



# IONO PHARMA

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Hassan Almoazen Ph.D.  
(Founder & CEO)

# Who are we?

- Private startup established as LLC in Memphis, Tennessee.
- Our focus is pediatric drug delivery systems.
- Seeking funding for our organic synthesis and preclinical studies of novel **E**pinephrine prodrugs.
- We have US and Chinese patents filed in 2018 & 2019 and are pending

# Problem

It is estimated that 150 million (2%) of the world population will experience anaphylactic shock at some point in life.

American College of Allergy, Asthma and Immunology

Anaphylaxis affects 1 in 50 people in the US.

Asthma and Allergy Foundation of America



# Symptoms associated with anaphylactic shock



# Current practice

EpiPen, Auvi-Q, Symjepi, and Adrenaclick are epinephrine autoinjectors

- Fear of injection
- Children miss-injecting
- Bending the needle
- Inconvenience to carry
- Complex instruction
- Limited shelf life



# Inconvenient to carry: A Daily Hassle



According to patients/parents, inconvenient when:

- Going to concerts
- Going through airport security
- Going for a run
- Kids go for a sleep-over
- At school

# Market size

The annual EpiPen sales were 8 million devices  
total annual revenues were about \$1.1 billion in  
2016.

Source: Mylan profitability analysis provided to U.S. Congress (2016)

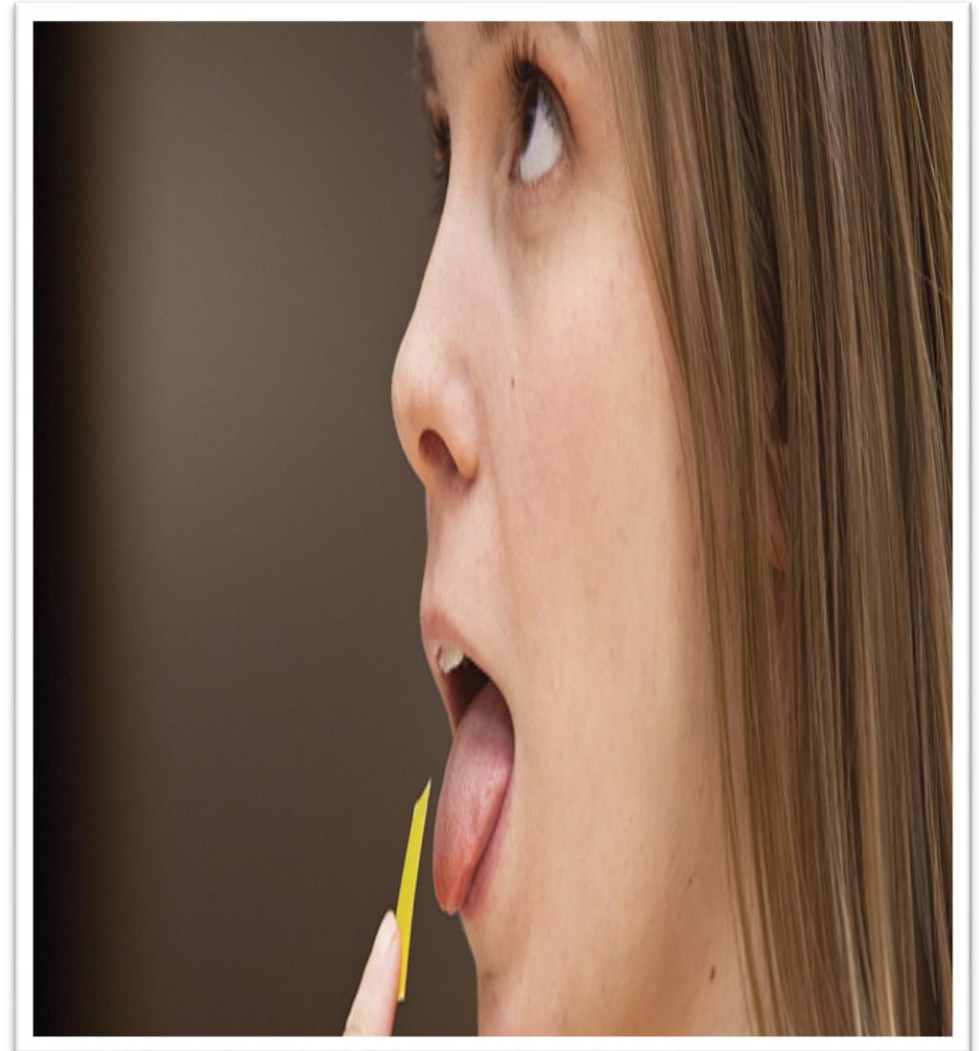
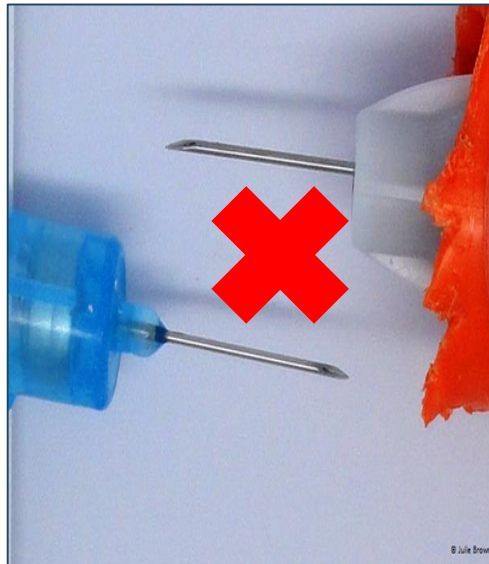
The global estimate of epinephrine market is about  
\$2 billions (2017).

<https://www.coherentmarketinsights.com/market-insight/epinephrine-market-2401>

# Our technology is different!

Epinephrine prodrug  
**Epi Relief**

- Needle free
- Easy to use
- Easy to carry
- Better shelf life
- IP protected

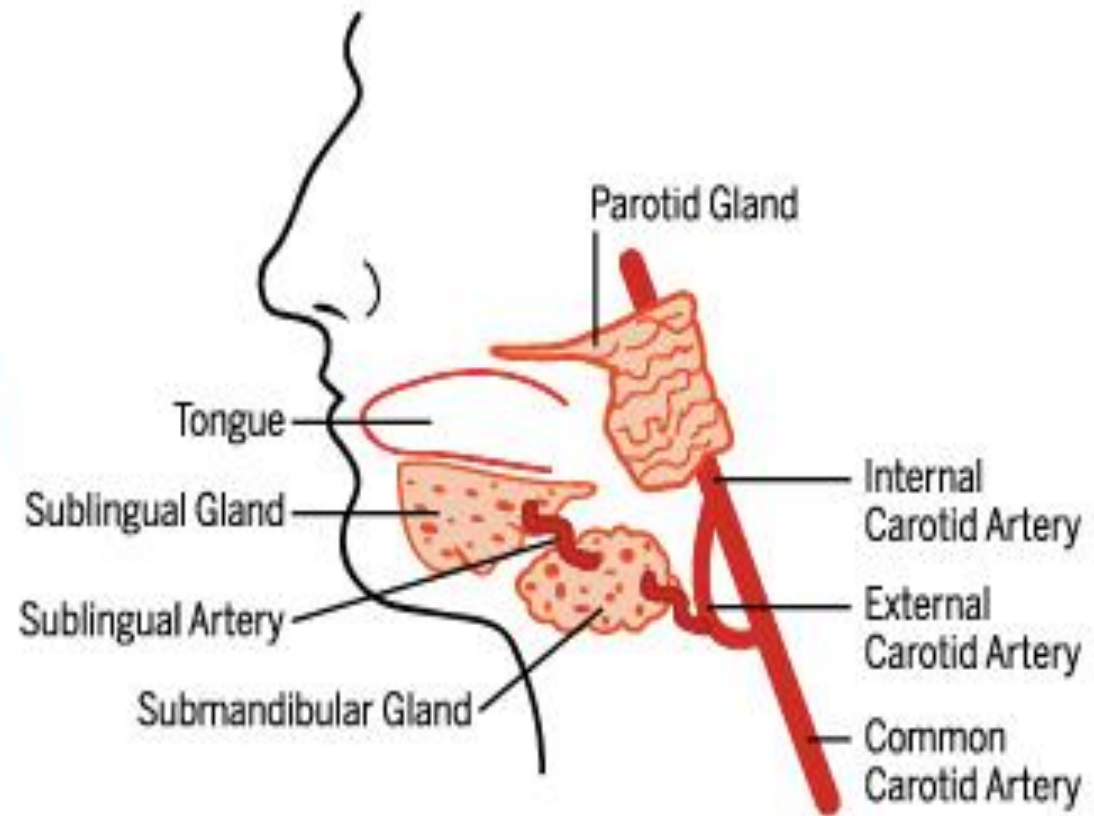
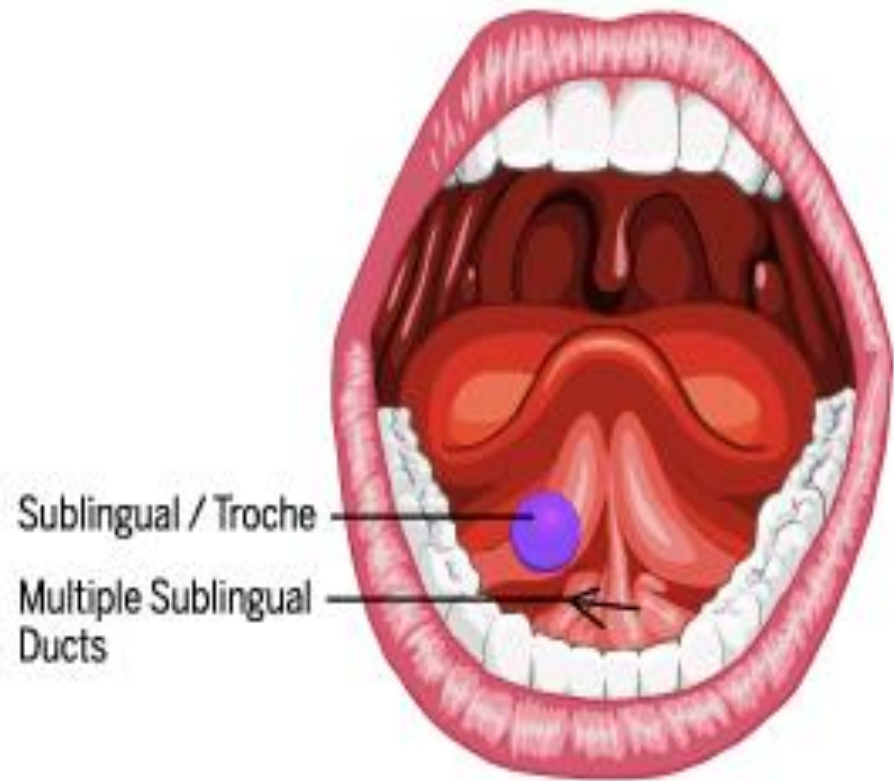




# How does Epi Relief compare to the current standard of care?

	<b>AutoInjector</b>	<b>Epi Relief Strips TM</b>
<b>Needle-free</b>	No	Yes
<b>Simple to use</b>	No	Yes
<b>Convenient to carry</b>	No	Yes
<b>2-3 year shelf life</b>	No	Yes
<b>Multiple dose flexibility</b>	No	Yes

# Epirelief sublingual Approach



# FDA pathway to approval: 505(b)(2)

Pre-Clinical Research	Clinical Studies
1.5 Years	<4 Years

- Significantly shorter and less expensive FDA route than new drug
- Structural modification of an existing drug with well-known attributes (prodrug)

# Founder & CEO

Hassan Almoazen, Ph.D. in Pharmaceutical Sciences  
Long Island University, Brooklyn, New York.

Associate Professor at the Dept. of Pharmaceutical Sciences  
University of Tennessee Health Science Center  
Memphis, Tennessee

Developed multiple proprietary drug delivery systems for  
Pediatrics (transdermal, sublingual and oral liquids and solids).



# Competition

## On the market:

- Mylan (EpiPen)
- TEVA (tevaepinephrine)
- Kaleo Inc (Auvi-Q)
- Adamis Pharmaceuticals (Symjepi)
- Impax laboratories (Adrenaclick)

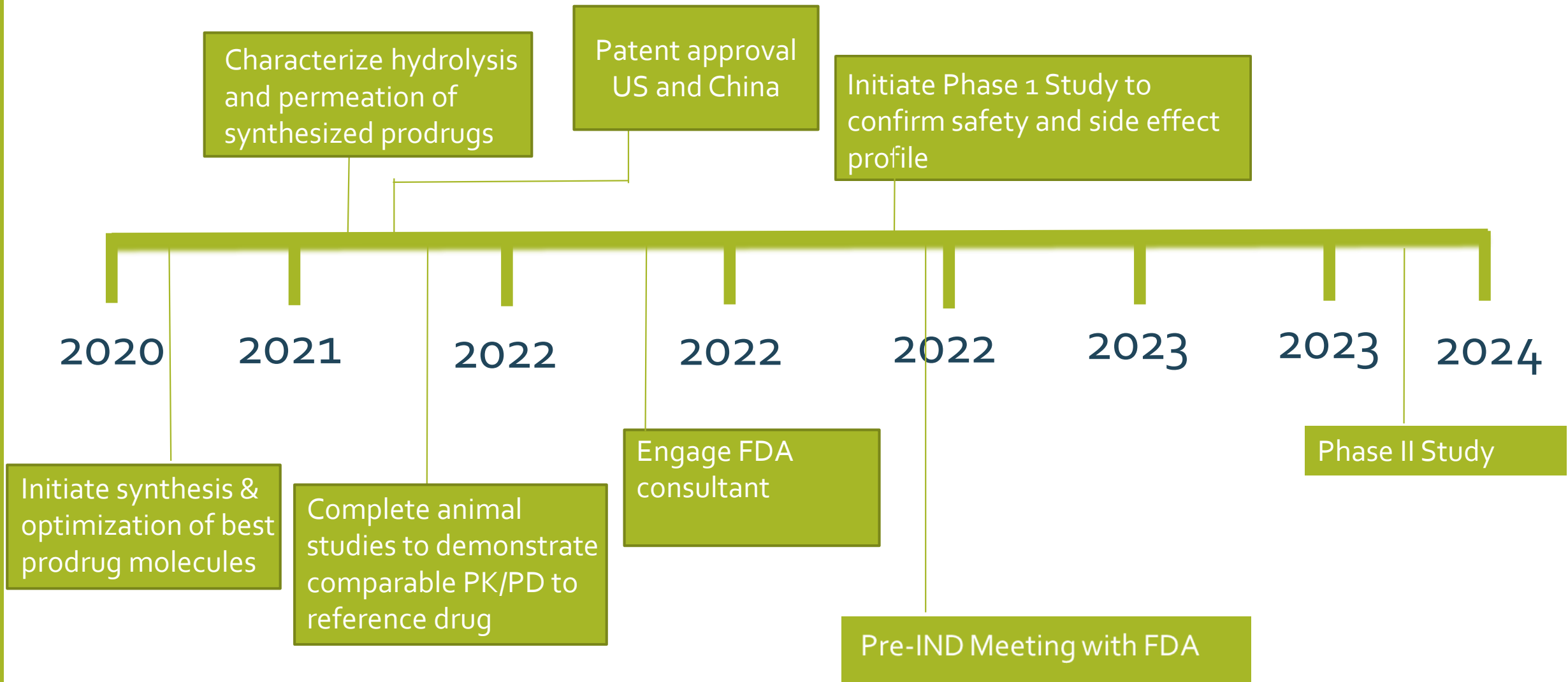
## In development:

- MannKind Corporation oral powder Inhaler
- Insys Therapeutics nasal spray
- Aquestive Therapeutics sublingual film
- ARS Pharmaceuticals nasal spray
- Stella Pharma oral powder Inhaler

# Our needs

We are seeking seed funding 250K for organic synthesis, complete in vitro & in vivo studies, construct FDA road map for clinical studies for future Epinephrine phase I & II clinical studies.

# Preclinical activities: \$250K



# Use of seed funds \$250K

- Optimize synthesis of the top prodrug molecules
- Characterize hydrolysis and permeation of targets
- Complete animal studies to demonstrate comparable PK/PD to reference drug
- FDA consultant



# Exit Strategy

- Acquisition Candidates
  - Upjohn/Mylan
  - Merck
  - GSK
  - Hikma



# Thank you

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