathology, regulatory affairs, and clinical affairs. Mike's experience includes creation of a histopathology company that has since been absorbed into a mid-sized CRO, serving as Director of Safety Evaluation at Scios, Inc., and Manager of Toxicology Studies at Genentech. While at Genentech, he was an important contributor for the preclinical development of several biotech drugs that ultimately made it to the marketplace. Mike started in the preclinical development business in 1975 with Baxter Laboratories, after graduating with a BS degree from Southern Illinois University.

David Lee MD, F.A.C.S – Chief Medical Officer
Orthopedic Spinal Surgery

A Member of American Association of Neurological Surgeons, Congress of Neurological Surgeons, Southern Neurosurgical Society, American Medical Association, Southern Medical Association, Southern Pain Society, North American Spine Society, American College of Spine Surgeons, American College of Surgeons and Mississippi Neurosurgical Society.

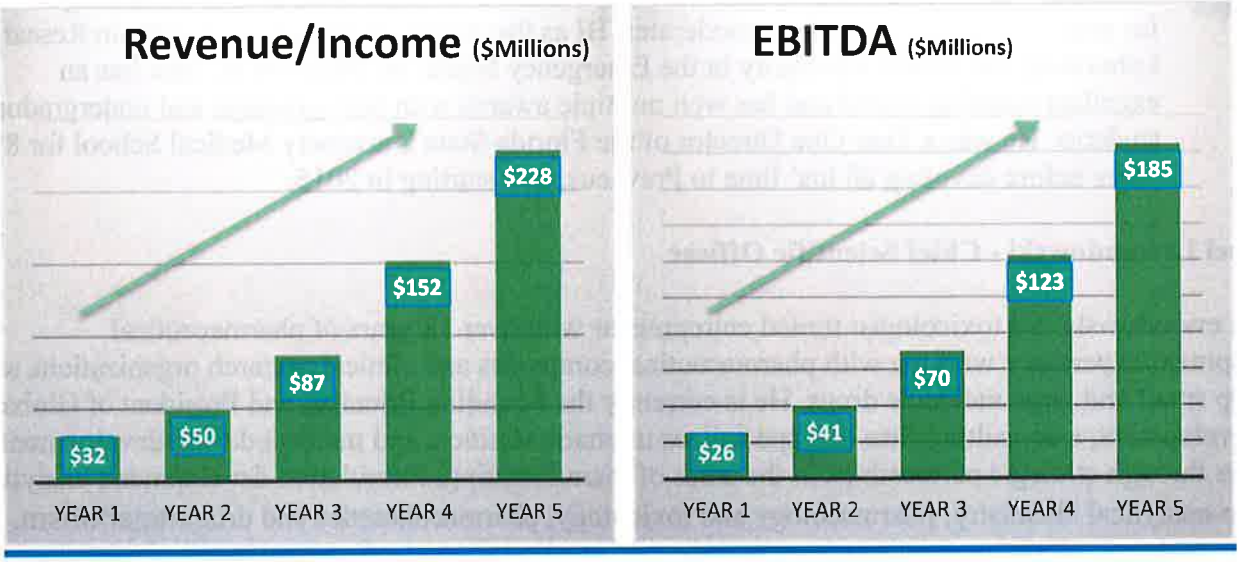
Brett Favre- Former American Football Quarterback
Professional Football Hall of Fame, Super Bowl Champion XXXI, Bowl Champion
Hattiesburg, Mississippi

Competition

PresolMD, LLC is the first mover into the market of concussion prophylactic preparations- PreVPro™. currently has no competition. We estimate that an aggressive national and international mass-marketing and distribution effort will result in market entry by big-pharma and other large multi-national consumer products companies within 2 – years.

Sales & Marketing Strategy & Financial Projections

The Company is finalizing the novel formulated and clinically testing PreVPro™. in partnership with the NFL Affiliate Groups currently. Pre-launch sales activities and planning for a national, mass-media campaign leading to a Fourth Quarter 2019 launch in the United States are also underway. The Company has already engaged with several prominent NCAA athletic programs, Professional Sports Teams as well as youth sports organizations. Future international connections and a novel focus on protecting the elderly will begin in the new year.



PreVPro™. includes a revolutionary group of natural botanical extracts that will invent the pre-concussion prophylactic market. Our network of nationally recognized, iconic sports figures and aggressive mass-media PR campaign will catapult PreVPro™. into the national spotlight. Our timing is perfect as global awareness has heightened regarding the long-term dangers of TBI, CTE, PTSD, and other conditions caused by concussions. Military applications alone can relieve billions in long-term health care burden. The Revenue displayed are anticipated, based on an

average of 10,000 units sold per month initially, with growth projections based on industry highs and lows.

The Company will initially focus on three outlets for product distribution and sales:

- Direct Sales through a PreVPro Distribution Network
- Internet Online Sales driven by proprietary customized software, that distributors will utilize for training, certification, marketing, and order processing.
- Military registration, approval and sales on the GSA and 2 other fee schedules.

PreSolMD, LLC Milestones Achieved to Date

- Since inception in June of this year, the Company has achieved the following:
- Completed a unique formulation of botanical ingredients that provide a cascade of benefits to the brain.
- Met the production and manufacturing timeline for the first 10,000 units of PreVPro™ to be released in November 2019.
- Designed and completed two dog studies to demonstrate entry into the brain, peaking at 2 hours and remaining there for 6 hours.
- Conducted 3 PreVPro™ Voluntary Safety Studies on 63 children
- Provided Product Samples and cultivated relationships with 6 NFL Active Teams and 100 NFL Retired Players. Next Target is the NBA and College teams.
- Recruited NFL Active and College Players and Spokespersons to serve as Ambassadors for the product including Brett Favre, Byron Williams, Mark Rypien, David Ross, Abby Wambach, Steve Mariucci, Ed 'Too Tall' Jones, Kurt Warner and others.
- Recruited an Executive Management Team to launch operations in July of 2019
- Trademarked PreVPro™
- Raised $650,000 in investor funds
- Introduced Prevacus and PreVPro™ to the DOD through discussions with Dr. Dwayne Taliaferro, Head of all Congressionally Directed Research. A presentation to his team on PreVPro™ and Prevacus at Fort Meade is being scheduled for by year end.

Funding

The Company is seeking $2 Million for the initial funding that will allow it to fully execute the Company's business and growth plan. The Company continues to attract investors including strategic partners that add value and expertise that benefits the Company and the Company's stakeholders.

Use of Proceeds:

- Sales Operations
- Manufacturing/Inventory
- Multi-media Marketing Activities
- Research
- Growth Capital

Value Proposition/Highlights

- First mover into a vast market with no competition.
- Partners are nationally recognized celebrities and professional sports figures and with significant marketing power and social media following.
- Cross and multi-channel distribution model in a vast global market provide initial stability and great revenue growth potential.
- Novel product backed by decades of clinical research and proprietary ingredients and processing methods that are technically difficult and cost prohibitive to duplicate, create significant barriers to market entry by competition.

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PresoIMD, LLC

Contact: Jake Vanlandingham

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As illustrated:

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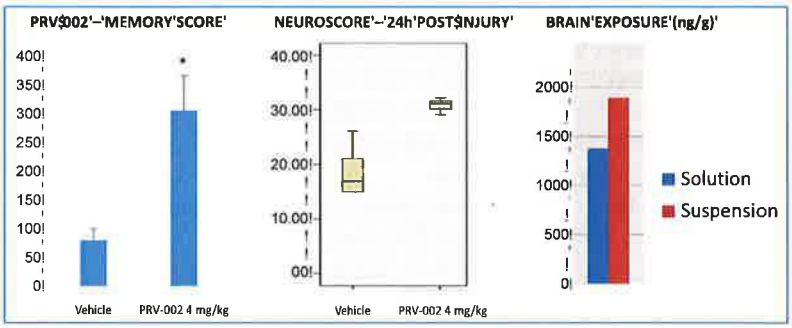

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- Use of PRV-001 and PRV-002

In Preparation

- Solid state chemistry
- Formulation
- Next-generation analogs

Current development status (reflected in the timeline below):
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Financials and Valuation:
To date, Prevacus Inc. has raised approx.11 million dollars of private and State funding in support of API manufacturing, preclinical research and development, formulation and toxicology/safety studies. We are currently seeking $8.75 million dollars in funding to initiate and complete Phase 1A/B Clinical Trials and synthesize all drug needed and FDA requirements for Phase 2 Clinical Trials. The current tranche which covers Phase 1A/Formulation/Fill and Finish is 3.5M of the 8.75M at $1.25/share. We are currently working with members of a public and private alliance to complete this raise including Large Angel Groups, Venture Capital, NCAA, the Department of Defense, Hospitals, Foundations and Professional Sports Leagues.

Management Team:

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- Ph.D. in Neuroscience (Florida State University)
- Assistant Director of Brain Research Laboratory, Emory University
- Over 18 years of experience in Neuroscience research
  - Published on effects of neurosteriods on recovery following head trauma
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Dr. Robin Allgren- Clinical Advisor

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- Over 25 years of experience in product development, clinical trials and FDA interactions
- Past VP of Clinical Development and Senior VP of Product Development – pre-IND through NDA

Dr. Deepa Deshpande- Regulatory Affairs Specialist

- Ph.D. in Pharmaceutical Sciences (West Virginia University)
- 20 years of experience
- Domestic and international regulatory expertise

Key Advisory Members and Associates:

Medical

- Jack Khattar –President and CEO of Supernus Pharmaceuticals
- Alex Lin-Neuroradiologist, Brigham and Women's Hospital in association with Harvard University
- Derrick Henneke – MBA, President and CEO of Xcellience
- Steve Jordan– Orthopedic Surgeon, Andrew's Institute
- James Andrews- Orthopedic Surgeon, Andrew's Institute
- Jay Alberts – Bioengineer, Cleveland Clinic
- Frank Carruba – CEO Neurologix
- Ronald Hayes – Neuroscientist, Banyan Biomarkers
- Michael Hoffer – Navy Officer and Neuroscientist, Miami University
- Dorothy Kozlowski – Neuroscientist, DePaul University
- Jay Clugston-Team Physician University of Florida, PI CARE Consortium
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- Health and Human Services, Mississippi

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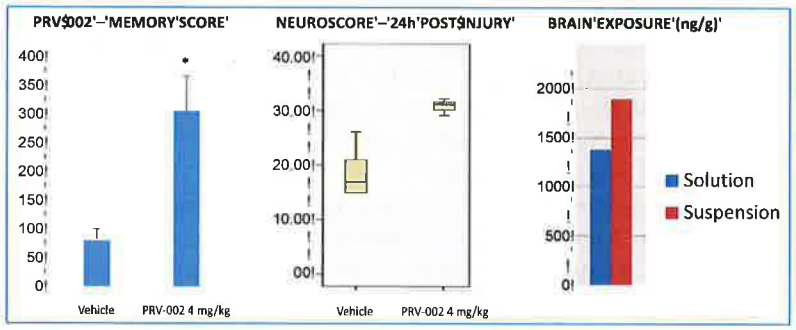

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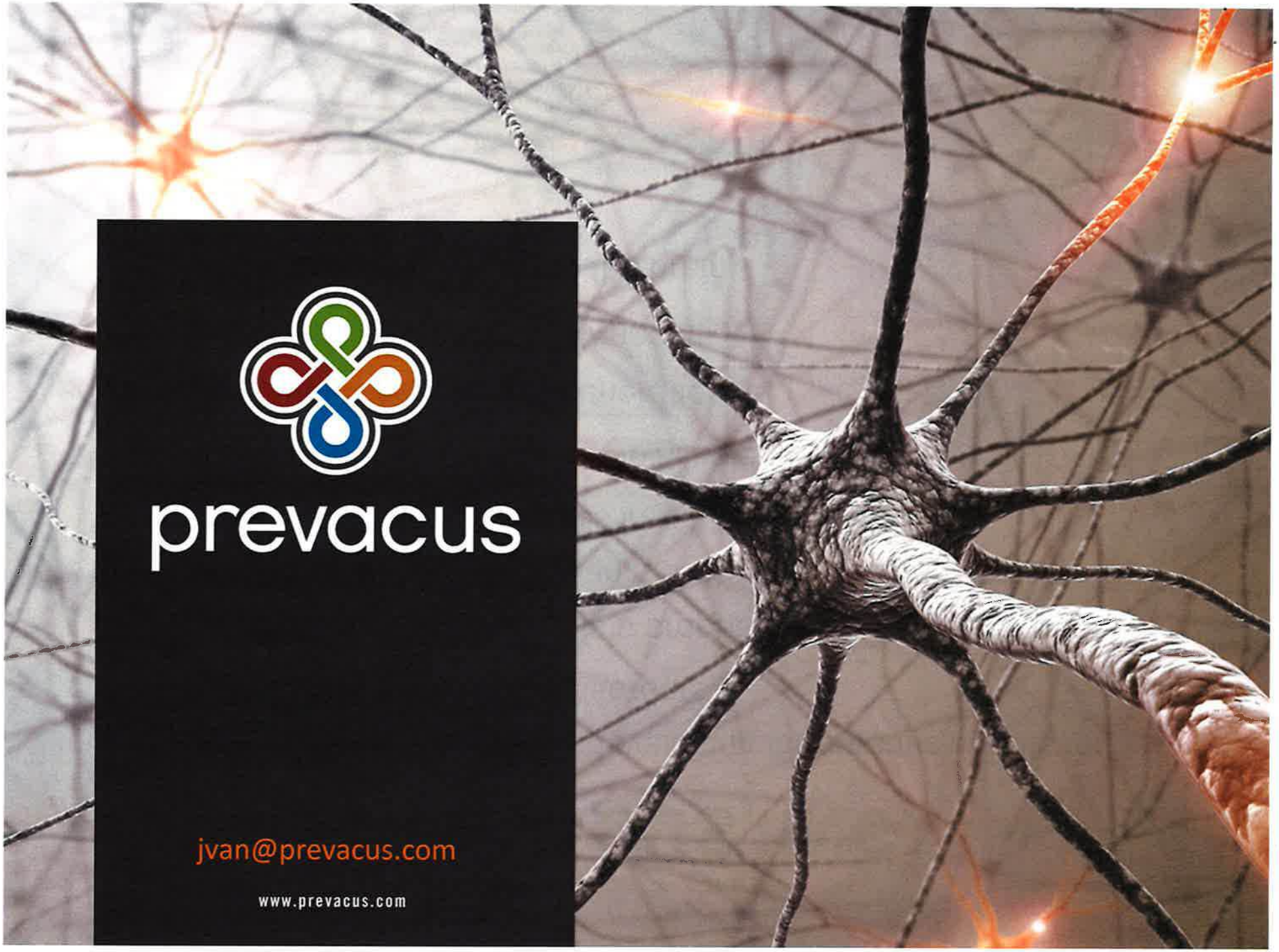

prevacus
jvan@prevacus.com
www.prevacus.com

PREVACUS, INC.

- A clinical stage company developing therapeutic agents for concussion and related disorders
- Lead molecule PRV-002 is a proprietary neurosteroid with proven in vivo efficacy in animal concussion models and safety in toxicology studies in rat, monkey and dog.
- 15 other novel analogs are available

  for future research and generations
- Intranasal delivery of PRV-002 allows

  rapid targeted delivery to the brain

ABOUT mTBI

- **Concussion**
  - a type of traumatic brain injury, or TBI, caused by a blow to the head or upper body causing the brain to shake inside of the skull….. 'the slinky effect'

- **Symptoms and Outcome**
  - a change in mental status such as amnesia, disorientation, mental fogginess, confusion, nausea or vomiting, blurred vision, headaches
  - at least 21 distinct symptoms are known to be caused by concussion

CONCUSSION

- Mild Traumatic Brain Injury (mTBI or concussion) represents a significant **unmet medical need**
  - > 5 Million reported incidences per year in the US alone
  - Estimated medical costs in the US is $10-15 Billion per year
- Current standard of care is **rest**, analgesics for headache and anti-depressants and ADHD medications when needed
- Repeat concussions lead to early dementia and suicidal ideation related to Chronic Traumatic Encephalopathy (CTE)

HIGH RISK GROUPS

- **Athletes**

  - Athletes that sustain one concussion are **75%** more likely to sustain a subsequent head injury

- **Military personnel**

  - Military personnel have a **25x** higher frequency of developing Post Traumatic Stress Disorder (PTSD) following a concussion

- **Elderly**

  - One-third of individuals over 65 fall each year. One-half of deaths associated with falling are from brain injury

Estimated costs for non-pharmaceutical treatment of a single concussion patient is $12,000

PRV-002 API-MANUFACTURING

The cost of the Final Drug Product for a 14-day treatment of mTBI is estimated to be about $300.

Cost to manufacture API, PRV-002

About $1.5M for 5 kg

- Average amount need per 14-day treatment regimen @0.613 mg (0.322 mg/kg/day x 70kg x 14 days = 315 mg)
- 5kg of API = 15,873 14-day treatment regimens
- Cost of API per 14-day treatment = $94.50

the cost of the excipients: Included in cost above

PRV-002 MARKET POTENTIAL

Estimated cost per treatment

$2,000 margin per dose regimen (14 days) with an estimated cost of goods of $300

Revenue to Prevacus

Capturing 1.5M concussions per year, annual revenue from PRV-002 is estimated at **$2.25B**

Savings to Healthcare Industry

If PRV-002 reduces concussion recovery time by an average of 30% for 1.5M patients per year, the estimated annual savings to the healthcare industry could be as high as **$6B**

TIMELINE

Q3/19-Q4/19- Formulation/Fill and Finish in Applicator

Q1/20- Phase 1A Clinical Trial

Q2/20-Q3/20-Phase 1B Clinical Trial

Q4/20-Q4/21- Phase 2A (Athletic Setting-NCAA)

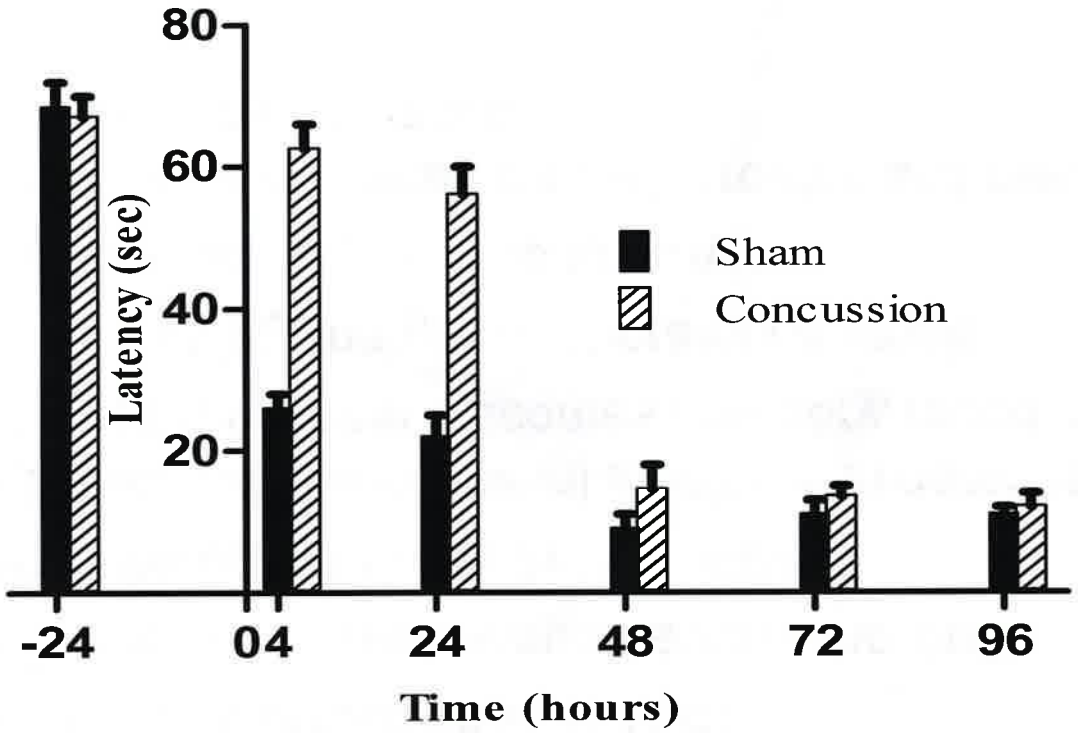
Q4/21-Q3/22- Phase 2B (Emergency Hospital Setting)

TBD- Phase 3/FDA

ABOUT PRV-002

- PRV-002 is a First-in-Class neurosteroid for the treatment of concussion (mTBI)
  - Lipophilic with easy transport across the BBB
  - Administered intra-nasally
  - Highly efficacious in animal studies with demonstrated improved functional outcomes (memory, mood, motor)
  - 380-fold safety margin in laboratory animals
  - No observed drug-related toxicity
  - Composition of matter, synthetic routes and methods of use owned by Prevacus

MEASURING CONCUSSION



Our proprietary concussion model leads to memory and learning impairment for 48 hours.

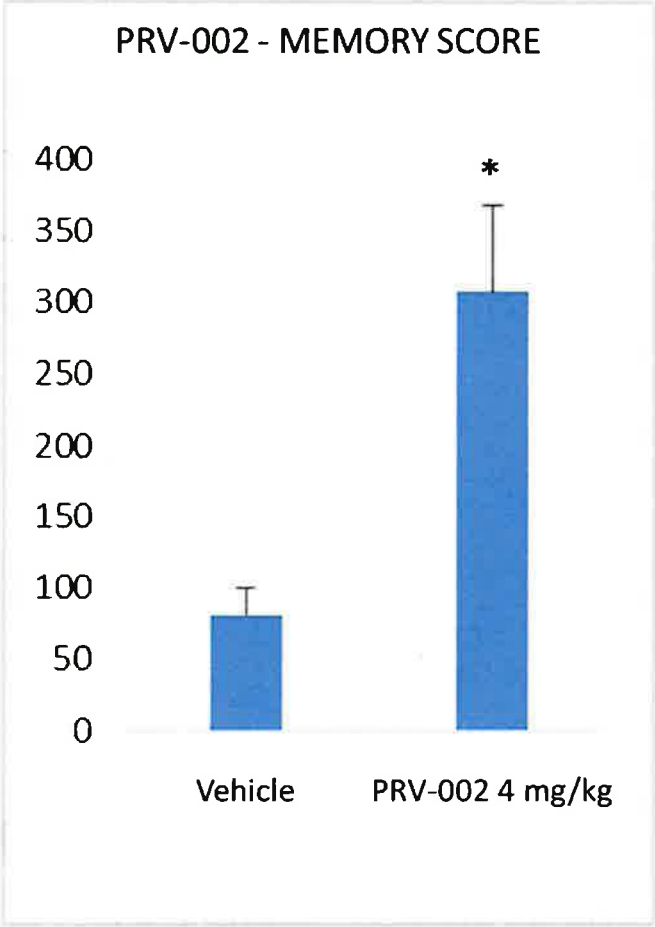
Published: VanLandingham et al, Florida State University

TREATING CONCUSSION

Morris Water Maze – Memory Score

- Subject rats were trained in a Morris Water Maze
- Subject rats were then subjected to concussion model
- Post injury, rats were treated with either vehicle or PRV-002 intranasally administered as a solution
- Memory score was established based on performance in the Morris Water Maze

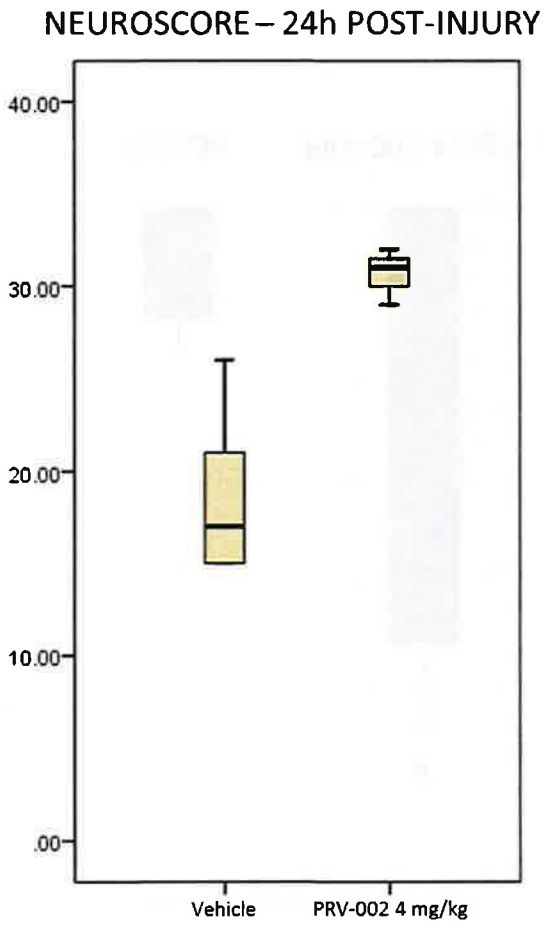
*denotes significance at $p<0.05$, $n=8$, time at 48hr post-injury



TREATING CONCUSSION

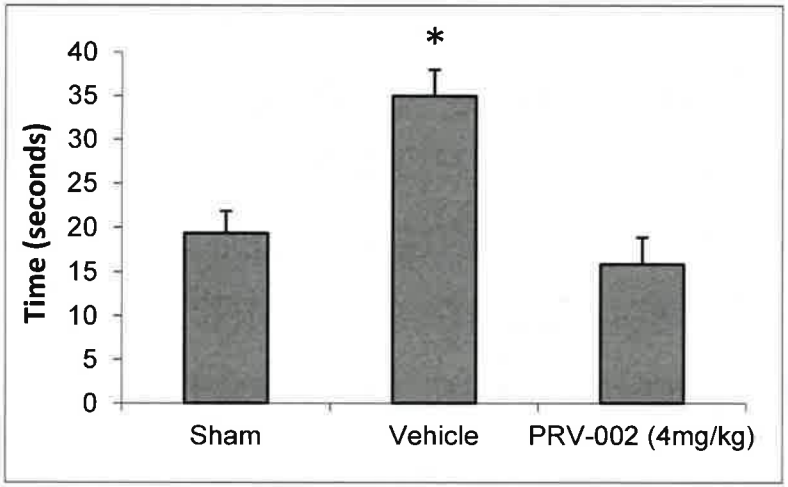
Sensory-motor function was scored using the neuroscore neurobehavioral battery

- 4 separate movement behaviors are analyzed
- Vestibular damage associated with concussion is the primary predictor for PCS and PTSD



TREATING CONCUSSION

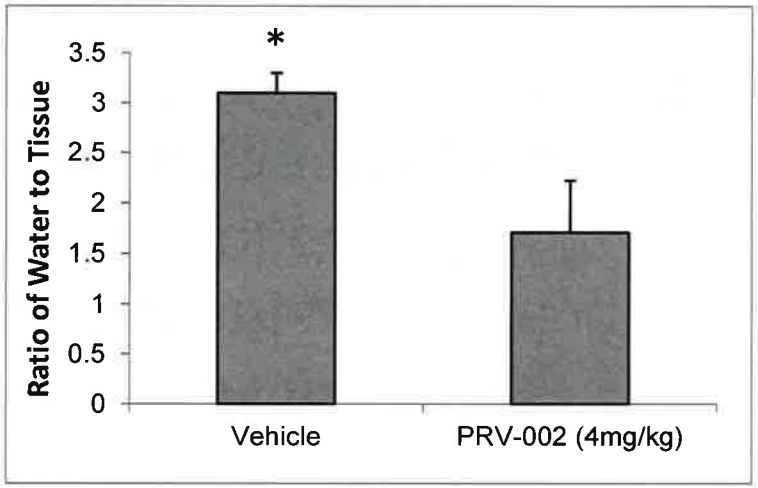
Thigmotaxia: Anxiety



- Thigmotaxia a.k.a. wall-hugging represents fear-like anxiety in animals with brain injury
- PRV-002 reduces mTBI-related thigmotaxia

*denotes significance at $p<0.05$

Cerebral Edema



- Edema or swelling can occur after TBI and result in increased intracranial pressure (ICP)
- Elevated ICP is associated with poor outcomes including increased mortality
- PRV-002 reduces mTBI-related edema

*denotes significance at $p<0.05$

PRV-002 MECHANISM

PRV-002 binds to the Pregnane X Receptor (PXR)

- The PXR is an intracellular receptor found in neurons, glia and the endothelium of the blood brain-barrier
- Binding of PRV-002 to the PXR activates multiple gene response elements promoting transcription of anti-inflammatories (CD55), anti-oxidants (gluthione s-transferase) and efflux channels (P-Glycoprotein) for toxins and fluid

PRV-002 TOXICOLOGY

- Acute and sub-acute dose ranging studies were executed in rats and dogs – SC, IN, IV routes
  - MTD (IV) = 38 mg/kg
  - Signs of toxicity were limited to vehicle
- 14-Day GLP toxicology in rats and dogs
  - Rat: MTD = 46 mg/kg
  - Dog: MTD = 46 mg/kg
  - No drug-related effects noted in hematology, blood chemistry, BW, FC, or histopathology (except for slight nasal turbinate irritation)

PRV-002 ADMINISTRATION

Breath-propelled Intranasal (IN) administration allows rapid and direct accessibility to the brain

- requires patients to blow into the device which closes the soft palate eliminating the flow of drug to the lungs or esophagus
- Minimizes systemic exposure and side effects
- Maximizes patient compliance
- Enhances dosing efficiency
- Compact and lightweight-Field Deliverable

PHASE I CLINICAL TRIAL

- To be run in Australia (Healthy and Concussed)
  - Tax benefits
  - Ability to execute before filing IND with FDA
- SAD/MAD format in healthy volunteers
  - Intranasal administration
  - 4 cohorts (8 subjects/cohort)
    - 6 subjects randomized to PRV-002 dosages
    - 2 subjects randomized to vehicle
  - Dose levels set at 0, 0.1, 1.0 and 4.0 mg
  - PK samples to be taken at 1, 2, 4, 8 and 24-hours post dose
  - Patients to be observed for 5 days post final dosing

PHASE II CLINICAL TRIAL

- To be run in United States
- Subjects to be college athletes
  - 18-24 years of age
  - Pre-injury baseline established at beginning of sports season
    - Allows each patient to serve as own baseline control
    - Baseline to include ImPACT, King Devick, vestibular balance and biomarker measurements
  - 3 proposed cohorts (vehicle, low dose, high dose)
  - 14 days of BID dosing via proprietary nasal device

Over 25 universities and clinics identified as study sites of interest

PRV-002 SUMMARY

- PRV-002 – a First-in-Class neurosteroid for the treatment of concussion
  - IP covers composition of matter, methods of preparation and methods of use
  - No competing products currently available
  - Pre-clinical efficacy established
  - No drug-related toxicity observed
  - Nasal formulation finalization in progress
  - Phase I clinical trial planned for Q1/2020
  - Phase II clinical trials planned for Q4/2020