

Innovacell Corporate Overview

Reclaim your health through
Regenerative Medicine

16 November 2022



innovacell

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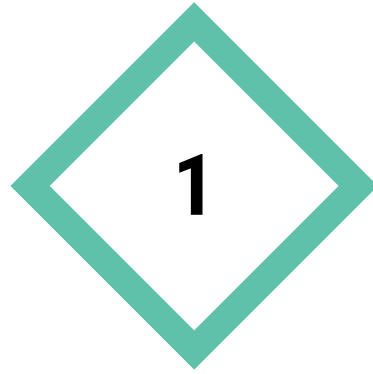
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Business Overview



Who We Are

- ❖ **A sector-leading regenerative medicine biotechnology** company that was initially founded in Austria (2000)
- ❖ Developing cell therapy **treatments for Incontinence.**
- ❖ **Reorganized and established as a Japanese company** in 2021 to prepare for a listing in 2023 on the Tokyo Stock Exchange

FI is an Unmet Medical Need

While fecal incontinence **significantly reduces a patients' quality of life**, it is termed **the silent affliction** because patients are embarrassed and rarely seek medical attention.*¹

The loss of dignity associated with losing control over one's bodily functions can lead to embarrassment, shame, frustration and depression.

It's common for people with fecal incontinence to try to hide the problem or to avoid social engagements.



Fecal Incontinence is an indication that greatly affects a patient's quality of life



*Fecal incontinence (FI) is a prevalent condition that occurs in up to 15% of the Western population and significantly impairs quality of life *²*

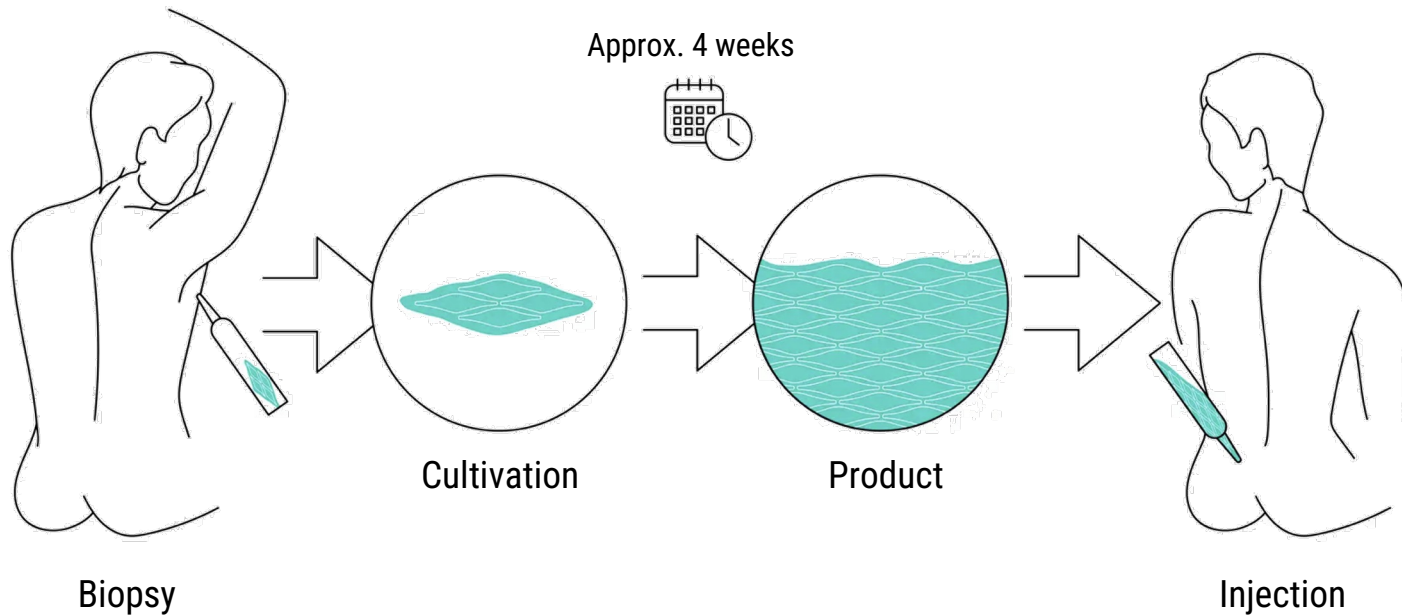


*1: <https://doi.org/10.3862/jcoloproctology.65.101>

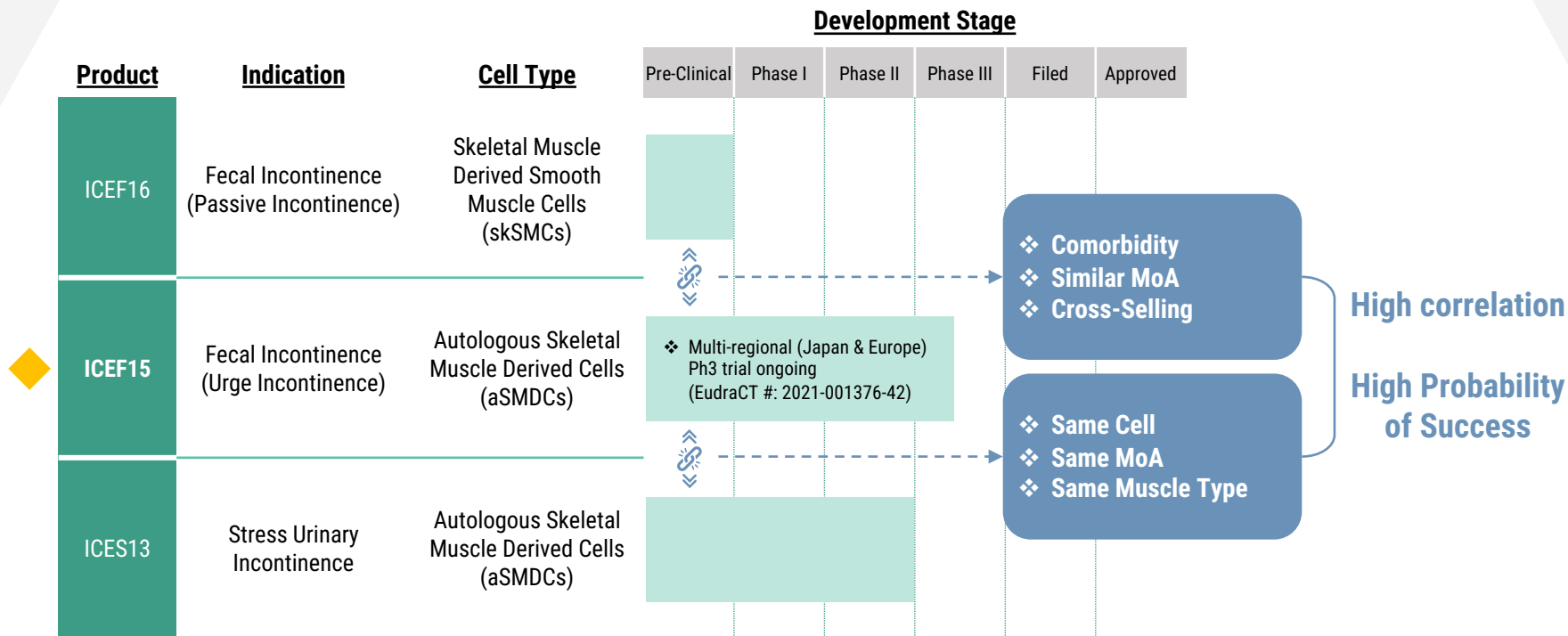
*2: Sharma A, Rao SSC. Epidemiologic Trends and Diagnostic Evaluation of Fecal Incontinence. Gastroenterol Hepatol (N Y). 2020;16(6):302-309

Innovacell's Treatment at a Glance

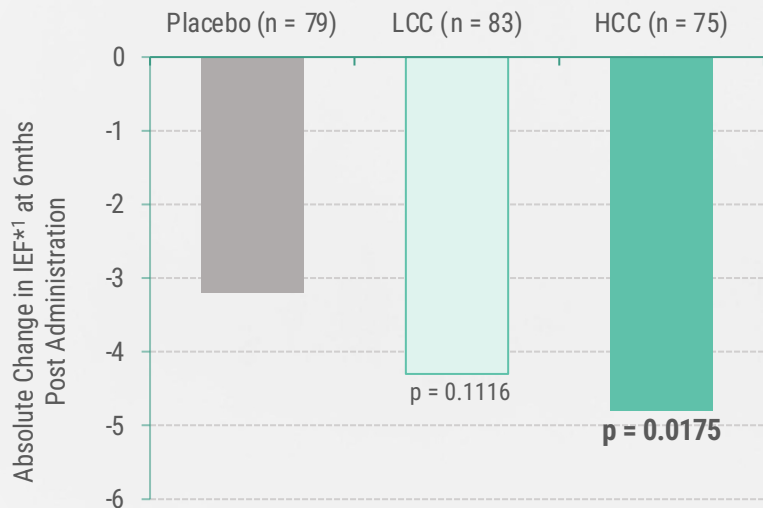
Innovacell has designed **Innovative Cell** therapies that use a patient's own cells to treat the underlying cause of incontinence and **restore a patient's dignity**



Strategically Selected Pipeline Products In Advanced Clinical Stages



ICEF15 Phase 2b Clinical Trial Results



High Cell Count (HCC) dose Showed Statistically Significant Reduction in Incontinence Episodes vs. Placebo

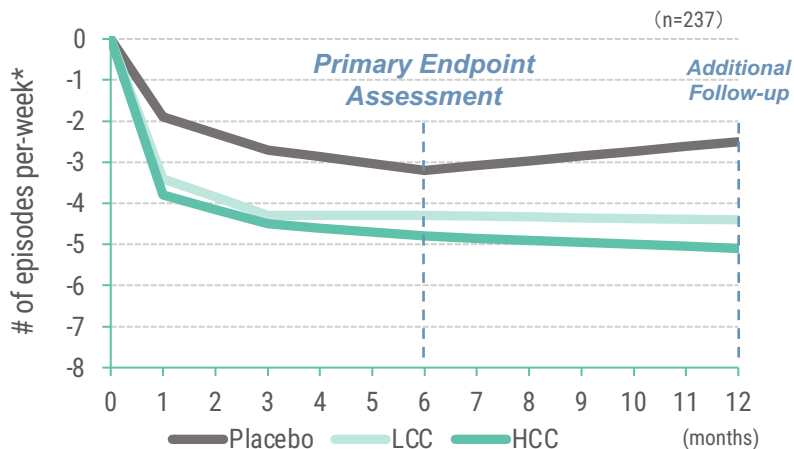
*1: IEF = Incontinence Episode Frequency (per-week)
* LCC = 5 million cells, HCC = 50 million cells
PMID: 35961517 DOI: 10.1016/j.jcgh.2022.07.039



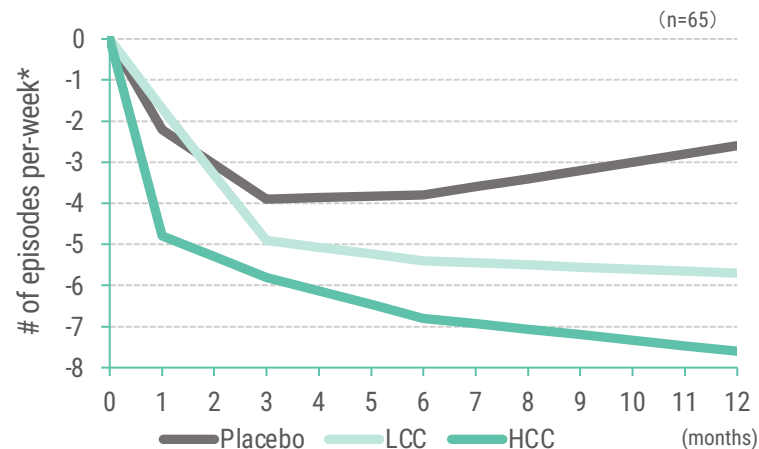
ICEF15 Phase 2b Sub-Group Analysis

The sub-group's high cell count (HCC) cohort shows the potential to **cure patients and provide long-lasting effects**

Results for all Participants



Results for Sub-Group



Sub-group includes patients that are both:

- ❖ **Less than 10 years** from symptom onset
- ❖ **Greater than 2 episodes** per week (excluding traces)



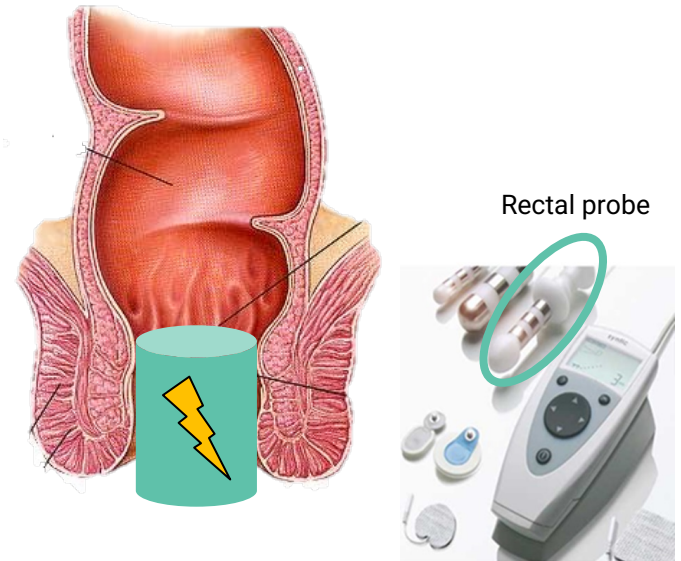
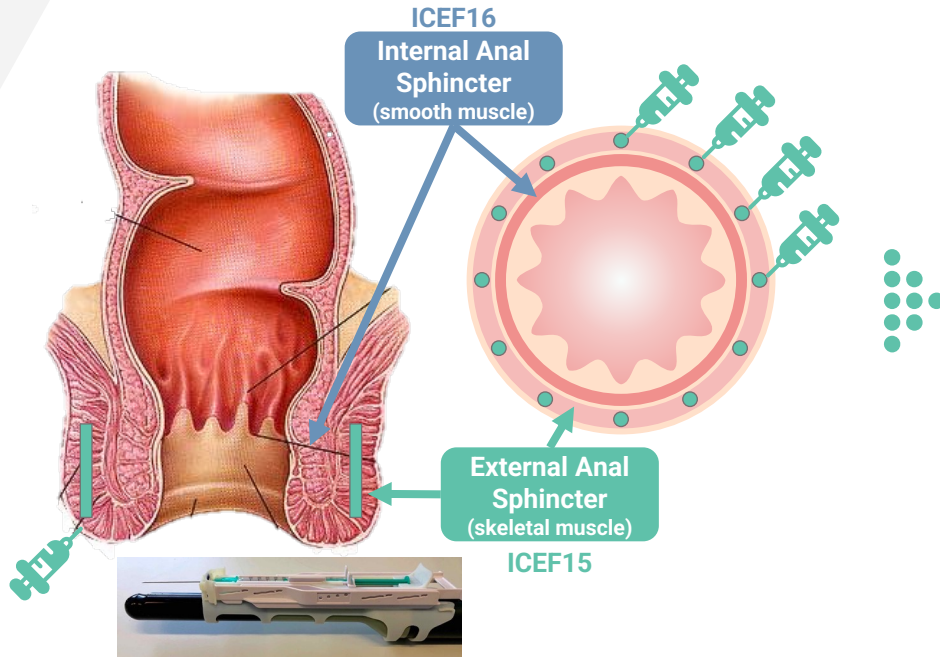
Phase III Patient Population

* The median number of incontinence episodes per-week for study participants was around 8

ICEF15/16 Administration

Administration consists of 12 injections into the external anal sphincter

20min Post-administration electrical stimulation twice a day for 4 weeks

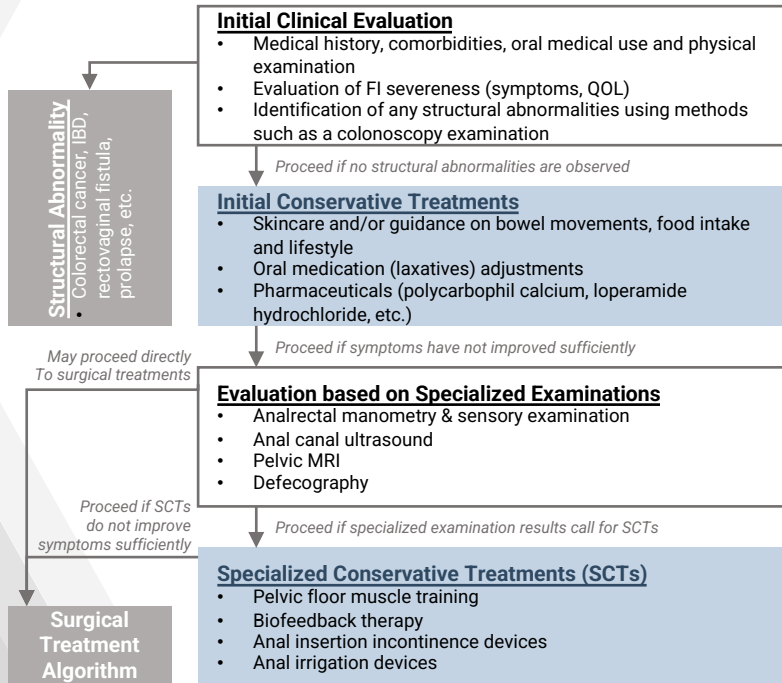


Administered using an ultrasound probe mounted needle guide

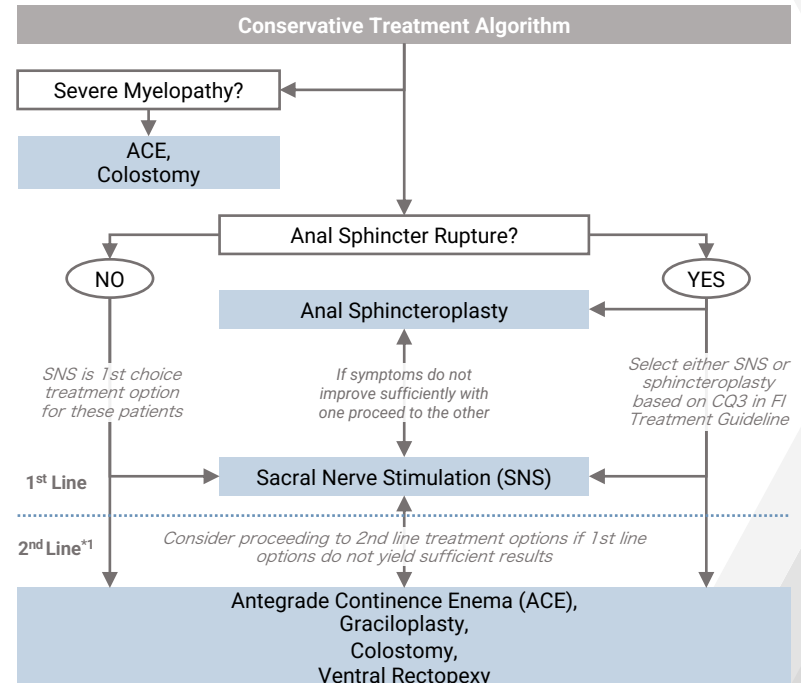
ICEF15/16 Positioning (1/2)

The Japanese fecal incontinence treatment algorithm proceeds from conservative treatment options to surgical treatment options

1. Conservative Treatment Algorithm for FI



2. Surgical Treatment Algorithm for FI

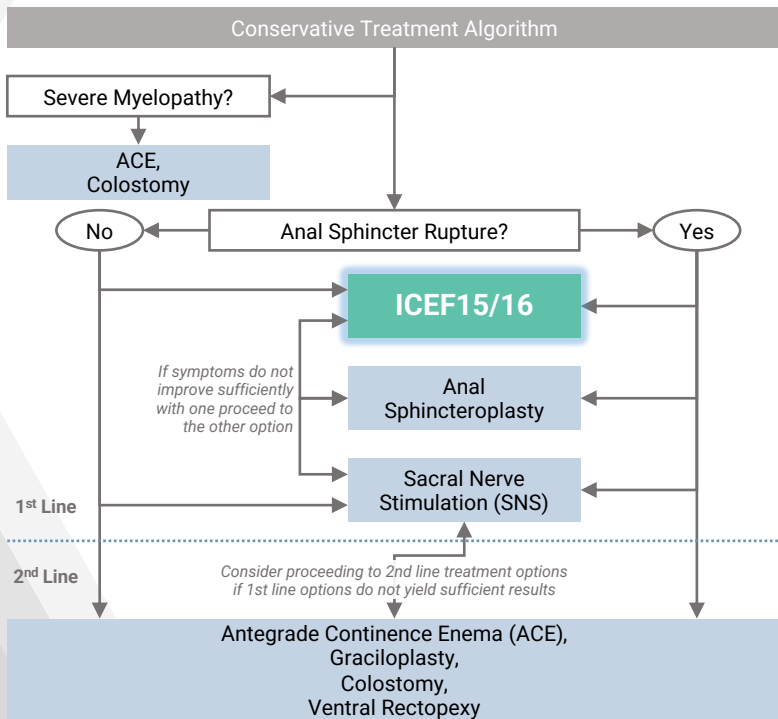


*1: Upon consultation with the patients, physicians may choose to skip 1st Line treatment options and proceed directly to 2nd Line treatment options. Furthermore, if 2nd Line treatments are conducted first, one may move back to 1st Line treatments later.

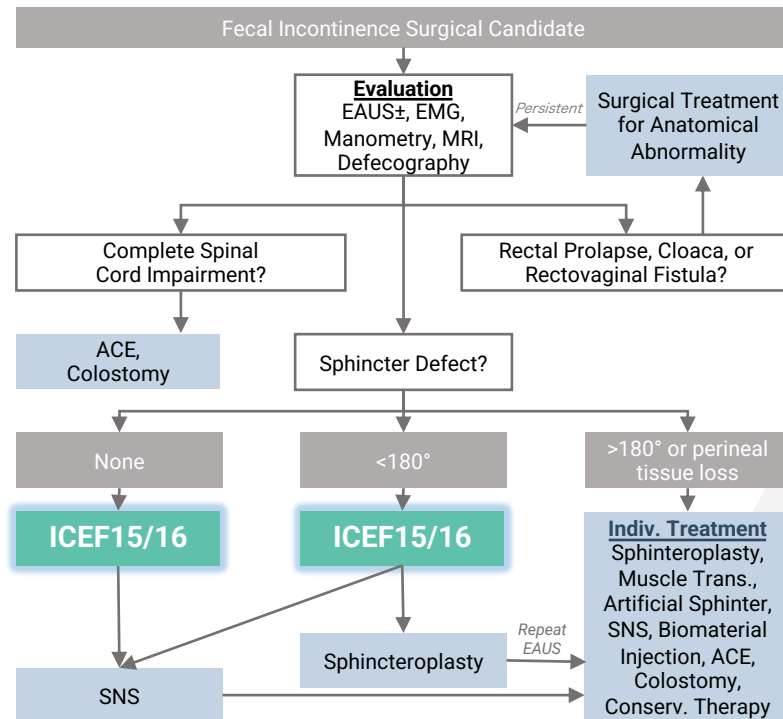
ICEF15/16 Positioning (2/2)

Clear positioning within both Japanese and European treatment algorithms

ICEF15 Positioning (Japan)






ICEF15 Positioning (Europe)



Limited Competition (Fecal Incontinence)

Approved FI Treatment Options for ICEF15 & 16 Target Patients

 Scalpal	Anal Sphincteroplasty	<ul style="list-style-type: none"> ❖ JSCP recommendation level is Grade B ❖ Long-term (5yr+) efficacy is low ❖ 2nd operation isn't recommended
	Sacral Nerve Stimulation	<ul style="list-style-type: none"> ❖ Requires 2-week test stimulation period ❖ MRI contraindication ❖ Relatively Expensive ❖ High psychological barrier
 Injection	None	 UNADDRESSED MARKET




Patients settle for sub-optimal temporary measures



Innovacell's market segment

Cell Therapy FI Treatment Options Under Development

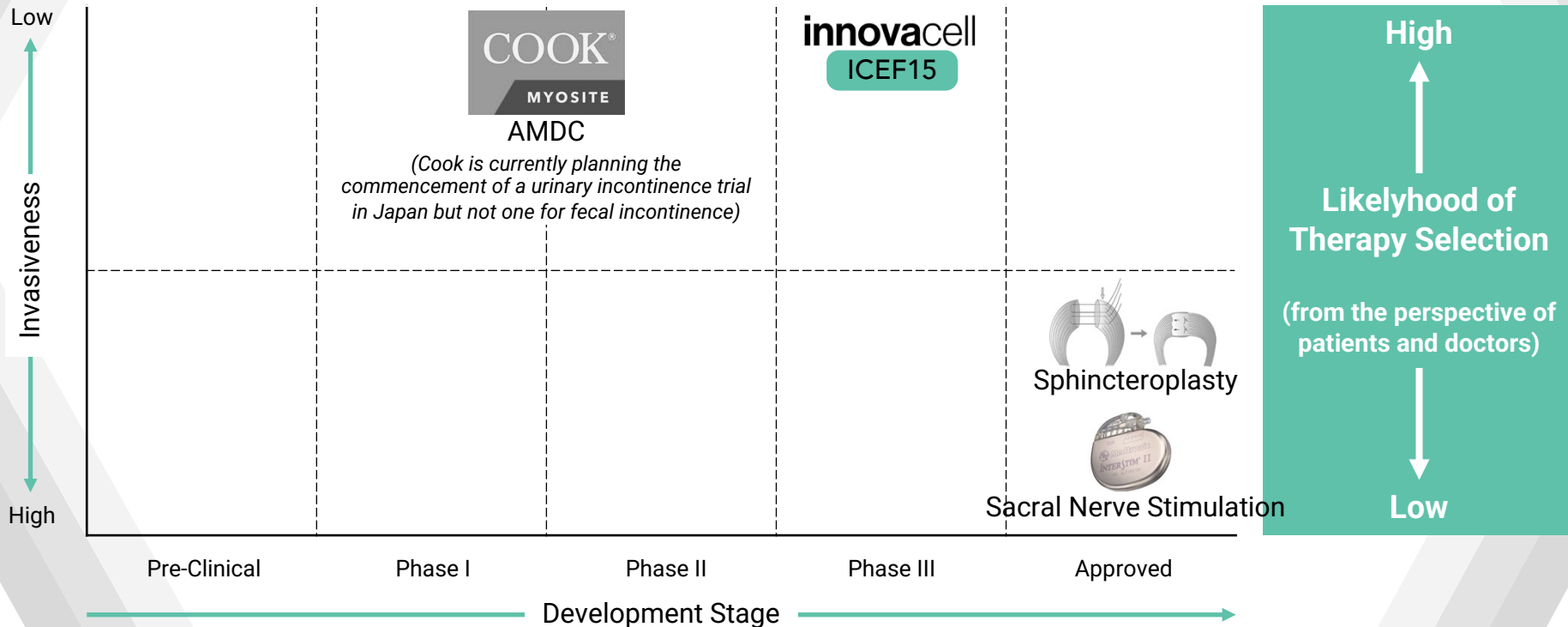
	AMDC (Cell therapy being developed by Cook Myosite Inc.)	Japanese reimbursement price will be pegged to ICEF15's price as the "similar efficacy comparison method" will be used
-----------------------------------------------------------------------------------	--------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------



5~ year delay vs. Innovacell




(Currently undergoing Ph1/2 trial)

Less Invasive than Existing First Line Surgical Options



Limited Competition (Urinary Incontinence)

Approved SUI Treatment Options for ICES13 Target Patients

 Scalpal	Burch Procedure	<ul style="list-style-type: none"> ❖ Surgical bladder/urethra damage possible ❖ 3 in 4 patients develop lower urinary tract dysfunction
	Urethral Slings	<ul style="list-style-type: none"> ❖ 1 in 4 patients develop complications
 Injection	None	 UNADDRESSED MARKET





Patients settle for sub-optimal temporary measures



Innovacell's market segment

Cell Therapy SUI Treatment Options Under Development

	MPC (Cell therapy being developed by Muvon Therapeutics AG)	Currently undergoing Phase 1 trial
	AMDC-USR (Cell therapy being developed by Cook Myosite Inc.)	Phase 3 didn't meet primary endpoint



Multiple year delay vs. Innovacell

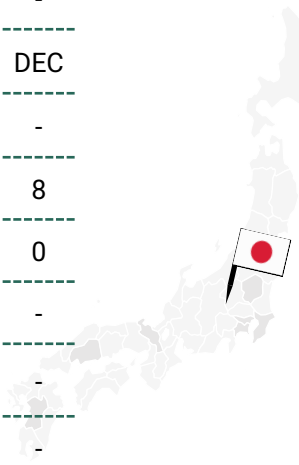
A teal-colored diamond shape with a white center, containing the number 2.












2

ICEF15 Phase III Multi-Regional Clinical Trial

Progress of Phase III MRCT in Europe & Japan

Trial approval obtained in 10 out of 11 countries and **enrollment has started in 3 countries** (as of 31 OCT 2022)



											
	BG	ES	UK	SE	PO	IT	DE	FR	CZ	AT	JP
CA*1 Approval	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	✓
IRB*2 Approval	✓	✓	✓	✓	✓	-	✓	✓	✓	-	-
SIV*3	✓	✓	DEC	✓	JAN	JAN	DEC	TBD	NOV	TBD	DEC
Enrollment Started	✓	✓	-	✓	-	-	-	-	-	-	-
Total # of Sites	1	7	1	3	1	4	1	6	2	1	8
Sites Activated	1	7	0	1	0	0	0	0	0	0	0
Recruited	6	6	-	0	-	-	-	-	-	-	-
In Screening (failed screening)	0 (5)	0 (1)	-	0 (0)	-	-	-	-	-	-	-
Biopsy Obtained	1	1	-	0	-	-	-	-	-	-	-
Dosed	0	4	-	0	-	-	-	-	-	-	-

*1 Competent Authority

*2 Institutional Review Board

*1 Site Initiation Visit

A teal-colored diamond outline is centered at the top of the page. Inside the diamond is the number 3.

3

Corporate Overview

Leadership



Colin Lee Novick | Rep. Director/CEO

A leader with a wide range of expertise in the field of regenerative medicine coupled with a great deal of experience in executing projects in the same field.

Japanese & English



Jason Sieger | Rep. Director/COO

Globally recognized executive with extensive operational / management experience in capital markets and pharmaceuticals (particularly with cellular products).

Japanese & English



Yasushi Hosono | Director/CFO

One of the few executives who has achieved IPOs for three companies (including two global offerings) that also has CFO experience at a listed regen medicine firm.

Japanese & English

Masters (Law)



Ekkehart Steinhuber | Director*

22 years of leadership experience across 3 continents (Europe, Asia and Africa) as a member of the Novartis Group and a long-time leader of Innovacell.

German & English

PhD (Economics)



Rainer Marksteiner | Director/CSO*

Innovacell's scientific founder, who is involved in all core aspects of the company; patenting, pre-clinical / clinical development, and GMP Manufacturing.

German & English

PhD (Microbiology)

* Ekkehart Steinhuber and Rainer Marksteiner are also directors of Innovacell AG, each being the Managing Director/CEO and Director/CSO, respectively.

Organizational Structure

External Directors

TBD

TBD

Board of Directors

Yasushi
Hosono

Rainer
Marksteiner

Ekkehart
Steinhuber

Colin Lee
Novick

Jason Sieger

Audit & Supervisory Board

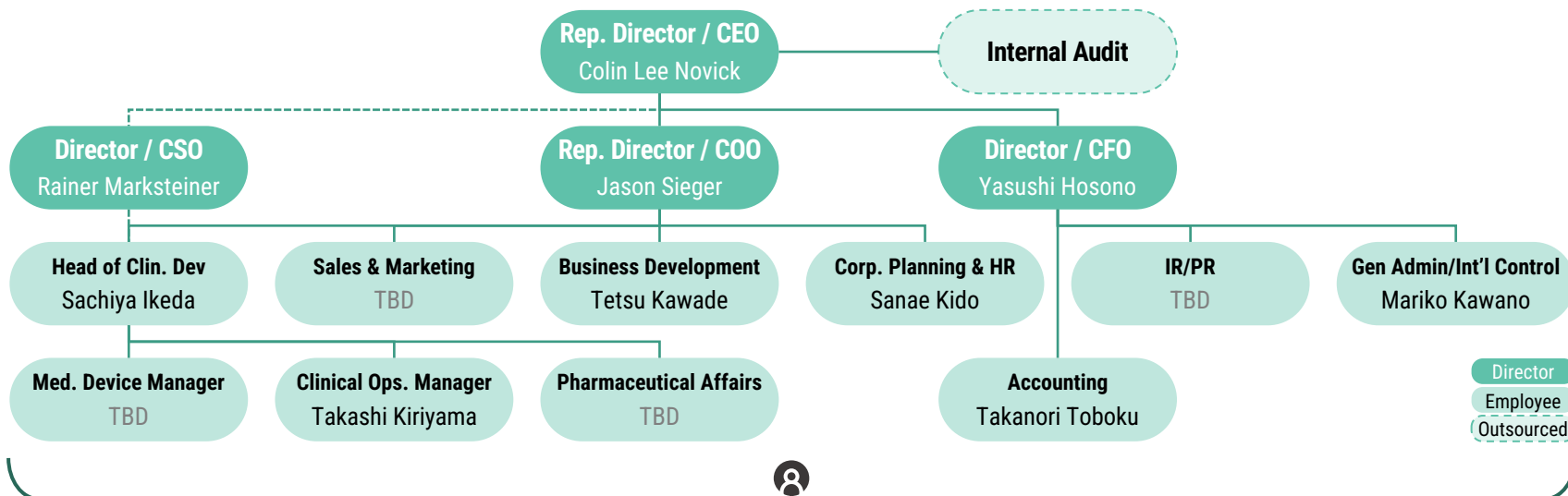
Shigeru
Takagi

TBD

TBD

Internal

External



Director

Employee

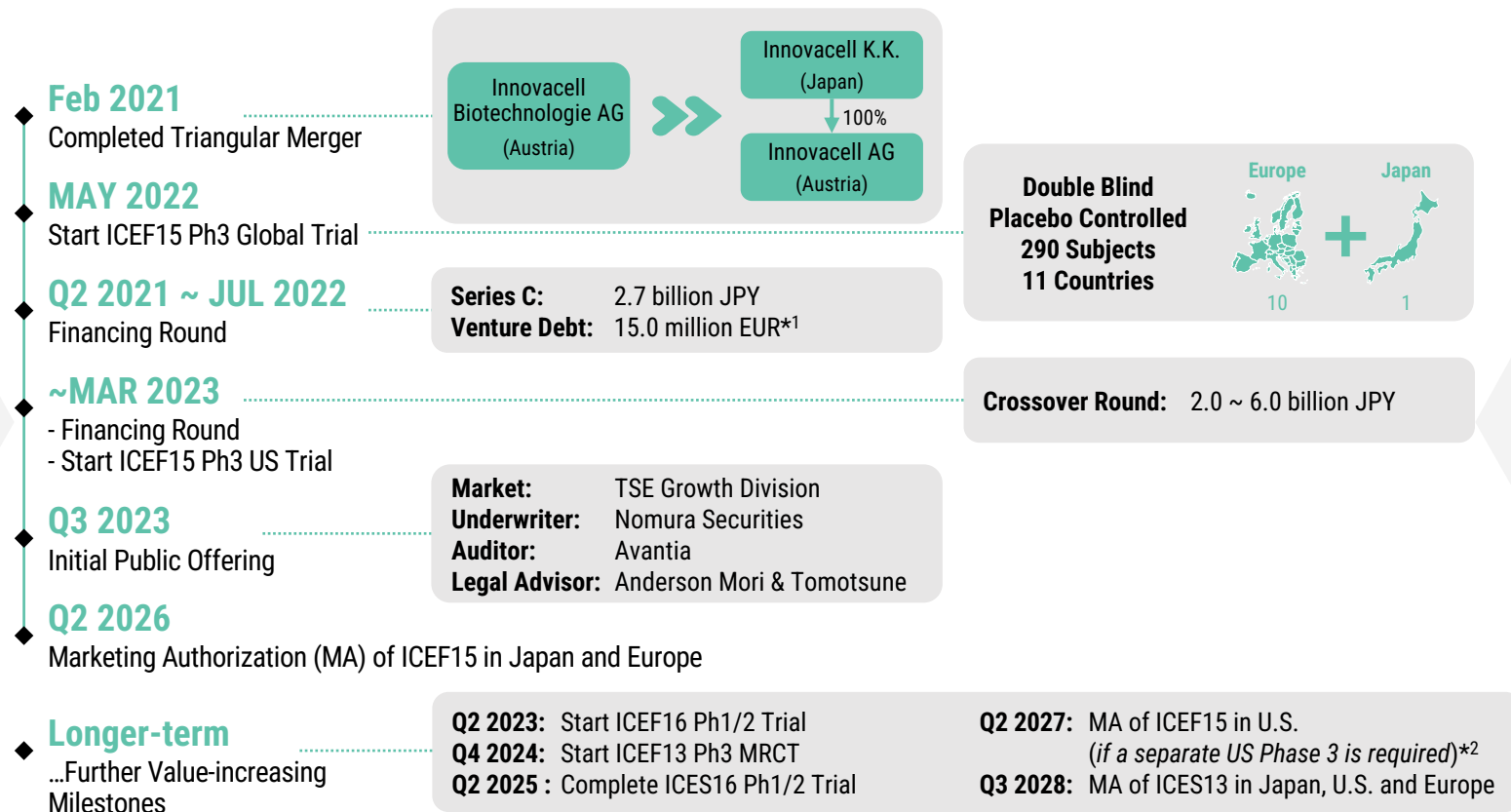
Oversourced



Innovacell Group Total Headcount

40

Recent History and Future Milestones



*1 Venture debt from the European Investment Bank (EIB)

*2 Looking to confirm with the FDA if a separate Phase III study is necessary for approval in the US



4

Investment Highlights

Our Value Drivers



Strategy

- ❖ Strong focus on **underserved market** estimated at SOM = **1.3 trillion JPY***1
- ❖ **First to market** (vs. competitors with/in same tech/market) to establish market advantage
- ❖ Value creation through **clearly defined MoA***2 and **positive clinical results**
- ❖ **Strict quality and cost management** using proprietary GMP manufacturing facility



Clinical Evidence

- ❖ **Enrolled/dosed ~300 patients***3 to date
- ❖ Strong safety profile
- ❖ **Less invasive** than existing treatments
- ❖ **Clear clinical positioning** within current treatment algorithm



Pipeline

- ❖ 3 first-generation autologous pipeline products
 - ✓ ICEF15 = **started phase 3**
 - ✓ ICES13 = completed phase 2
 - ✓ ICEF16 = preparing for phase 1
- ❖ **One step away from marketing authorization of ICEF15** in Japan and Europe via a single global phase 3 clinical trial
- ❖ **Closely linked success between ICEF15 and ICES13/ICEF16** due to same MoA*2, cell type, disease cause and cross-selling potential



People

- ❖ Highly **qualified management and R&D organization** in Japan and Europe
- ❖ **Entrepreneurial spirit** throughout the organization
- ❖ **Corporate governance** and high standards of ethical behavior as a high-priority

*1: circa 9.2 billion EUR, circa 9.6 billion USD

*2: MoA = Mechanism of Action

*3: circa 300 patients enrolled in ICEF15 trials (including ICES13 trials and this number is circa 900 patients)

Corporate Track Record



2 successful Phase 2 clinical trials
(no failed late-stage clinical trials)



7 clinical trials conducted in total
(circa 900 patients enrolled of which 600+ were dosed with cells)



15+ years of experience in GMP production and controls



Extensive regulatory experience with the PMDA, EMA and FDA



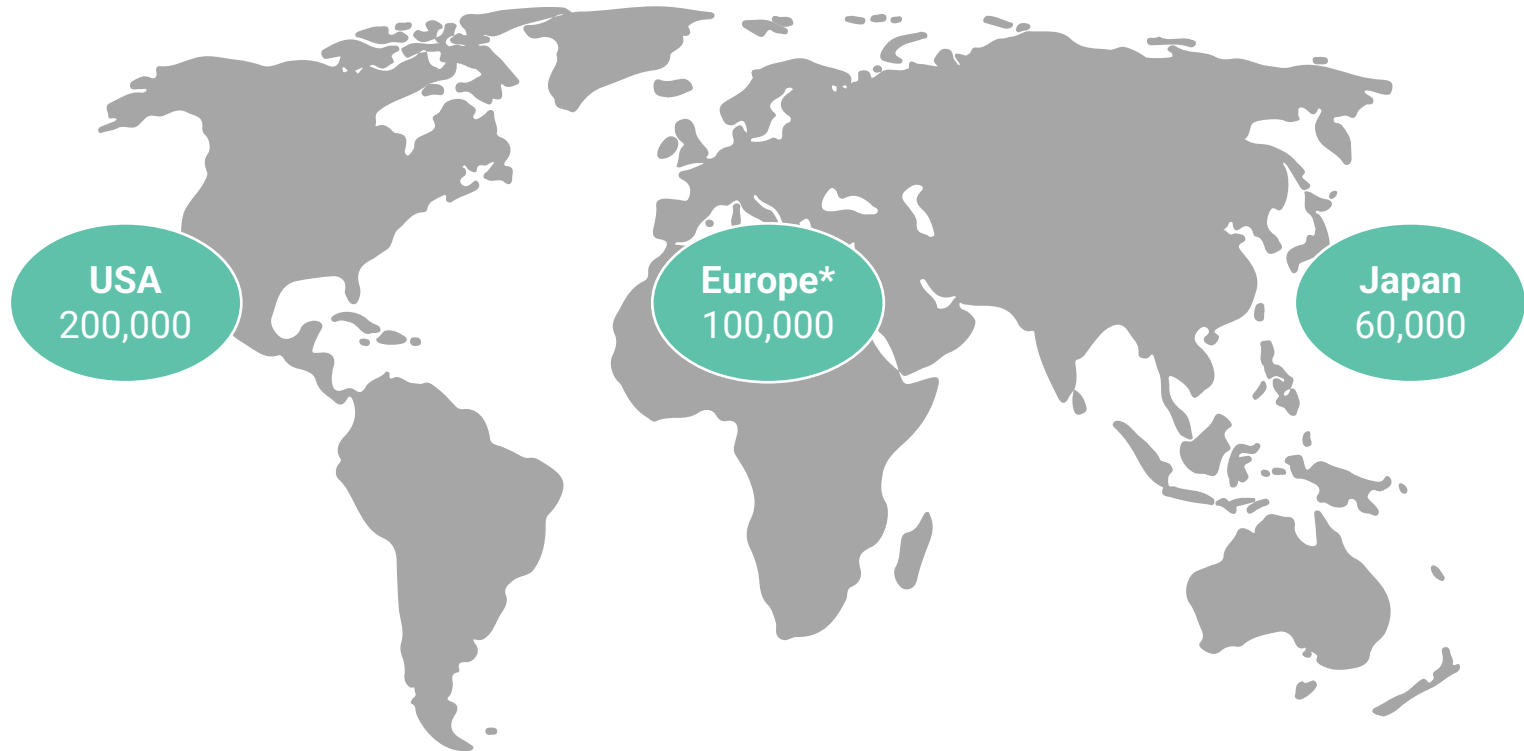
Raised 15.1BB JPY (circa 107.1M EUR) to date

- ❖ Equity: 9.19BB JPY
- ❖ Grants: 0.66BB JPY
- ❖ Loans: 4.75BB JPY
- ❖ Tax Bonus: 0.56BB JPY

* GMP = Good Manufacturing Practice
* PMDA = Pharmaceuticals and Medical Devices Agency

* EMA = European Medicines Agency
* FDA = U.S. Food and Drug Administration

Estimated Target Patient Population for ICEF15



* Europe's Big 5: Germany, UK, France, Italy and Spain

Series C Capital Raise

Amount 2.7 billion JPY

Post-Money 18.5 billion JPY

Use of Funds

ICEF15 Global Clinical Trial

ICEF16 Pre-clinical and FIH Trial

Operating Expenses

❖ Japan

❖ Europe

IPO Preparation

Repayment of Debt




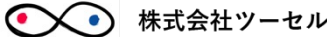


Other

❖ Innovacell AG also signed an agreement in DEC 2021 with the European Investment Bank for a 15 million EUR venture debt credit line and had the debt disbursed in JUN 2022

Peer Group Comparison (vs. Private Biotechs)

Innovacell's post-Series C valuation is appropriate

when compared to their peer group of non-listed Japanese cellular therapy biotechs.

	Product	Clinical Dev. Phase	PMDA Pivotal List	FIH Study	Competitor Products in Dev.	Cumulative Trial Participants	Has Marketing Partner	Overall Rating	Valuation
	ICEF 15	3	3	3	3	3	1	16	18.5 billion JPY
	HS-001	2	3	2	2	2	3	14	22.4 billion JPY
	MEG-002	2	1	2	3	1	1	10	18.0 billion JPY
	gMSC1	3	1	1	2	2	3	12	13.8 billion JPY
	NIB-102/ TAK-102	1	1	1	1	2	3	9	34.2 billion JPY
	iCM/iPIC	0	1	0	2	1	3	7	10.5 billion JPY

Rating Legend

Pre-clinical = 0
Phase I = 1
Phase I/II = 2
Phase III = 3

On list = 3
Not on list = 1

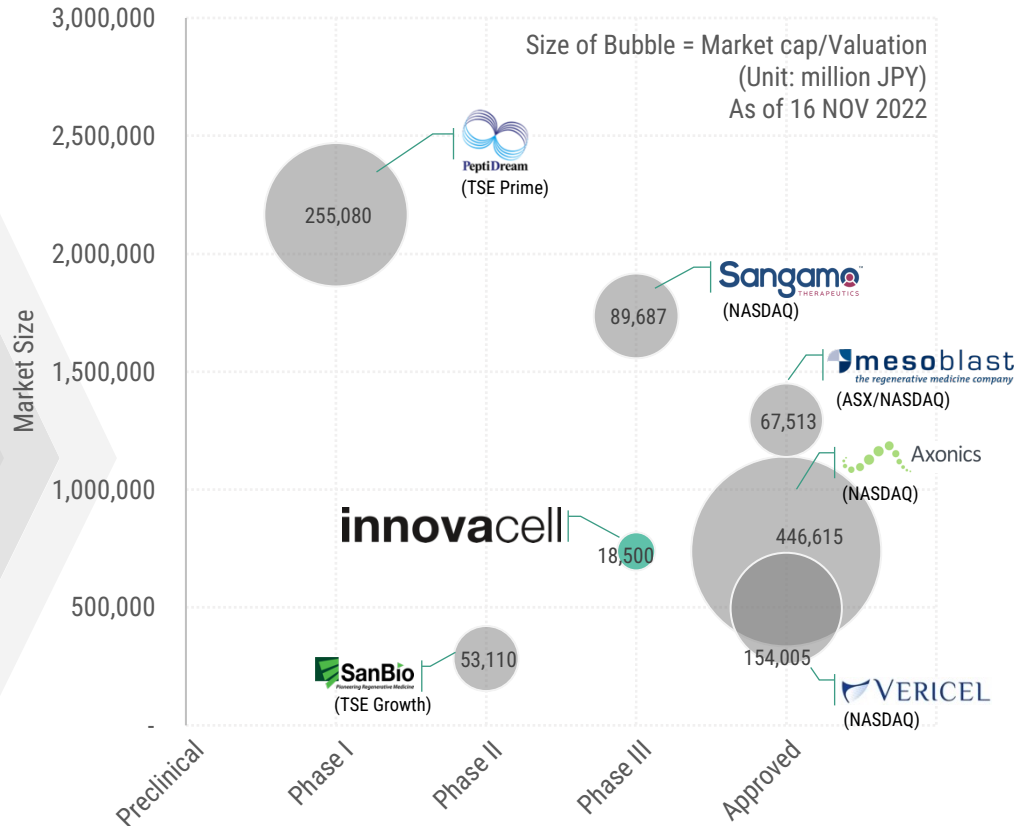
Pre-clinical = 0
FIH Study = 1
Clin. Resch = 2
Others = 3

100~ = 1
10~99 = 2
0~9 = 3

0~9 = 1
10~99 = 2
100~ = 3

Yes = 3
No = 1

Peer Group Comparison (vs. Public Biotechs)



Even in the currently difficult public biotech environment **Innovacell's post-money valuation still provides significant upside for investors** when compared to various peer group listed regenerative medicine and advanced medicine biotech companies.

- PeptiDream's market size = peptide drug market size
- Vericel's market size = global knee cartilage repair market
- Sangamo's market size = global hemophilia market size
- Axonic's market size = same as Innovacell's
- Mesoblast's market size = global heart failure market size
- SanBio's market size = global TBI market size



Thank You!