



Developing the First Drug for Core Symptoms of Autism

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Applying Yale Research to a Breakthrough Treatment for Autism

Market: No drugs are approved to treat core symptoms of autism
Most costly pediatric/developmental disease in the US;
annual burden ~ \$250 billion*

Biology: Oxytocin: Most promising clinical data for autism; controlled trials on four continents
Naloxone significantly amplifies oxytocin efficacy in monkeys; breakthrough potential



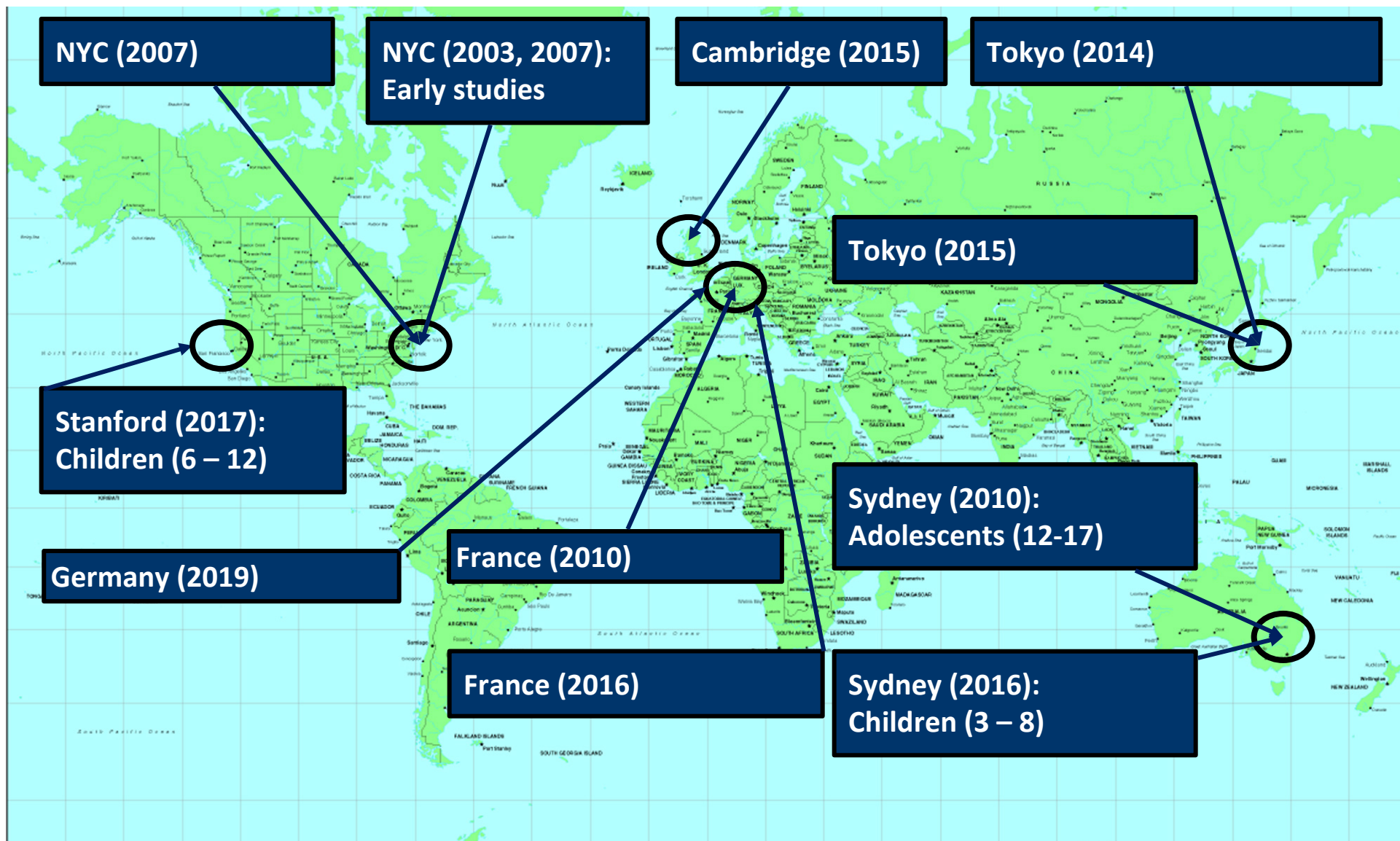
Product: **Multiple layers of intellectual property;** Yale patent being prosecuted by Saul Ewing
Yale brings: Patent-pending addition of naloxone to improve oxytocin efficacy
Pastorus brings: Efficacy/safety enhancement with patented formulation and delivery

Team: Yale researchers: Inventors on pending oxytocin/naloxone patent; recognized experts
Pastorus: MD/PhD Neuroscientists (two from Yale); successful track record repurposing drugs

Economics: \$300,000 for **meaningful clinical study designed to demonstrate compelling treatment**
Favorable ROI: Successful trial plus current/pending patents → Valuation > \$20 million

* <https://www.autismspeaks.org/autism-statistics>

Biology: Oxytocin, a human hormone, has the strongest clinical data set in autism -
Success vs. core symptoms of autism in placebo-controlled trials on four continents



Studies in adults unless otherwise noted

Yale research:
Naloxone amplifies oxytocin's pro-social effects in monkeys; breakthrough potential

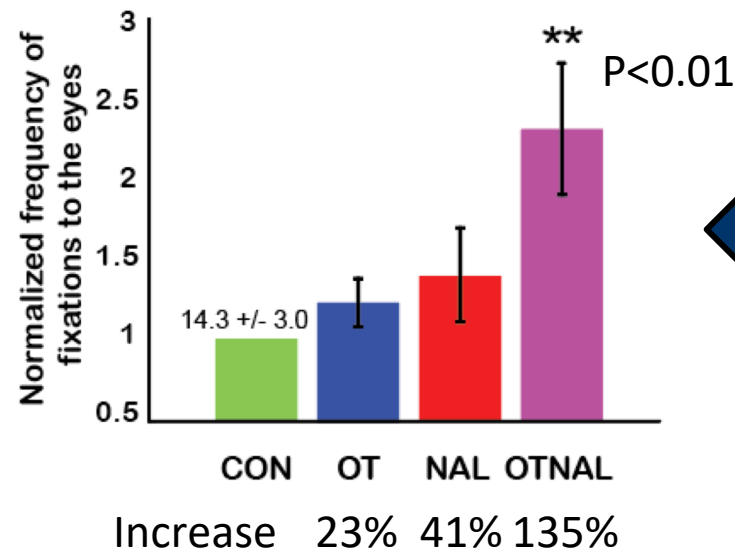
Product: Multiple layers of intellectual property; Yale patent being prosecuted by Saul Ewing

Yale patent (pending): Amplification of oxytocin efficacy via addition of naloxone

Monkeys:

Frequency of looking at the eyes of another monkey

Patent prosecuted by Saul Ewing Arnstein & Lehr; so far no specific objections to claims.



Adding naloxone amplifies oxytocin's social effects ~ 5x

CO = control group. OT = oxytocin. NAL = naloxone.
OT + NAL = oxytocin + naloxone combination

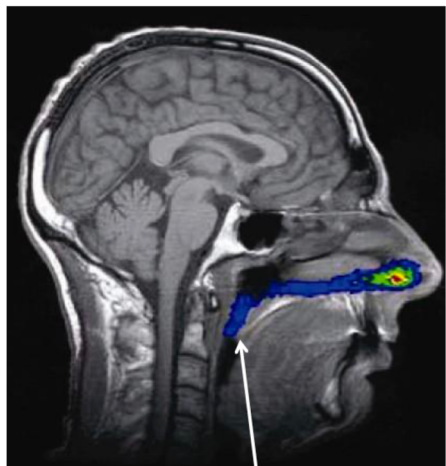
Multiple layers of intellectual property:

(1) Yale [oxytocin + naloxone] pending patent

(2) Pastorus formulation patents

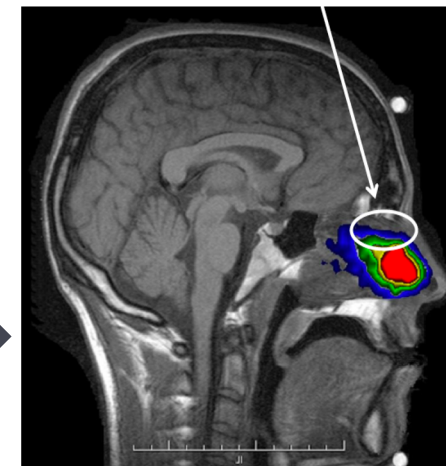
(3) Pastorus delivery patents

Tests performed
with radio-
labeled Flonase®
by independent
UK laboratory



Existing spray-bottle technology:
Loss to off-target areas

Pastorus' patented, controlled,
turbulent-flow delivery technology:
Efficient delivery to preferred target



Problems with current technology	Pastorus product solution
Dose consistency decreased by individual variability of nasal cavity and way device is held	Patented, precisely-controlled, turbulent-flow geometry increases dosing consistency, enhances delivery to brain
Concentration in anterior, lower, less-vascular areas of nose; less bloodstream absorption ^{1,2}	Distribution to more-vascular areas; absorption increased; direct access to brain via olfactory area

Yale team: Extensive experience in basic and clinical science relevant to autism



Steve Chang, PhD

- Associate Professor of Psychology and Neuroscience, Kavli Neuroscience Institute, Child Study Center, Cognitive Science
- > 10 years studying oxytocin and fundamental social behaviors in non-human primate models

Research to be done at a Yale clinical center; details being finalized

Pastorus core team/board: Successful commercializing/repurposing track record; two Yale alumni



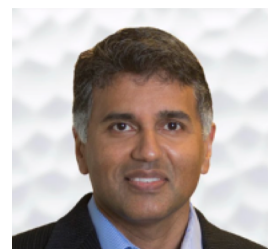
Glenn Cornett, MD, PhD: Chairman, CEO

- Founded Navitas Pharma, repurposing European cardiovascular drug; successful exit 3.5 years later
- McKinsey; Eli Lilly (strategy, marketing), Razorfish (VP, strategy practice)
- Structuring/valuation on deals driving > \$1 billion in value
- MD (U Michigan, Distinction in Research), PhD (neuroscience, UCLA)



Jay Kranzler, MD, PhD: Chief Medical Officer

- 25 years as CEO of public companies
- Founder of McKinsey healthcare practice
- CEO, Cypress Bioscience (repurposed milnacipran for fibromyalgia)
- Pfizer VP External R&D Innovation
- Thought leader on emerging CNS treatments
- MD (Yale), PhD (neuroscience, Yale)



Srinivas Rao, MD, PhD: Senior Advisor

- Currently Chief Science Officer, ATAI (London-based investment firm)
- Chief Medical Officer at DepoMed, Axial Biotherapeutics
- While Chief Scientific Officer at Cypress Bioscience, identified and repurposed milnacipran for fibromyalgia
- MD (Yale), PhD (neuroscience, Yale)

Economics:

\$300,000 for meaningful clinical study designed to demonstrate compelling efficacy

- Finalize trial / EEG methods
- Formulation
- **Milestones:**
 - Protocol ready
 - Team trained
 - Drugs obtained
 - Patient recruitment completed
- **Timeline:** Q3 2021

- Analyze data
- **Objective:** Oxytocin and naloxone together increase social function relative to placebo or oxytocin alone
- **Milestones:**
 - Demonstrate treatment efficacy in autism
 - Select optimal dose
- **Timeline:** Q2 2022 – Q3 2022z

1Q 21

2Q 21

3Q 21

4Q 21

1Q 22

2Q 22

3Q 22

Study Site:

Yale Child Study Center

- Collect data from 20 autistic patients
- **Milestones:** Data collected from all patients
- **Timeline:** Q4 2021 – Q1 2022

Favorable ROI:
Successful trial plus
current/pending
patents → Valuation
> \$20 million

Possible exit if data
are strong

Longer term: Fast Phase II factorial with EEG; through Phase III in 4-6 years for ~\$25-50 million with lean, focused program. Good safety → Abbreviated tox: Oxytocin occurs naturally in the brain and naloxone interacts with it when administered. A successful drug for core symptoms of autism should yield revenues > \$1 billion / year.