Precision medicine platform for behavioral & mental health, starting with ADHD

Decline in physiological response Learn More



## Iluria at a glance

Successful Clinical Trials & Real World Data













Real world data and end-users' usability testing

Major Milestones Achieved

- Product V1 released
- Verified regulatory & reimbursement pathways
- Patents: ADHD US & China granted (exp. 2040) and pending in additional territories;
  Anxiety and Depression - pending
- Started commercialization process in the US and UK

Pilots with Industry Leading Partners













**Experienced Team** 

- Extensive experience in evolving technologies into commercial products
- In-depth knowledge of the mental health industry
- Vast experience in B2B activities
- Track record in operating in clinical and regulated environments

Significant Opportunity (ADHD)

129M Children 279M Adults

\$16K

Annual costs per patient

\$8B

market size (US+EU)









Ran Izraeli **VP Product &** Corporate Development



Noam Katz, PhD **VP Data Science** 





**Ariel Michaeli** VP R&D





**Birkat Klimshtein Levy** Co. Founder & Board Member





**Prof. Liran Carmel** Scientific Advisor





Vincent Mancinelli II Pharma Advisor





Ramzi Nashashibi Clinical Advisor (Special Education)

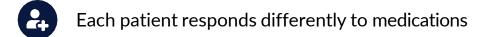




**Prof. Itay Berger** Medical Advisor

Google Scholar

Problem - determining medication efficacy in mental health is an opaque process



Is the intended cognitive effect being achieved?

Is the dosage too high/low? What is the correct intake timing?

Balancing between side effects and efficacy

Are effects accurately conveyed to clinical teams?



Lack of objective data makes it nearly impossible to determine efficacy



## Our initial focus – children and adolescents ADHD Current processes are subjective, resulting in very low adherence



Initial medication calibration can take over 2 years



<50%

Adherence to treatment in the initial 90 days



**6**≣ \$15K

Annual institutional cost per US patient



Prevalence

10% in children **5%** in adults



\$1.6K

Annual out of pocket expense per US patient

Current methods for determining efficacy are fundamentally lacking



# Solution - first of its kind precision medicine technology using physiological data to evaluate efficacy & safety



Create account, download app to any wearable & smartphone



Wearable sensors collect biometric info e.g.movement, angular movement, HR/HRV



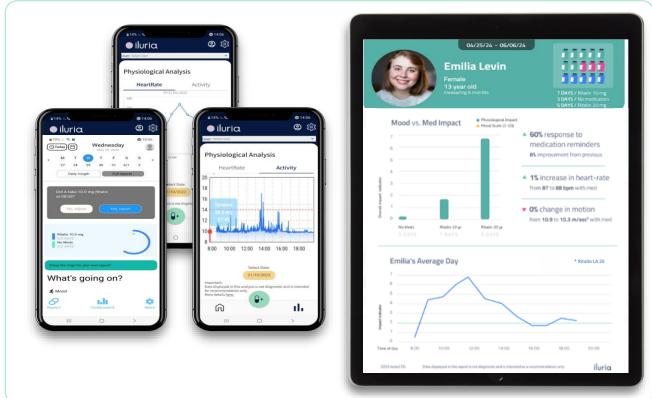
Proprietary machine learning & algorithmic processes



Share information with physicians to calibrate medication

## **User Interface - V1**





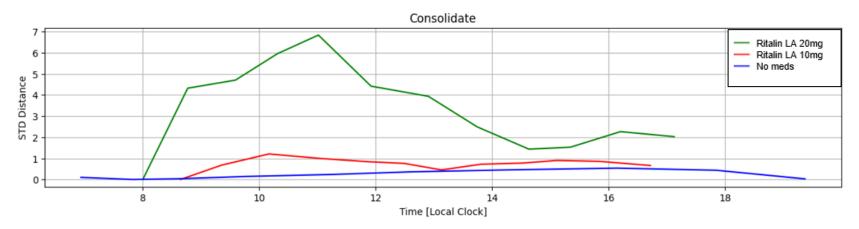


## **Case Study**

"Even though my son was struggling, we considered discontinuing his treatment due to uncertainty. However, Iluria's analysis transformed our perspective by clearly demonstrating the impact of each treatment. This helped us stay committed, resulting in remarkable improvements in his academic performance and behavior."

Ilan, father of a 10-year-old with ADHD

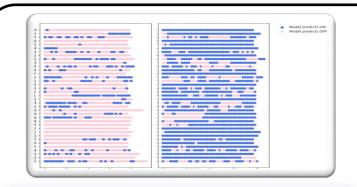
#### Intraday







### We have successfully completed three studies with top-tier medical partners



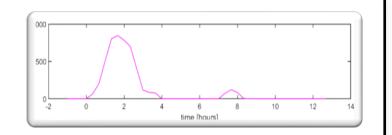






Adults - finalizing

Our study demonstrated that mathematical analysis of physiology can be utilized to measure ADHD with compliance to the clinical guidelines





The scale-up study demonstrated that we are able to provide insights on the treatment effectiveness patterns on an hourly basis





#### **PHARMA ECOSYSTEM** Revolutionize engagement &

#### **PHYSICIANS**

Enhanced engagement using objective data points



adherence



#### **PROVIDERS**

Increase speed to calibration utilizing fixed reimbursement pathways



#### PATIENTS / PARENTS

Easy at-home adoption, shortened timeline to calibration



Reduce direct &, opportunity costs, accelerate timing



#### **SCHOOLS**

Lower administrative costs and burden of manual questionnaires





### **UNDERSTANDABLE** DATA



**REMOTE TRACKING** 



**DATA-DRIVEN INSIGHTS** 

## **Go to Market Strategy**

36-42 month: endorsement from pharma players: Digital companion to enhance compliance to treatments

30 months: Large Providers/Children's Hospitals (capitated coverage) Coverage - value-based care (a higher PMPM) + potentially adding CPT codes

24 months: Initial small-scale traction from private clinics (fee for service) Coverage (CPT codes) - RPM/RTM codes (~\$125/month); GMBT1-3 (in 2025)

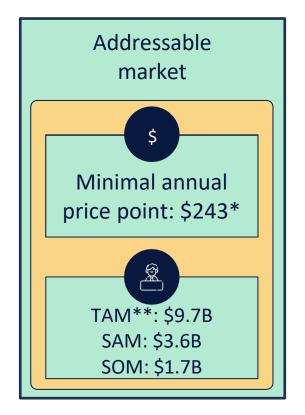
18 months: paid pilots (initiated discussions with several pharma manufacturers)

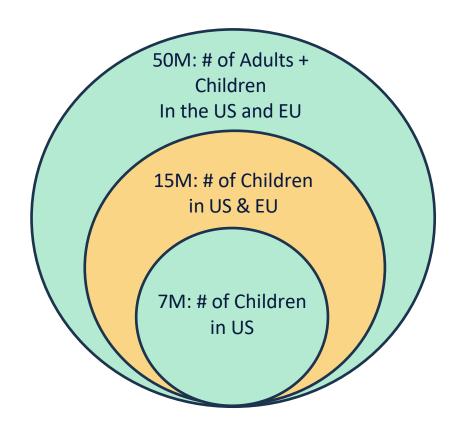
#### **Other Processes**

UK: Co-commercialization process

Under evaluation: Employers/benefit brokers; Wearable manufacturers

## The ADHD market opportunity is large & growing





<sup>\*15%</sup> of estimated cost saving, before adding impact on compliance and reimbursement

<sup>\*\* #</sup> of Children with ADHD worldwide is 129M and the number of adults is 279M

## **Regulatory Pathway**

<u>US</u> FDA

> EU CF

<u>UK</u> UKCA

Non-Medical

Class II 510(k)

Class IIa Decision Support Software

Class I

HIPAA + GDPR

- Initial step: pre-submission
- Existing predicate device (Qbcheck)
- 18-24 months time frame
- Under Medice cooperation
- Existing reference (Qbcheck)
- 24 months time frame
- Clinical data already exists
- Validating need for local study
- 12-18 months time frame

4 months time frame



## ADHD case study: Iluria fills a big gap in the ADHD market









Calibration/Monitoring



**Behavioral Treatment** 



Therapy (non pharma)







Existing solutions:

- Subjective & manual questionnaires
- Patient reported Outcome solutions





























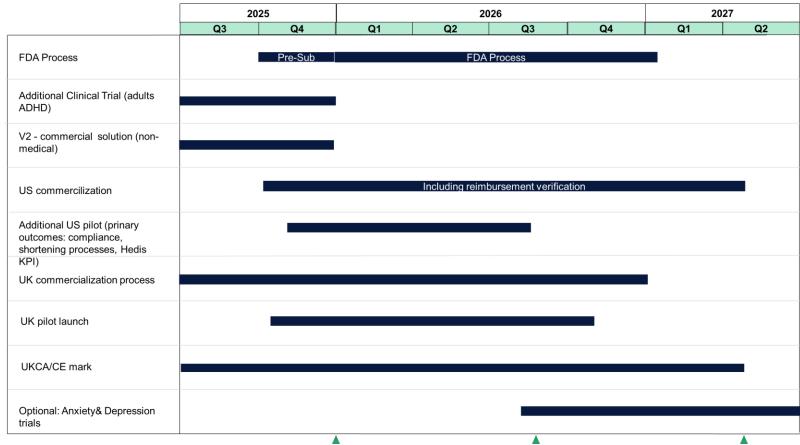






## Product Roadmap (+ risk mitigation)





## Ask and Use of Funds

## Iluria is raising \$1M (1st tranche of a \$3M round)

- 2-year roadmap for commercial level solution
- Initial milestone (\$1M tranche):
  - UNMC pilot to solidify economic KPIs
  - FDA 510K class II pre-submission
- Expense breakdown: 45% R&D; 39% business development and admin; 16% regulatory and reimbursement

## Thank you!



For additional information and gettign involved please contact us:

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