

Platform technology to modulate inflammation quickly at home using a wearable ultrasound device

iniabiosciences@gmail.com



www.iniabiosciences.com



#### Patient journey

Global burden

100,000

Kidney transplants every year



## Patient journey

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100,000

Kidney transplants every year

Standard of care

\$30,000/<sub>YR</sub>

Cost of immunosuppressant drugs



## Patient journey

Global burden

100,000

Kidney transplants every year

Standard of care

\$30,000/<sub>YR</sub>

Cost of immunosuppressant drugs

Problem

30%

Risk of rejection



#### Problem



#### Our solution

System overview



#### Our solution

Non-invasive treatment with real-time monitoring



Confidential Wearable Device Design Patent in progress



# Ultrasound stimulation

#### Noninvasive sub-organ ultrasound stimulation for targeted neuromodulation

Victoria Cotero<sup>1</sup>, Ying Fan<sup>1</sup>, Tea Tsaava<sup>2</sup>, Adam M. Kressel<sup>2</sup>, Ileana Hancu<sup>1</sup>, Paul Fitzgerald<sup>1</sup>, Kirk Wallace<sup>1</sup>, Sireesha Kaanumalle<sup>1</sup>, John Graf<sup>1</sup>, Wayne Rigby<sup>1</sup>, Tzu-Jen Kao<sup>1</sup>, Jeanette Roberts<sup>1</sup>, Chitresh Bhushan<sup>1</sup>, Suresh Joel<sup>1</sup>, Thomas R. Coleman<sup>2</sup>, Stavros Zanos<sup>2</sup>, Kevin J. Tracey<sup>2</sup>, Jeffrey Ashe<sup>1</sup>, Sangeeta S. Chavan<sup>2</sup> & Christopher Puleo<sup>1</sup>

#### First-in-human demonstration of splenic ultrasound stimulation for non-invasively controlling inflammation

Authors: \*Rachel S. Graham<sup>1</sup>, Daniel P. Zachs<sup>2</sup>, Victoria Cotero<sup>3</sup>, Catherine D'Agostino<sup>4</sup>, Despoina Ntiloudi<sup>5</sup>, Claire R.W. Kaiser<sup>2</sup>, John Graf<sup>5</sup>, Kirk Wallace<sup>3</sup>, Richard Ramdeo<sup>5</sup>, Thomas R. Coleman<sup>5</sup>, Jeffrey Ashe<sup>3</sup>, John Pellerito<sup>4</sup>, Kevin J. Tracey<sup>5</sup>, Bryce A. Binstadt<sup>6</sup>, Sangeeta S. Chavan<sup>5</sup>, Stavros Zanos<sup>5</sup>, Christopher Puleo<sup>3</sup>, Erik Peterson<sup>7</sup>, and \*Hubert H. Lim<sup>1,2</sup>

#### Noninvasive ultrasound stimulation of the spleen to treat inflammatory arthritis

Daniel P. Zachs<sup>1</sup>, Sarah J. Offutt<sup>2</sup>, Rachel S. Graham<sup>3</sup>, Yohan Kim<sup>2</sup>, Jerel Mueller<sup>2</sup>, Jennifer L. Auger<sup>3</sup>, Nathaniel J. Schuldt<sup>3</sup>, Claire R.W. Kaiser<sup>1</sup>, Abigail P. Heiller<sup>1</sup>, Raini Dutta<sup>3</sup>, Hongsun Guo<sup>1</sup>, Jamu K. Alford<sup>2</sup>, Bryce A. Binstadt<sup>3</sup> & Hubert H. Lim<sup>1,4,5</sup>







## Cytokine panel

Ultrasound stimulation to reduce cytokines

#### Human

0

Control



Mouse model

Graham, R.S. et al. medRxiv 2020

TNF Response (Log<sub>2</sub> Fold Change)

2

0

2-12

4

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#### Our solution

Non-invasive treatment with real-time monitoring





#### Our solution

Non-invasive treatment with real-time monitoring





#### **Patient Experience**

Non-invasive treatment with real-time monitoring





#### Competitors



#### Competitive advantage



Non-invasive treatment



Real-time monitoring



Digital health platform

No risk for over-suppression Easy and fast

Immediate read-out Cloud data upload

Communication with doctors



## Competitive advantage



Non-invasive treatment



Real-time monitoring



Digital health platform

No risk for over-suppression Easy and fast

Immediate read-out Cloud data upload

Communication with doctors



Transplant centers clustered

Patient access



Medicare

> 70 % covered by Medicare



Key Opinion Leaders

Fast adoption



#### U.S. kidney transplant market



#### Total U.S. transplant market for all organs



## INIA's pipeline

Upcoming indications to explore with our platform





#### **Business model**



## INIA's intellectual property strategy

Anticipated Patents:

- 01 Method of use for organ rejection + usability on spleen
- **02 Diagnostic** invention to detect specific biomarkers specific for organ rejection
- **03** Fully **integrated device with design** for the treatment and diagnostic components







Celia Leber, JD

Shelly Fujikawa, PhD, JD

**01** Initial patent analysis

02 Initial freedom to operate

**03** Provisional in progress



#### Team



#### SHEN NING CEO

B.A. in Biology and Society, Cornell University 15' M.D./Ph.D. in Neuroscience, Boston University 22'

Fulbright Fellow, MIT IMPACT Fellow, and BUnano Cross-disciplinary Fellow.





#### **PABLO ELVIRA** CSO

B.S. in Chemistry, University of Chicago 17' Ph.D. in Chemistry, Stanford University 22'

NIH predoctoral fellowship, the ChEM-H Chemistry-Biology Interface Fellow and the Center for Molecular Analysis and Design Fellow.





#### DRAGANA SAVIC, MSc, DPhil, MBA СТО

B.Sc. & M.Sc. & in Biomedical Engineering, Technical University of Denmark and Yale University 10' and 13'

D.Phil. in Physiology, University of Oxford 18' MBA, Quantic School of Business and Technology 21'

Postdoctoral Fellow, University of Oxford 22'



Technical University of ÷ ÷ Denmark





## Advisory Team



Stefan Tullius, MD, PhD Chair in Transplantation Surgery Brigham and Women's Hospital Harvard Medical School





David Salant, MD

Nephrologist

Boston Medical Center

Professor of Medicine

Vice Chair of Research



Paul Wilkes, LLB, EMBA Partner at Osney Capital



Damion Corrigan, PhD Professor of Biomedical Engineering





Arun Sridhar, PhD Stealth Bioelectronics, Galvani

GALVANI



Vinit Nijhawan Managing Partner MassVentures

MASSVENTURES





#### **INIA Milestones**



#### **INIA Milestones**





Craig Carter C3 Medical Device Consulting





#### **INIA Milestones**





## Roadmap



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#### Our Asks: \$2M





Ultrasound MVP Regulatory compliance (ISO/EIC) 510(k) clearance



# **Our Mission**

Platform technology to modulate inflammation quickly at home using a wearable ultrasound device.

iniabiosciences@gmail.com

Iniabiosciences.com

linkedin.com/company/inia-biosciences

Supplemental slides





#### Value add and de-risking one milestone at a time

2022



Task Duration



#### Use of Funds(\$2M)

Pie chart



## Proof of concept



## Proof of concept



#### Skin graft survival

Determine if device can improve skin graft survival

N = 21

4 donors

4 controls

12 experimental (4 parameters, 3 animals each)

Ultrasound parameters from 25-1000kPa from 1MHz transducer for 1s On/5s off burst (30min) response with skin graft survival

GO = response in skin graft survival

NO GO = No response in skin graft survival





## **Proof of concept**



BRIGHAM AND WOMEN'S HOSPITAL

Mass General Brigham





Cytokine response and optimization

Cytokine response with different parameter

N= 9

Output: toxicity/side effects?

Output: reduction of cytokines levels?

#### GO = response in cytokines

NO GO = Dangerous Off target effects



#### Dose response curve

Ultrasound stimulation to reduce cytokines





Cotero, V. et al. Nat Methods 2019

Zachs, D.P. et al. Nat Methods 2019



### **Regulatory Breakdown**



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#### Go to market strategy



# COSTSULTRASOUND WEARABLE<br/>DIAGNOSTIC DEVICE\$250<br/>\$350PRICING\$10K-30KULTRASOUND WEARABLE<br/>DIAGNOSTIC DEVICE\$60/month<br/>\$60/month<br/>DISPOSABLESONLINE PLATFORM\$0-120/year

#### REIMBURSEMENT

#### CPT codes:

97035 - Ultrasound Therapy

989X1 - remote therapeutic monitoring; initial set-up and patient education on use of equipment (2022)





EARLY ADOPTERS:



#### Our solution

Non-invasive treatment with real-time monitoring



IL-12

Infiltration

•

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## Funding rounds

Get 10X back and save organs



#### Our customers



Dr. Jean Francis

**BMC/BWH** 

"If you can show this works, we urgently need it" "I am a kidney donor to my son, and he was over suppressed by the drugs and got Lymphoma"





#### Top down market sizing



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#### INIA's added value

#### DRUGS

# \$30 000 ×

Immunosuppressant drugs per patient per year



New kidney transplant performed in 2018

## \$630M

Immunosuppressant drugs Lifetime (17 years life expectancy) for kidney transplants performed during. 1 year





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#### Pricing and healthcare savings

Allows us to place the price of our device at \$35,000

\$2,500/ month cost of drugs

**21,000** kidney transplant/ year (US) = \$600M

+ \$13M for routine testing

\$613M

\$400,000 cost of a kidney transplant \$35K

11 patients number needed to treat to yield financial savings



### Product



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#### Development stage





## Financial snapshots

After market launch

Description	Year 6	Year 7	Year 8	Year 9
REVENUE	35M	212M	494M	953M
NET PROFIT	13M	90M	213M	413M
GROSS MARGIN %	46%	46%	46%	46%
NET MARGIN %	36%	43%	43%	43%
EXPENSES	22M	121M	281M	540M



## Diagnostic platform co-develop with Biosens8

Nanotechnology-based platform diagnostic



