

## Company Description:

Focusing primarily on rescuing premature newborn babies with respiratory distress syndrome by the unprecedented enteral ventilation technology



## Company Details:

**Founded in:** 2021

**No. of employees:** 8

**Type of Ownership:** Private

**Stock exchange:** N/A

**Interviewee:** OZAKI Hiromu, Co-Founder & CEO

## Company Address:

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Doushin Kita-ku  
530-0035 Osaka  
Japan  
<https://evatherapeutics.jp/en>

## Introduction:

**March 2025:** As the company name self describes, the EVA (Enteral Ventilation via Anus) technology - for which the Ig Nobel prize (see Comments after the Interview) was awarded - will offer a new paradigm to save patients in respiratory failure.

Venture Valuation interviewed OZAKI Hiromu, Co-founder & CEO.

## Venture Valuation:

Your first project EVA101 for prematurely born babies with respiratory distress syndrome (RDS) aims to be used in combination with existing breathing methods such as pulmonary surfactant administration and standard respiratory support such as mechanical ventilation.

*Ozaki:*

When babies are born prematurely, the lack of pulmonary surfactants causes the alveoli to collapse due to the high surface tension. This condition is called RDS.

A study published in 2022<sup>1</sup> shows that by day 7 of age, 30% of premature newborn babies with RDS had died while the majority of those alive continued to need some respiratory support even after currently available standard therapy.

Depending on RDS conditions of each infant, we estimate (chart below) EVA101 could help rescue around 66% of RDS infants in Japan, U.S. and big five European countries.

Neonatal RDS Patients a year (Japan, US, EU5)				
	New Born	Pre-mature	RDS	EVA-101 Target
Jpn <sup>*1</sup>	800,000	90,000	15,000	10,000
US <sup>*2</sup>	3,350,000	350,000	70,000	46,000
EU5 <sup>*3</sup>	3,100,000	296,000	59,290	39,000
Total 100K target patients				

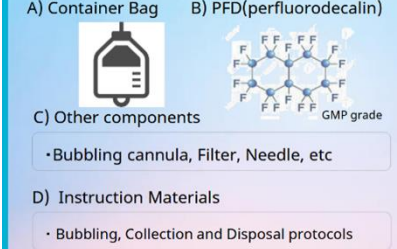
\*1: 厚生省, MDV Analyzer  
\*2: CDC and Brave Beginning  
\*3: UN, 人口比 vs US

The EVA101 kit is designed for supplemental breathing through the rectum with oxygenated perfluorodecalin (PFD), liquid oxygen.

The kit resembles an intravenous infusion bag but with an attached enema like nozzle. The bag contains PFD oxygenated liquid. PFD, approved as artificial blood in the U.S. in 1989, is an inert material and functions as interface between gas-lipid membrane. No cellular absorption is expected.

**EVA-101 Kit (Medical Device)**

A) Container Bag    B) PFD(perfluorodecalin)

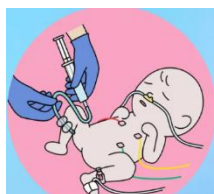


C) Other components

- Bubbling cannula, Filter, Needle, etc

D) Instruction Materials

- Bubbling, Collection and Disposal protocols



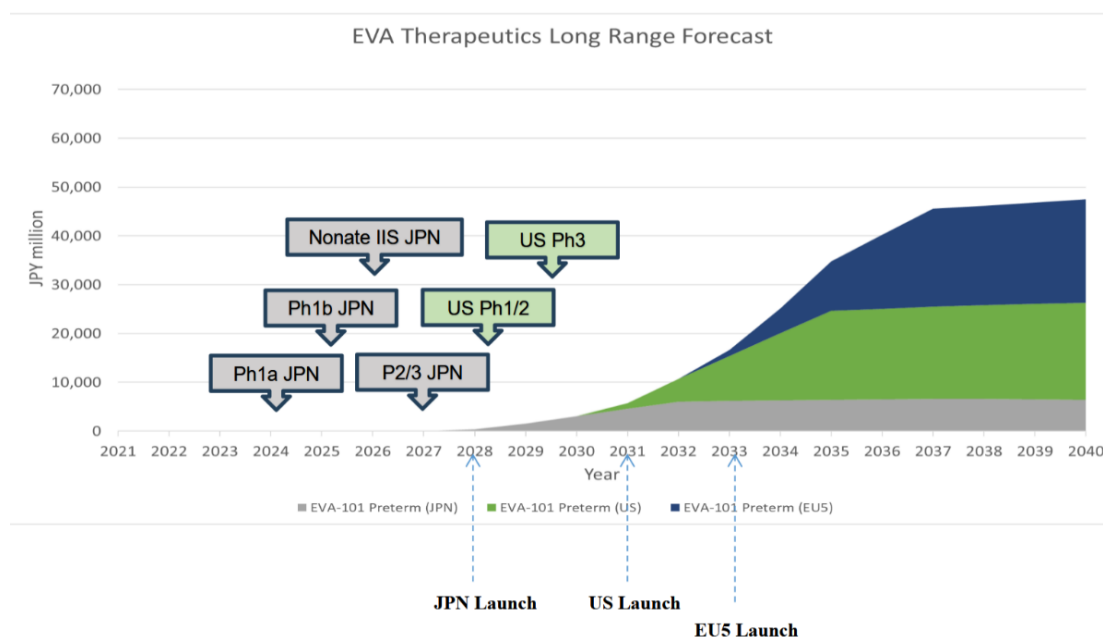
With a 3,000g newborn baby, around 30cc of PFD oxygenated liquid is applied each time, which enables enteral breathing to last about four to six hours.

<sup>1</sup> Bulimba et al. BMC Pediatrics (2022) 22:731

The body expels the PFD after around four to six hours, and then a fresh dose of PFD oxygenated liquid is infused. If one infusion works for four hours, six liquid exchanges will be necessary per day. This procedure should be repeated for a few days until the patient's oxygen level is stable.

### You are conducting phase 1 and 2 studies in Japan while preparing for discussions with FDA in the U.S. for an investigator-initiated clinical trial.

Last year we successfully completed a phase 1a clinical study in Japan to evaluate the safety and tolerability of EVA101 using non-oxygenated PFD with 27 healthy male volunteers. As the chart below shows, we are in the process of organizing the next clinical studies.



Hopefully EVA101 will be available in 2028 in Japan to save as many RDS infants as we can. Globally our plan is to launch the product in 2031 in the U.S. and in 2033 in the big five European countries.

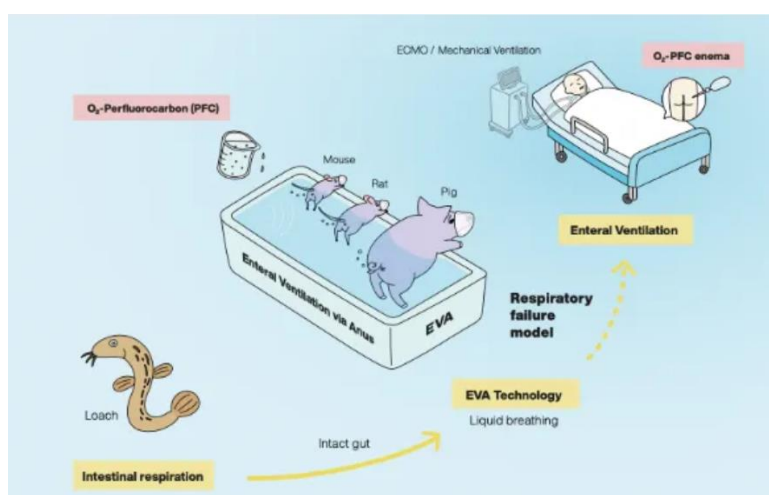
Developing our technology requires substantial investment. We are considering an M&A with compatible American or European multinational companies specializing in pulmonary surfactants in neonatology pharmaceuticals.

## VV Comments After the Interview

A major advantage of the EVA technology is that it is minimally invasive. Once the EVA101 proof of concept is established, various clinical applications are foreseen. "For example, in the field of emergency and intensive care, potential indications, including pneumonia, heart failure, airway burns, bronchial asthma, sever attacks, and cases where neither intubate nor ventilate are expected."<sup>2</sup>

The Ig Nobel Prize is awarded every year since 1991 to achievements in scientific research that "first make people laugh and then make them think".<sup>3</sup> It parodies the Nobel Prize. However, the Nobel laureates present the Ig Prizes in a ceremony at the Massachusetts Institute of Technology in the U.S.

Dr. TAKABE Takenori, an Ig Nobel Prize winner and Founder of EVA Therapeutics, noticed that loaches, ray-finned fish, are breathing through their intestines in low oxygen environments. He and his team studied if mammals could do the same. The illustration below is the front page of the paper "Mammalian enteral ventilation ameliorates respiratory failure" published on Med 2, 773-783, June 11, 2021.



When Dr. Takabe and his team started pre-clinical studies in the COVID crisis, they realized that many hospitals were seriously short of mechanical ventilators and ECMO (extracorporeal membrane oxygenation) to support breathing in people with severe respiratory failure. These indwelling medical treatments are physically hard for the patients and not easy to handle for medical staff.

<sup>2</sup> Translat Rebulat Sci. 3(3): 93-97, 2021; doi: 10.33611/trs.2021-015 "Enteral ventilation technology to combat severe respiratory failure"

<sup>3</sup> <https://improbable.com/ig/about-the-ig-nobel-prizes/>

## Contact Details

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Venture Valuation specializes in independent assessment and valuation of technology-driven companies in growth industries, such as the Life Sciences (Biotech, Pharma, and Medtech), ICT, Femtech, Nanotech, Cleantech and Renewable Energy. In addition to valuation products, Venture Valuation offers high-quality, focused information services like the Global Life Sciences Database, Biotechgate.com and this "*Let's Interview Series*" with companies with interesting technologies and services. We select and interview thriving companies and organizations especially in Switzerland and Japan.