



Orchard Bio Inc.

Business plan

2025 Summer



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Confidential

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1 Executive Summary

- ✓ We are a biotech company that develops new concept of cell therapy product, hAP cells* in which drugs (small compounds) are combined as one medicine.
- ✓ By 2050, we aim to achieve complete organ regeneration using hAP cells, extend the healthy lifespan of all living things, and bring smiles to all.
- ✓ We are currently seeking Series A funding, and will raise 80 million yen. We aim to achieve growth that exceeds the expectations of our shareholders and to IPO in 2029.

* hAP cell: holding Active Pharmaceutical ingredient cell

02 About US

Company overviews

2025/4/1時点

Company name

Orchard Bio Inc.

Mission

A hopeful future for all life through the spread of regenerative medicine

Establishment date

March 2021

Settlement date

December

Employees

Three

Capital

63 million yen

CEO

**Norio Uematsu**

Many R&D experiences in antibody, small compounds and cell therapy product in various Bio-Venture companies

Share holders

Tepia Investment and other parent companies: 88 %、Individual investors※: 12 %

Address

Kobe International House 22F, Gokoudori 8-1-6, Chuou-ku, Koube, Hyogo, 651-0087, Japan

What to achieve in medicine

Expanding availability of drugs (small molecules) in medicines.

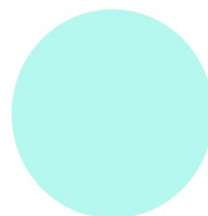


- Many efficient drugs are highly toxic and cannot be used as medicines.



- Increasing opportunities of unavailable drugs to be available as medicines.

Providing usefull cell therapy products to Unmet Medical Needs



- Current cell therapy products are still ineffective and extremely expensive

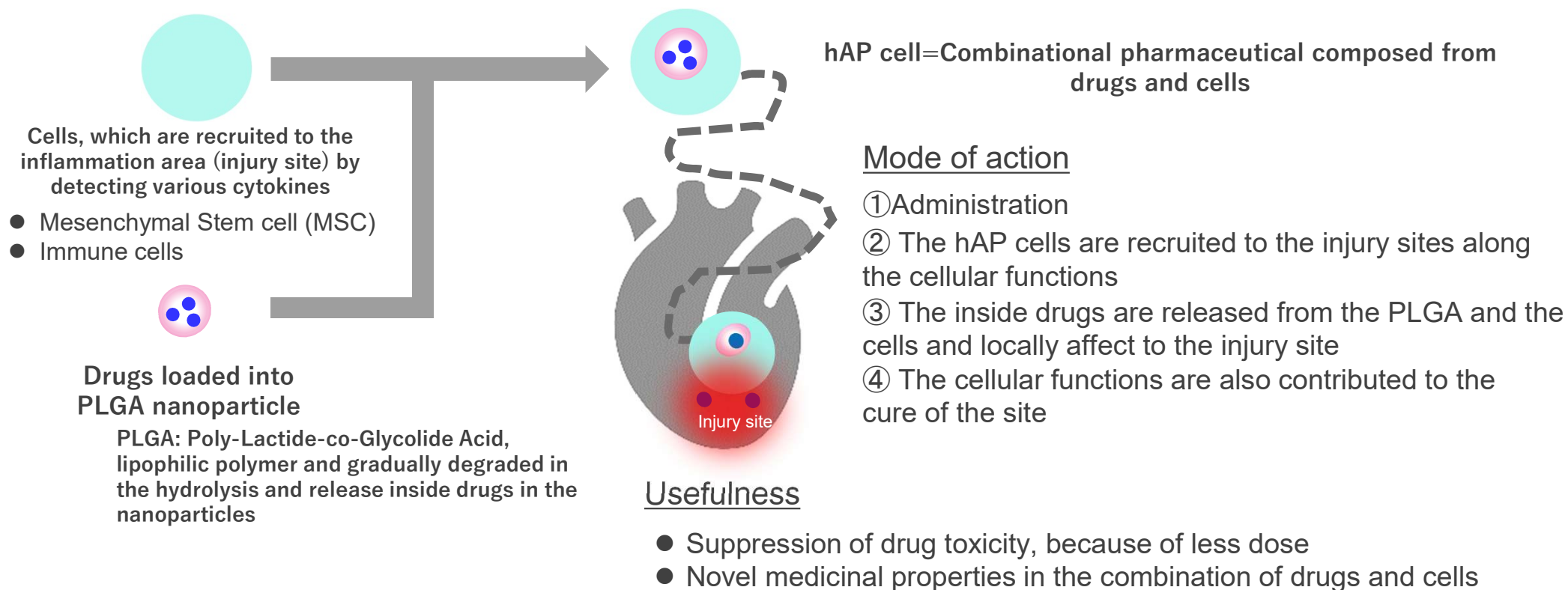


- a highly effective, relatively inexpensive cell therapy product are released to the market.

2 About US | Our Vision

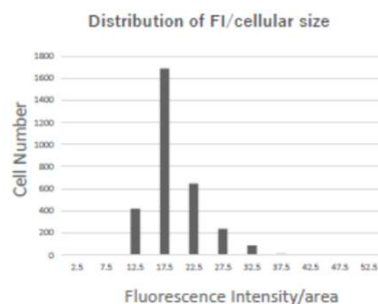
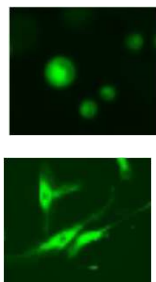
Our Approach

Combining drugs and cells in a pharmaceutical

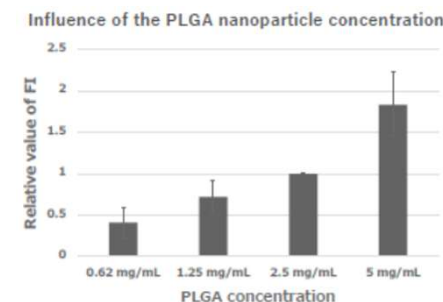


Characteristics of hAP cell

- Consistent incorporation of PLGA nanoparticles depending on cell size



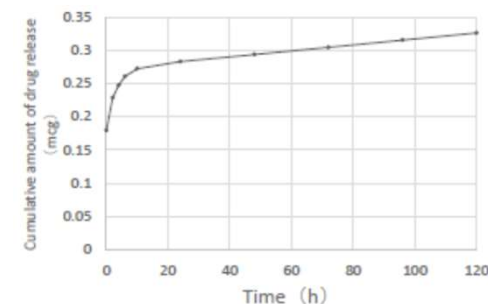
- Controllable PLGA nanoparticle incorporation by changing the nanoparticle concentration in the preparation.



- Consistent drug content in the same manufacturing process

Test number	Drug contents		
Test-1	45.7ng/10 ⁵ cells		
Test-2	52.5ng/10 ⁵ cells		
Test-3	46.1ng/10 ⁵ cells		
Test-4	41.8ng/10 ⁵ cells	Average	43.82
Test-5	36ng/10 ⁵ cells	SD	5.63
Test-6	40.8ng/10 ⁵ cells	CV	12.85

- Sustainable drug release from the hAP cell, up to 5 days



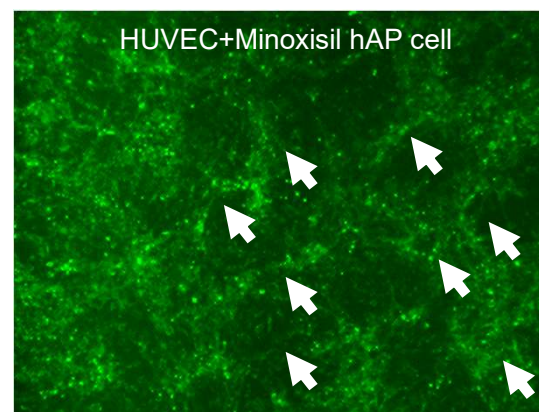
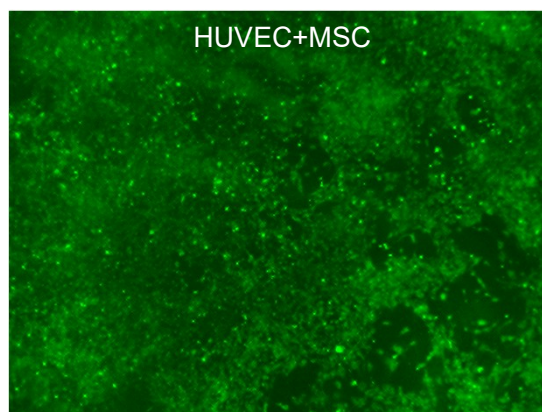
Example: Minoxidil hAP cell



Drug: Minoxidil
Cell: MSC

Availability of the Minoxidil hAP cell

- Novel medicinal properties Minoxidil, known to have vasodilatory property, exhibit enhancement of angiogenesis in the presence of MSC
- Suppression of drug toxicity Minoxidil hAP cell configuration enable to drastically reduce minoxidil dose to enhance angiogenesis,



Angiogenesis (the formation of blood vessel-like structures) was confirmed after 48 hours of co-culturing with fluorescently labeled HUVEC (Human Umbilical Vein Endothelial Cell).



Tissue regeneration by promoting angiogenesis in ischemic diseases

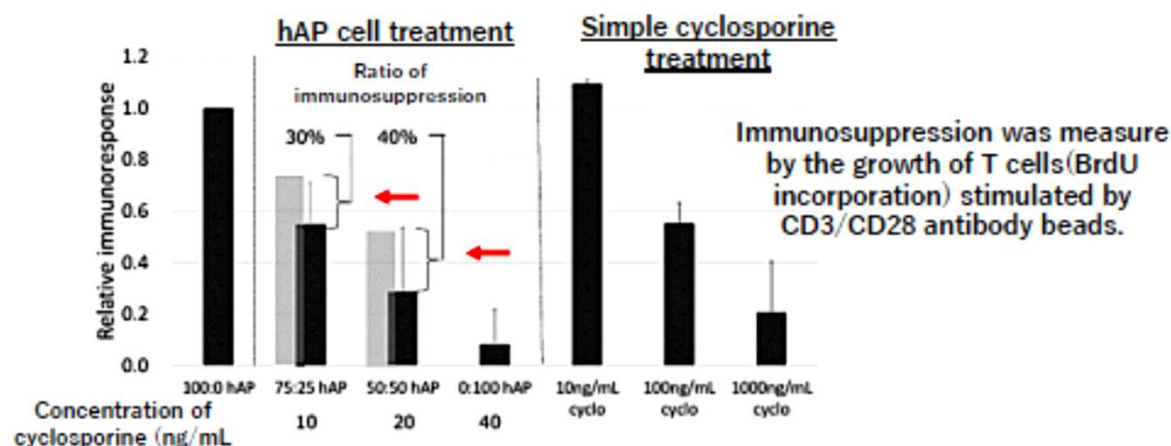
Example : Cyclosporine hAP cell



Drug: Cyclosporine
Cell: Peripheral Blood
Mononuclear Cell (PBMC)

Availability of Cyclosporine hAP cell

- Suppression of drug toxicity
- 1/10 of dose is sufficient for immunosuppressive activity in the hAP cell configuration

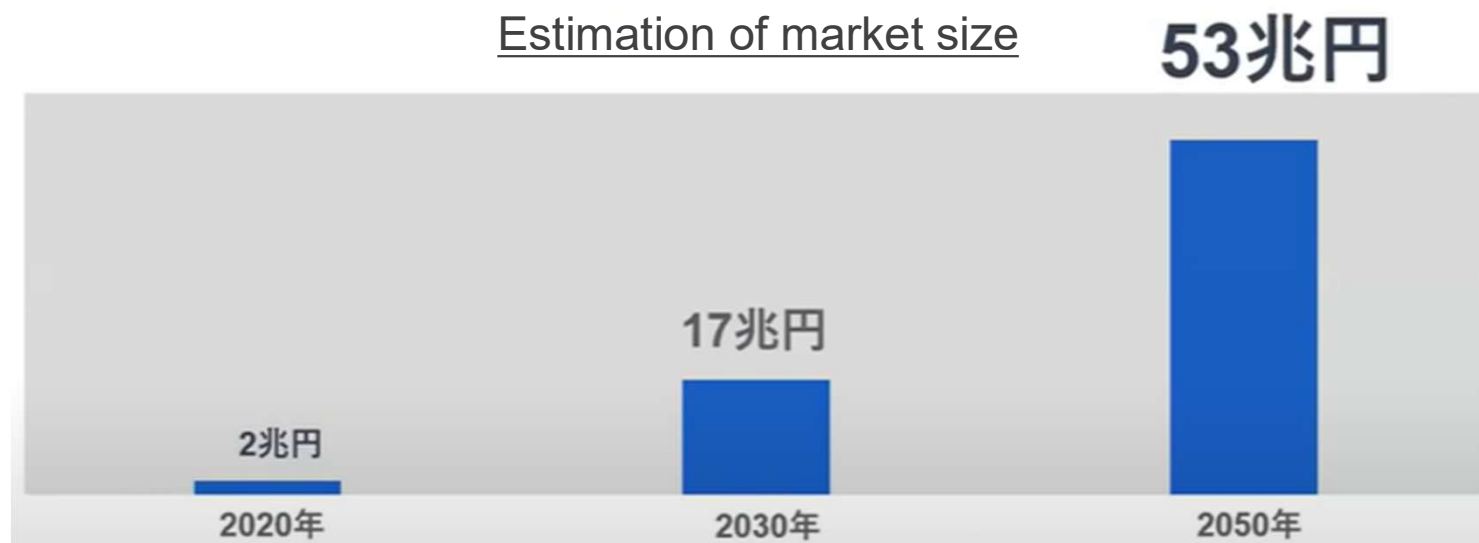


Log and moderate immunosuppression, beneficial for the treatment of autoimmune diseases and cGvHD

4 Market Opportunity

Market size of regenerative medicine

The global market is expected to expand to 50 trillion yen by 2050.

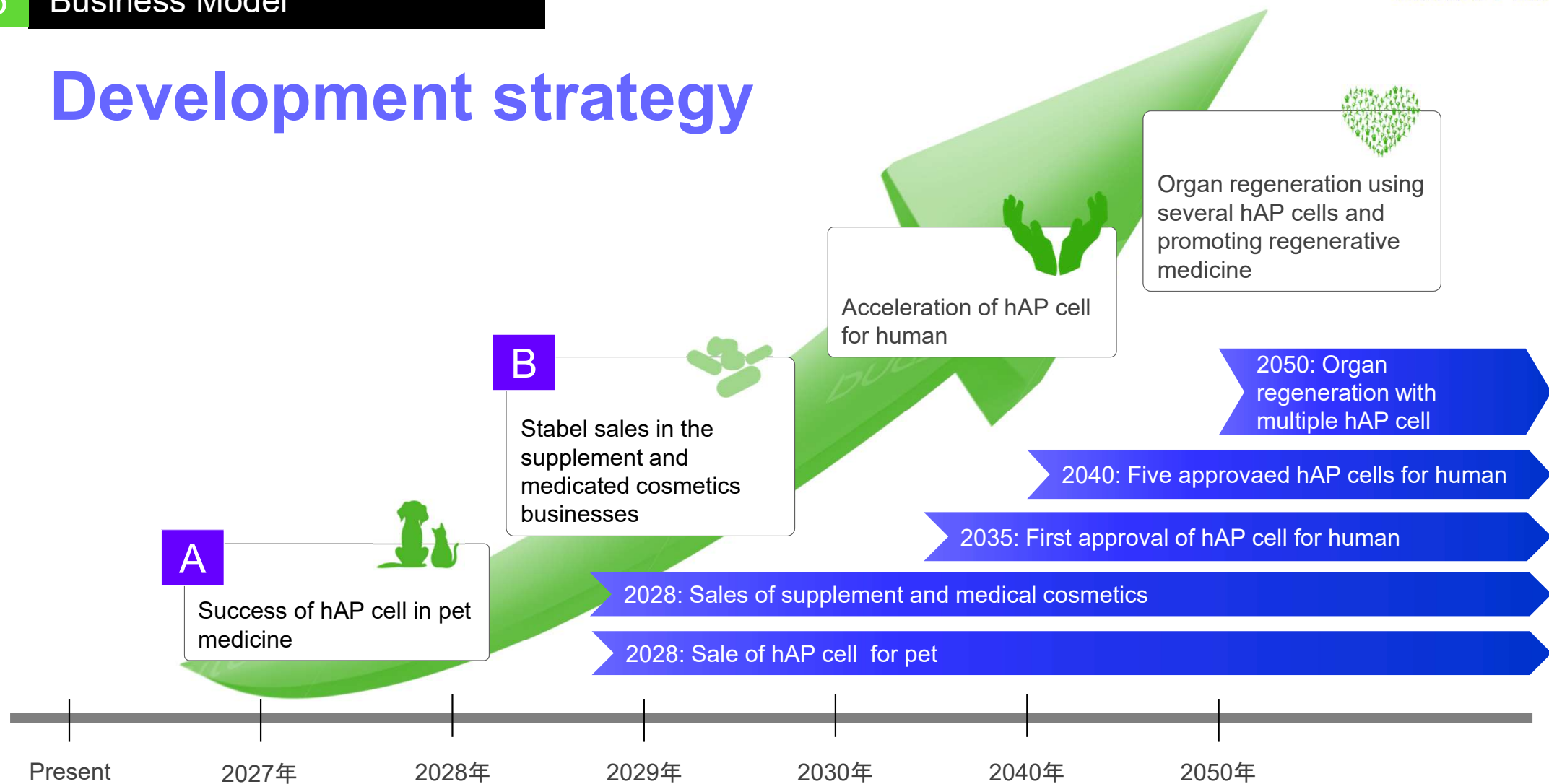


The initiative in this present stage enable to become key player in this market

(出所) 経済産業省『再生医療の実用化・産業化に関する報告書』より

5 Business Model

Development strategy



hAP cell development for pets

In order to bring hAP cells to market as quickly as possible, hAP cell for pets is first aimed

Strategy

- Treatment to renal failure in cats, whose numbers have already surpassed those of dogs in Japan is first target.
- The hAP cell will be sold for medical use, and then approval as a drug will be attempted, by conducting appropriate studies

[Ref 1] Renal failure in cats

The kidneys are important organs that filter waste products from the blood and excrete them as urine. When kidney function declines, waste products increase in the blood, interfering with the function of various organs in the body. In many cases, cats suffer from acute kidney injury due to ureteral stones or nephritis at around 5 to 6 years of age, and then develop chronic renal failure and uremia without fully recovering kidney function, dying around the age of 15.



[Ref 2] Market size of renal failure in cats

- Number of cats in Japan: Approx. 9.15 million
- Number of cats aged 7 years and older: Approximately 4.6 million
- Ratio of cats with kidney disease: 30-40% of seniors = Approximately 1.5 million
- Average annual treatment cost per cat: 270,000 yen
- Annual kidney disease treatment cost: Approximately 400 billion yen

(出所)一般社団法人ペットフード協会、アニコム損保

Approved cell therapy product for pet in Japan

A

Cell therapy for pets has already begun in Japan, so there is a basis for developing hAP cells for pets.

Product name: StemCure
Constituent cells: MSC derived from dog (allogeneic) adipose tissue
Content: 2.5×10^6 cells per 1 mL
Efficacy or effect: Improvement of clinical signs associated with thoracic and lumbar disc herniation in dogs

Planned hAP cell for renal failure in cats

[Drug essence] hAP cells composed of allogenic MSC and immunosuppressants (or antibiotics)
[Efficacy or effect] Therapeutic effect on feline renal failure (significantly higher immunosuppressive effect than existing drugs. Moreover, renal function recovery)
[Products provided] Kit of frozen cells and freeze-dried drug-loaded PLGA nanoparticles, buffer solution, preparation container

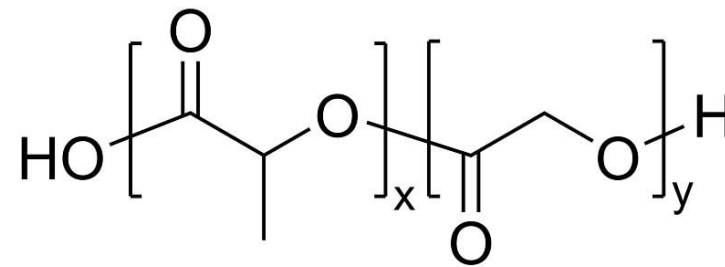


A Japanese chemical company expresses strong interest in developing hAP cells as a veterinary medicine

New business in healthcare

Aiming for early sales by applying hAP cell technology to healthcare

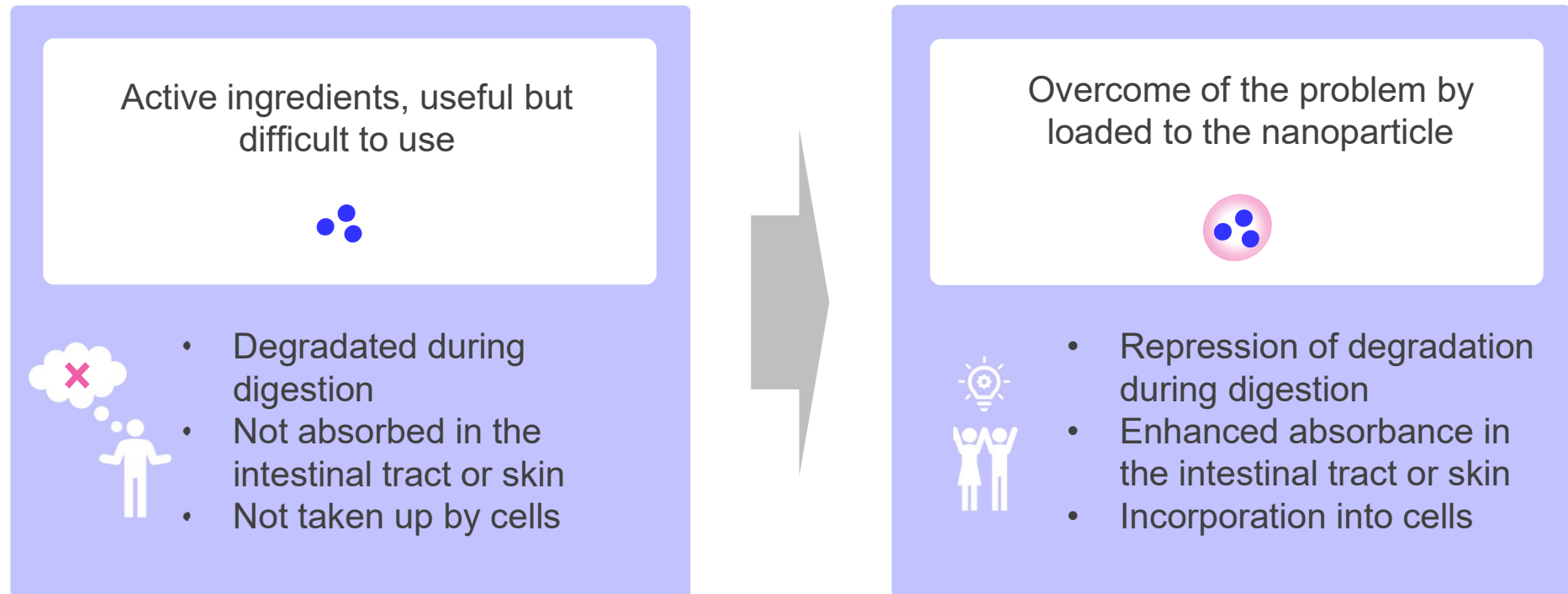
PLGA nanoparticle manufacturing technology to develop new supplements and medicated cosmetics



PLGA: A bioabsorbable polymer (PLGA: Poly-Lactide-co-Glycolide Acid) that slowly degrades through hydrolysis, allowing for sustained release of the contents in the nanoparticle.

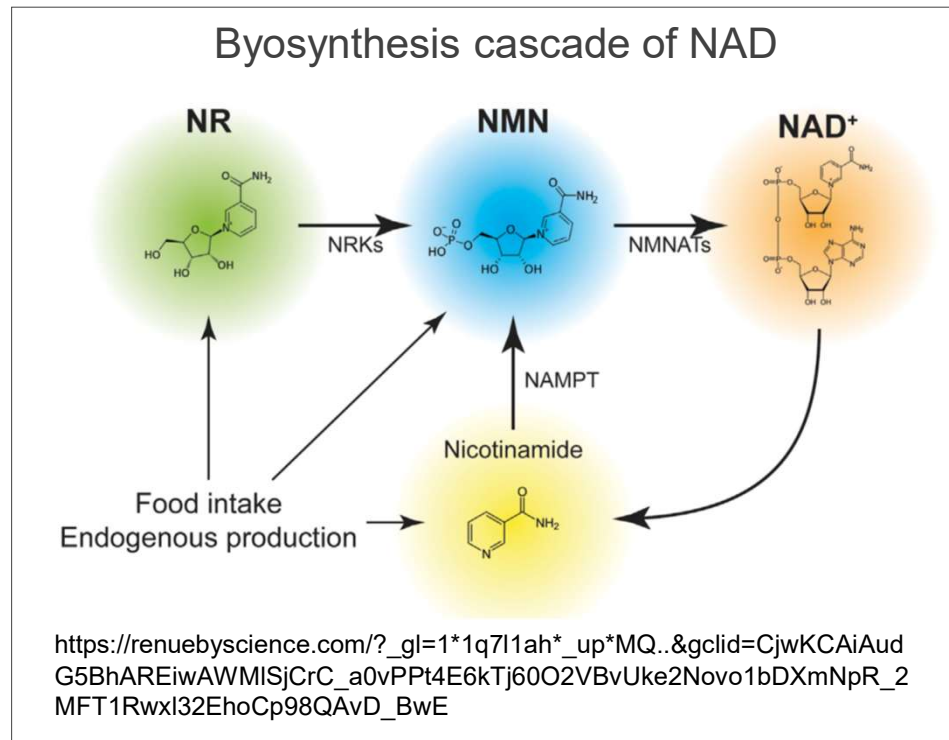
Approach in healthcare

Active ingredients, useful but difficult to use are loaded to PLGA nanoparticle and commercialized



Example of target compound

Anti-Aging substance: NAD (Nicotinamide Adenine Dinucleotide)



Anti-aging effect in NAD

Function as a substrate for various enzymes and contributes to many metabolic activities

- ✓ Repair of DNA damage
- ✓ Strengthening mitochondrial function
- ✓ Anti-aging effects via sirtuin proteins

The amount of NAD in the body decreases with age.

It is believed that supplementation of NAD can slow or improve aging status.

Currently commercialized anti-aging substances

NMN (Nicotinamide MonoNucleotide) ← precursor of NAD

- ✓ The global NMN market is expected to reach \$360 million in 2023 and grow at a CAGR of 10.9% to \$760 million by 2030.



- The North American market size is expected to grow from US\$ 60 million in 2023 to US\$ 120 million in 2030.
- CAGR during the forecast period is 9.7%, a growth rate of nearly 10%.



- The Chinese market size is expected to grow from US\$230 million in 2023 to US\$540 million in 2030
- CAGR of 11.5% during the forecast period, exceeding 10% growth.

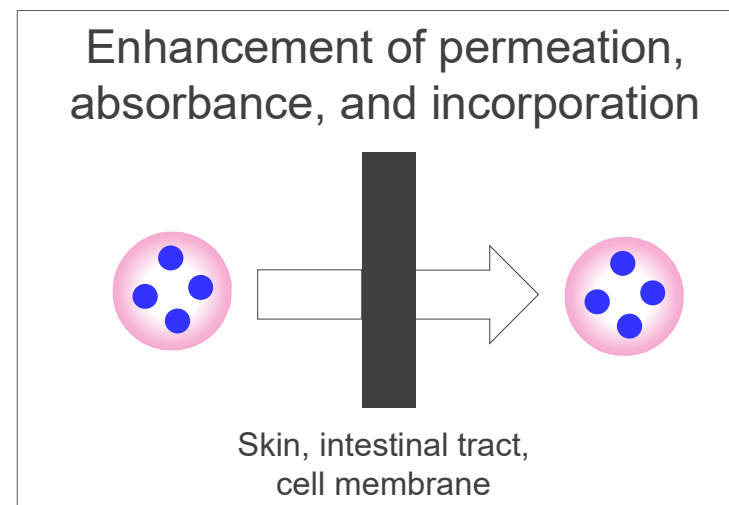
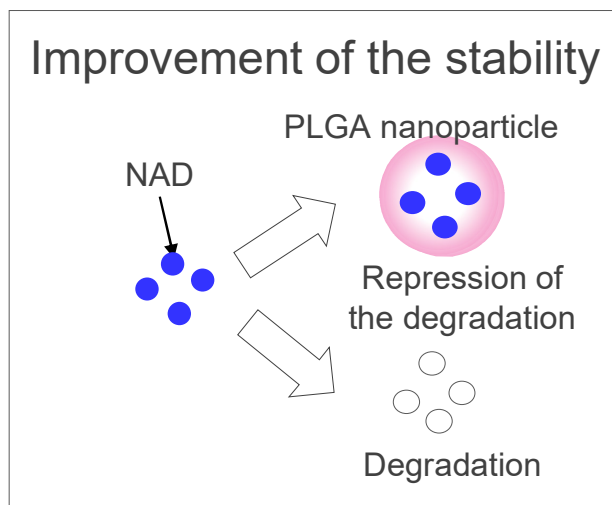


Although many clinical trials using NMN are being conducted around the world, there is still debate about the anti-aging effects of NMN.

Why NAD is not commercialized

- Unstable
- Not permeable through the skin nor absorbed through the intestinal tract
- Hardly incorporated into cells

Solution⇒NAD loaded PLGA nanoparticle



Difficulty in preparing NAD-Loaded PLGA nanoparticles **B**

- Because of hydrophilic characteristics of NAD, very poor loading efficiency into the lipophilic PLGA nanoparticle if conventional manufacturing protocol is used
- No papers and patents related to NAD-loaded PLGA nanoparticles.

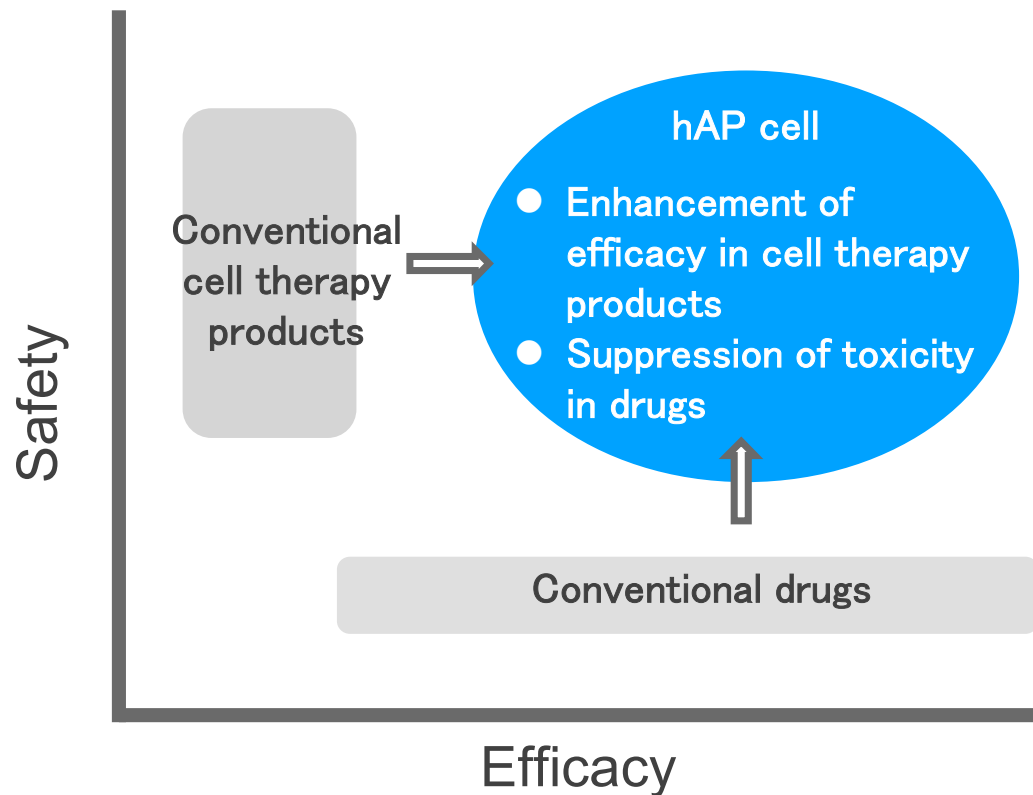
Expertises of Orchard Bio

By improving the composition of the solvents, high NAD loading efficiency into the PLGA nanoparticle is achieved (patent application in preparation).

This is applicable to other useful substances, such as vitamin C.

Usually Vitamin C derivatives but not Vitamin C are used in medicated cosmetics, because the Vitamin C is unstable, Therefore, making it into PLGA nanoparticles will be effective for commercialization.

Advantage for the competitors (Medical)

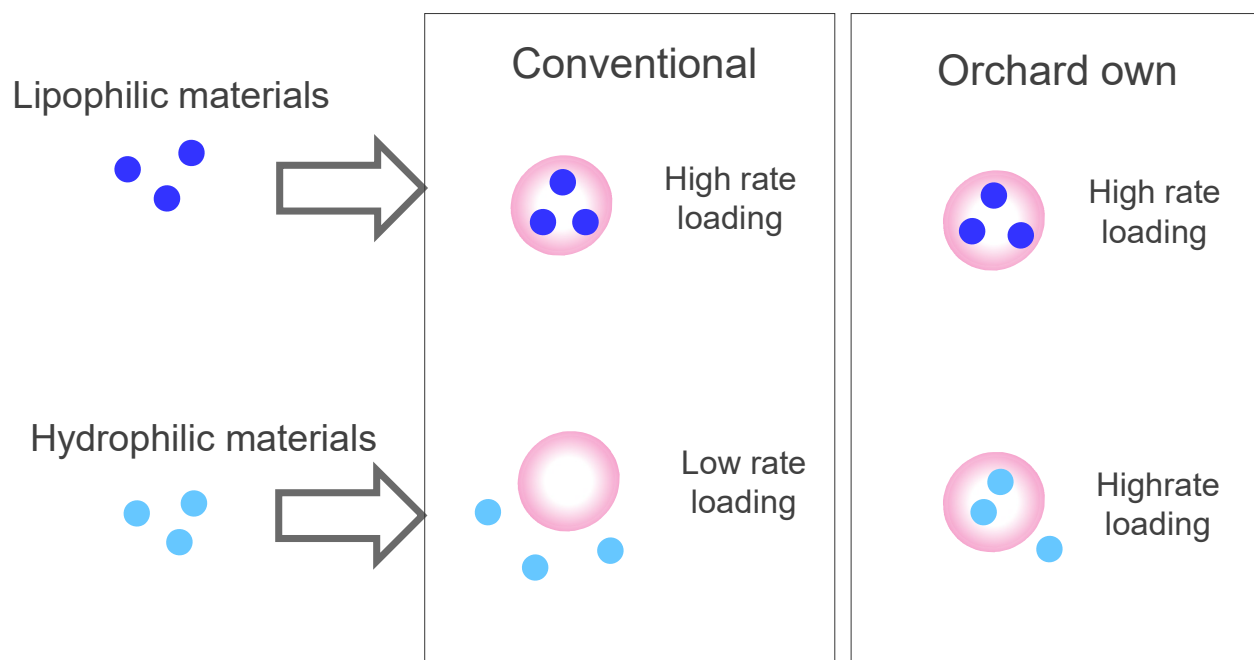


- Conventional cell therapy products: Although they are expected to be main players of regenerative medicine, current cell therapy products are not highly effective effectiveness and only a very limited number of products have been approved as medicines.
- Conventional drugs: they are basically used as symptomatic treatment, and side effects frequently occur.

hAP cells are aimed to establish a [new pharmaceutical position](#) by complementing the problems of cell therapy products and drugs.

Advantage for the competitors (Healthcare)

Material-loading technology into PLGA nanoparticles



- PLGA, highly lipophilic, is compatible with lipophilic materials, resulting in high rate loading to the nanoparticles
- On the other hand, hydrophilic materials are incompatible with PLGA, resulting in low rate loading to the nanoparticles.

Established manufacturing conditions that [increase loading rate of hydrophilic materials](#) in PLGA (patent application in preparation)

In house pipeline of hAP cells

hAP cells for human

hAP cell	Indication	Efficacy studies		Safety studies (non-clinical)	Clinical studies
		<i>in vitro</i>	<i>in vivo</i>		
Minoxidil hAP cell	Ischemic diseases. Alopecia				
Cyclosporine hAP cell	Autoimmune diseases				
(X) hAP cell	Fibrosis		Support of Professor Hirotake Kojima of the Faculty of Pharmaceutical Sciences, University for compound library.		
(Y) hAP cell	Cancers				

hAP cell for pets

Indication	Efficay studies (in vivo)	Safety assessment	Clinical studies
Renal failure in cats			
	Currently in discussions with a Japanese chemical company regarding joint research		

Patent information

Exclusive license right

- WO2016/076227: 幹細胞機能増強用スタチン封入ナノ粒子製剤、並びにそれを含有する機能増強幹細胞及びその製造方法



Prior patent to establish hAP cell concept

Related patent

WO2017/191808: 炎症性疾患治療用幹細胞の機能増強用スタチン封入ナノ粒子製剤、及びそれを含有する炎症性疾患治療用機能増強幹細胞

Additionally two patents were filed in March 2024

- hAP cells as a drug formulation that allows to reduce drug dosage
- Dedicated vessel for hAP cell preparation ⇒ approval of the patent (2025.06)



Patents necessary to exclusively implement the hAP cell platform business

THANKS



Orchard ✖ Bio

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