



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**

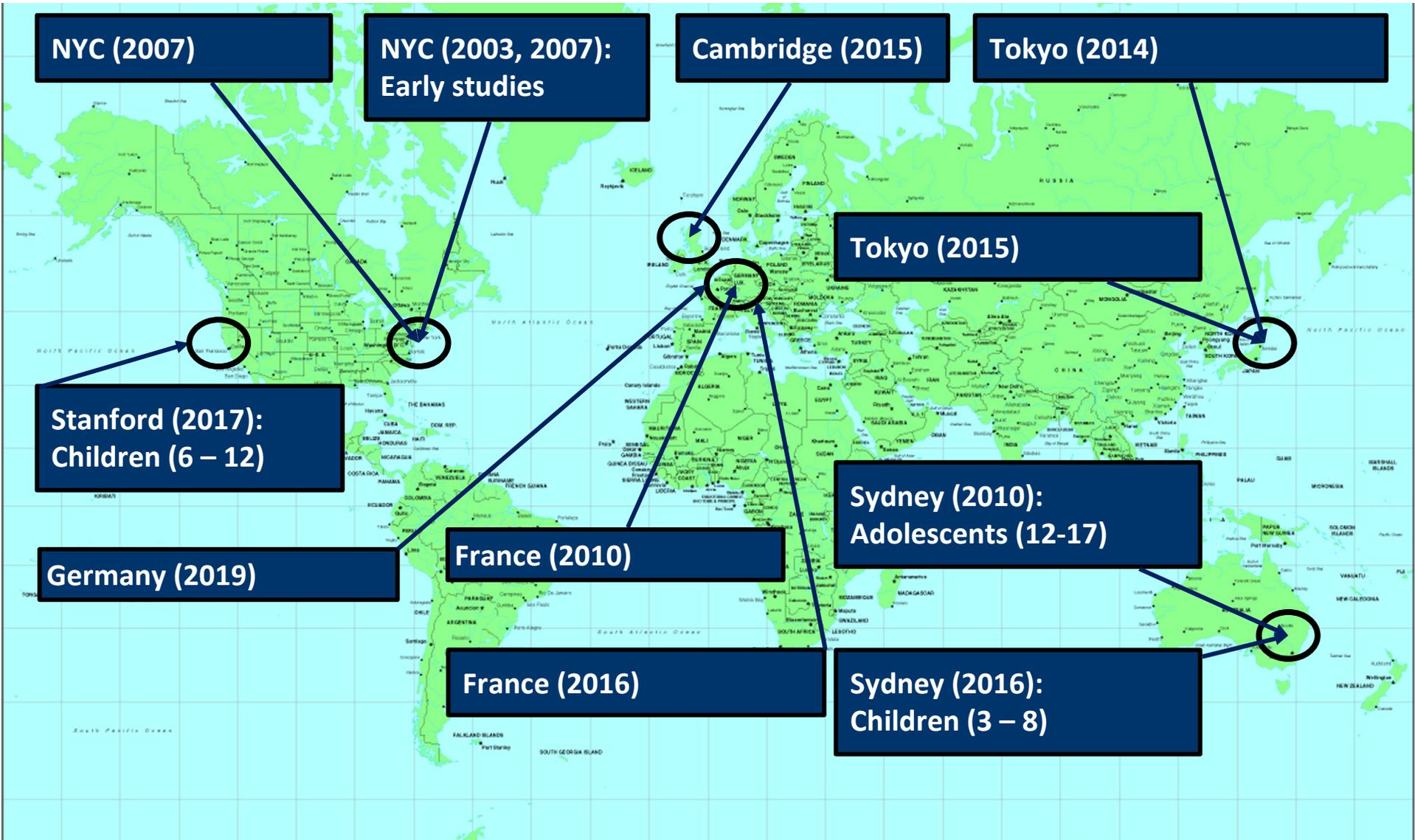
**Product:** **Multiple layers of intellectual property;** Yale patent being prosecuted by Saul Ewing  
**Yale brings: Patent-pending addition of naloxone to improve oxytocin efficacy**  
**Pastorus brings: Efficacy/safety enhancement with patented formulation and delivery**

**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**



# 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 prosocial effects in monkeys; breakthrough potential

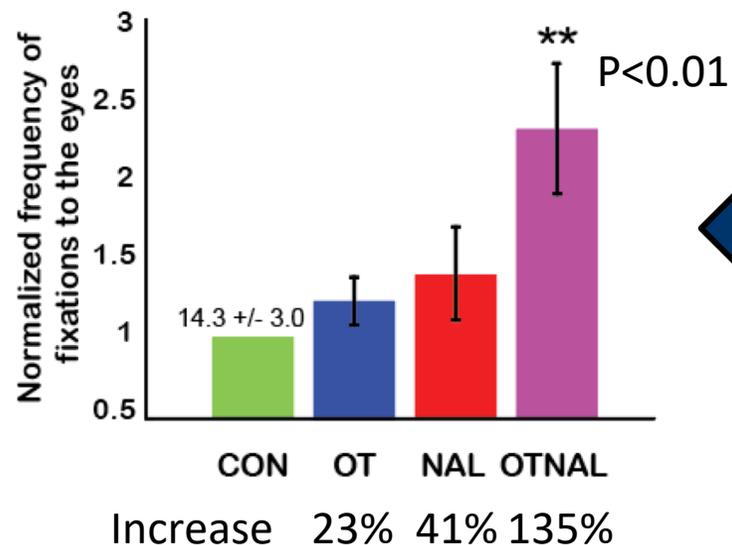
Product: Multiple layers of intellectual property; Yale patent being prosecuted by Saul Ewing

**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

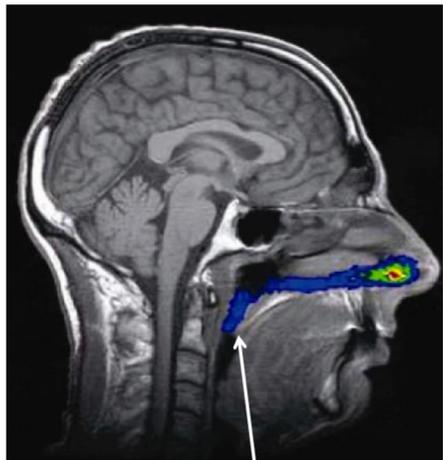
Multiple layers of intellectual property:

(1) Yale [oxytocin + naloxone] pending patent

(2) Pastorus formulation patents

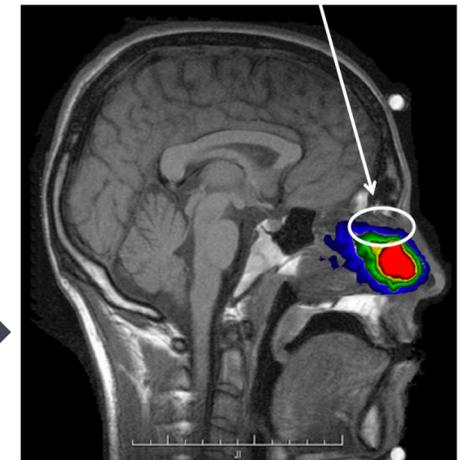
(3) Pastorus delivery patents

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**

Dose consistency decreased by individual variability of nasal cavity and way device is held

Concentration in anterior, lower, less-vascular areas of nose; less bloodstream absorption<sup>1,2</sup>

**Pastorus product solution**

Patented, precisely-controlled, turbulent-flow geometry increases dosing consistency, enhances delivery to brain

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



Favorable ROI:  
 Successful trial plus current/pending patents → Valuation > \$20 million  
 Possible exit if data are strong

**Study Site:**  
 Yale Child Study Center

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

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.