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Innovacell Inc.

(Correction) Quarterly Update Q3 FY2026

Creating a way Forward, Together

November 12, 2026



Partial Corrections to This Document

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This document is a revised version issued to correct inaccurate depictions found in the material disclosed on November 11, 2026.
The specific corrections made are as follows:

- Page 11 of this document (page 10 in the materials disclosed on November 11, 2026): the depiction of the internal anal smooth muscle and the position of the syringe in the cross-sectional diagram of the anus on the left side

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Overview of Innovacell's Development Pipeline

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- **All products in our pipeline targeting full approval in Europe, Japan and the U.S.**

Product	Target indication	Cell type	Development stage: Preclinical	Phase I	Phase II	Phase III	Approval
ICEF15	Urge fecal incontinence	Autologous skeletal muscle-derived cells (aSMDC)	• Japan-Europe-USA multi-regional Phase III clinical trial (ongoing) • (EudraCT #: 2021-001376-42, clinicaltrials.gov #: NCT04976153)				
ICES13	Stress urinary incontinence	Autologous skeletal muscle-derived cells (aSMDC)	• Phase II trial completed • Preparing for Phase III trial				
ICEF16	Passive fecal incontinence	Skeletal muscle-derived smooth muscle cells (skSMC)	Phase I clinical trial underway	Today's agenda			
TBD*	Dysphagia	Autologous skeletal muscle-derived cells (aSMDC)	• Preparing for preclinical POC studies				

*: A joint research project with Saga University

ICEF15 Progress

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- **We plan to complete enrollment in the ongoing Phase III trial by the end of 2026**

Design of the ongoing clinical trial

- **Multi-regional Phase III** clinical trial (the Fidelia trial)
- Currently underway in **11 European countries, Japan, and the United States**
- Positioned as a **confirmatory trial supporting full approval**

of Randomized Patients (Enrollment progress as of October 21, 2026)

Austria	Japan	Spain	Others	Total	Remaining
49	50	46	149	294	※

※ Enrollment of the originally planned number of patients (290 cases) has been completed in Europe and Japan
※ Accordingly, inclusion in the trial has ended in Europe and Japan in the summer of 2026
※ **The plan is to enroll U.S. patients (target: 10 or fewer) by the end of 2026 and complete enrollment of all cases**
(Plan to allocate the patients who withdrew from the clinical trial after enrollment to the U.S. patient enrollment)

Progress on Preparations for the Commercialization of ICEF15

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- **A commercialization partner in the U.S. has already been selected, and partnership negotiations in Japan and Europe are entering their final stages**

U.S.

- A definitive agreement has been signed with EVERSANA (disclosed in July 2026)
- EVERSANA is a company that provides pharmaceutical commercialization services worldwide

Europe

- We have narrowed down to a single potential partner
- We are currently negotiating the draft of the formal contract

Japan

- We have narrowed down to a single potential partner
- Negotiations regarding the specific terms of the partnership are currently underway

ICEF15 Commercialization Timeline

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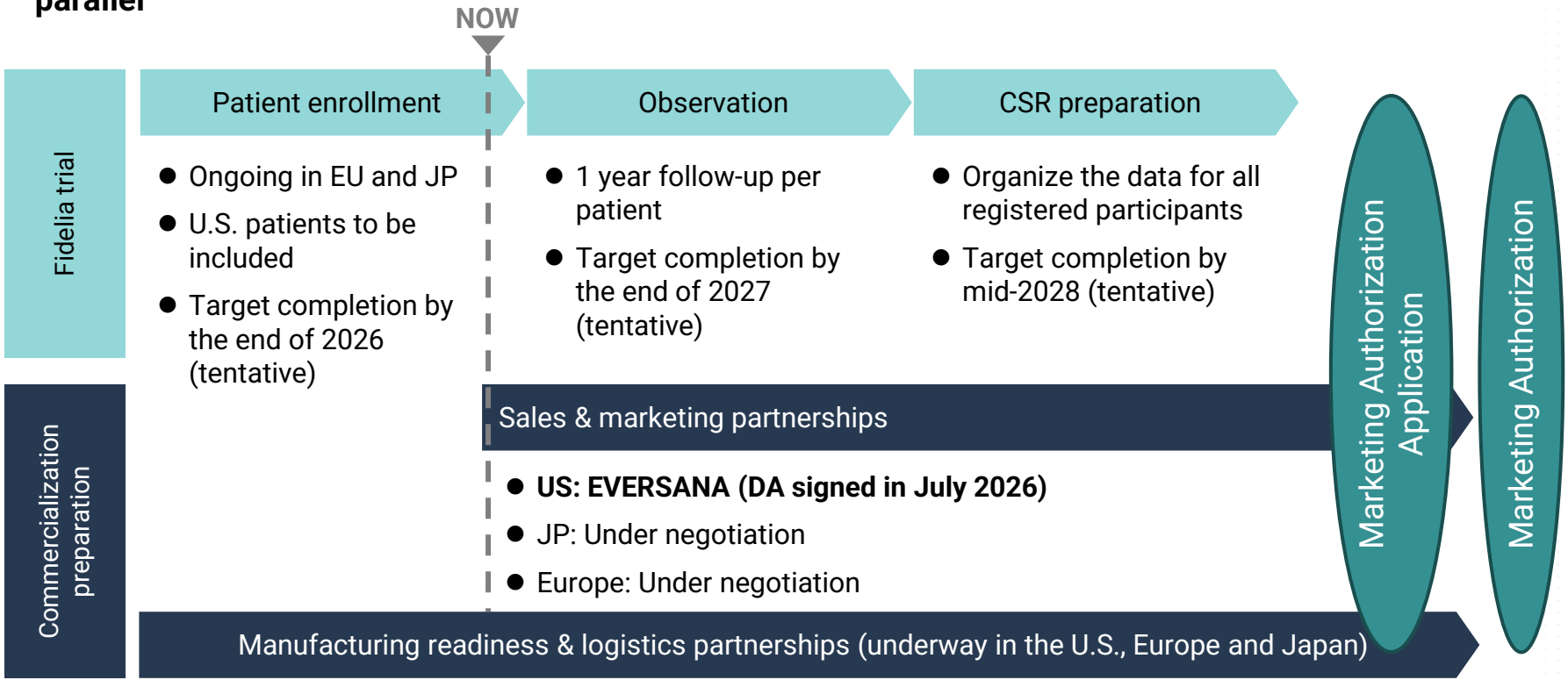
- **Steadily advancing the multi-regional Phase III clinical trial while building global commercial capability in parallel**



Progress of Other Pipeline Products

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- **ICEF16 is expected to become our group's third pipeline product in human clinical development**

ICEF16

- A pipeline for restoring and regenerating **internal anal smooth muscle** (see the next pages for details)
- Target indication: **Passive fecal incontinence**
- **A Clinical Trial Application for the first-in-human Phase I clinical trial has been submitted to authority (disclosed in Nov 2026)**
- **Aiming to enroll the first patients in the first quarter of 2027**

ICES13

- Target indication: Stress urinary incontinence
- Phase II trials completed in Europe
- Preparations for Phase III clinical trial have already begun

Mechanism of Action of ICEF16

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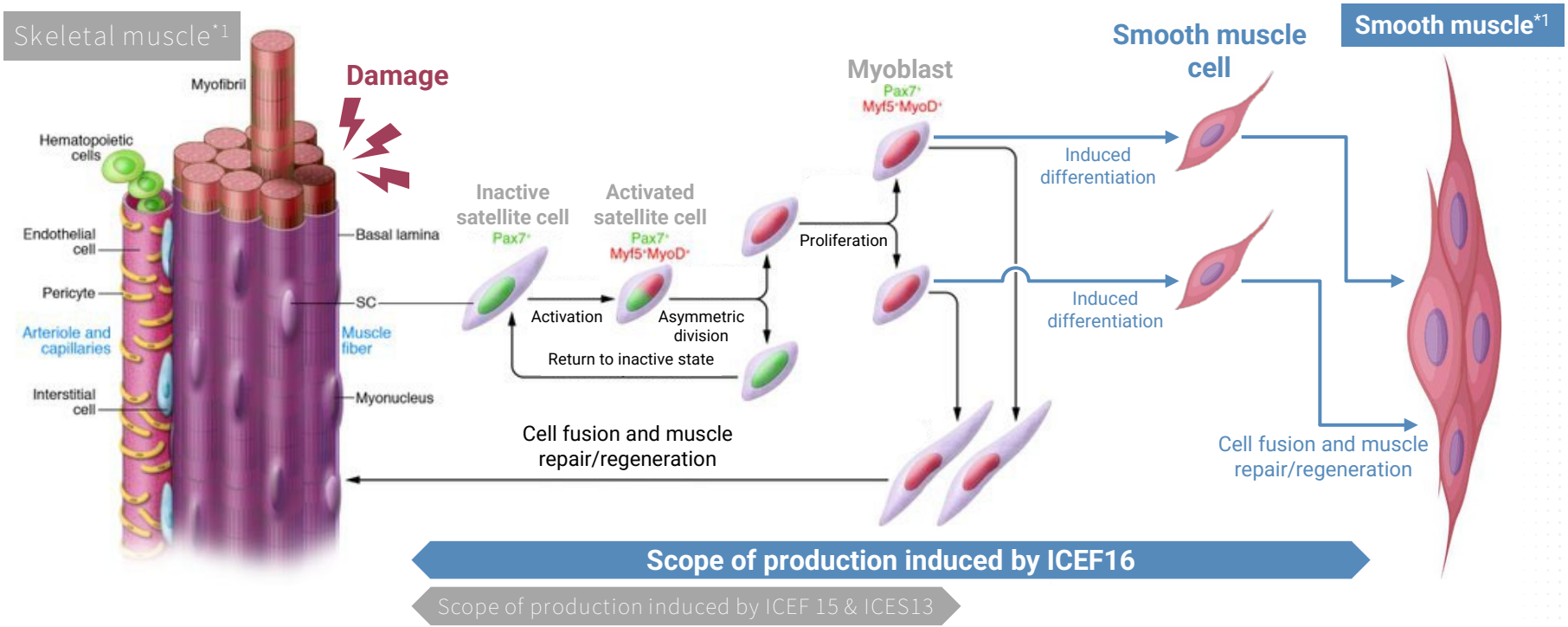
- **ICEF16: Myoblasts are induced into differentiating into smooth muscle cells and administered to the affected area to restore and regenerate smooth muscles**
  (Reference) ICEF15 and ICES13: Myoblasts are cultured from satellite cells and administered to the affected area to restore and regenerate skeletal muscles



*1: Image: J Clin Invest. 2010;120(1):11-19. https://doi.org/10.1172/JCI40373

ICEF16 Treatment

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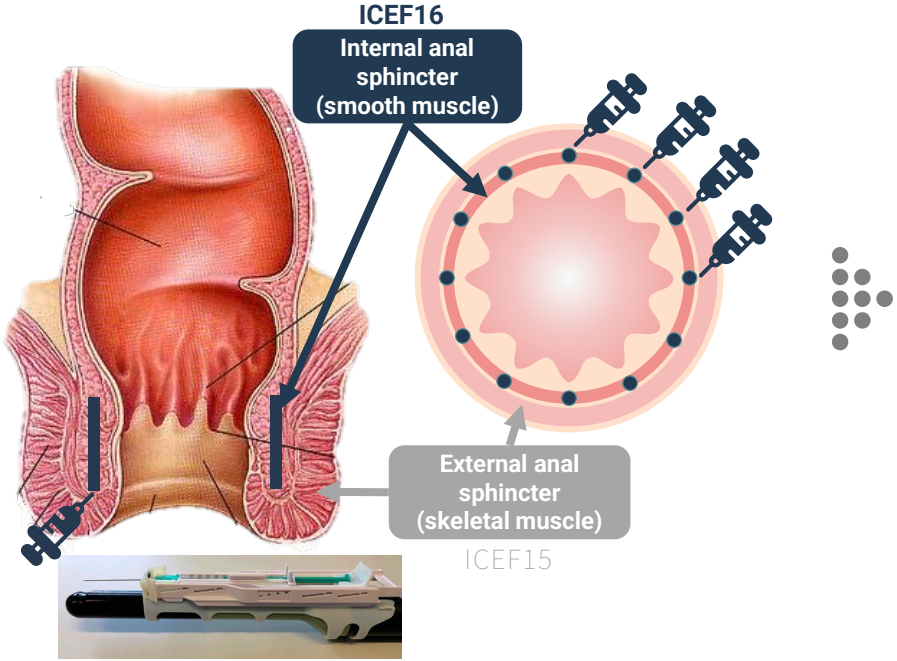
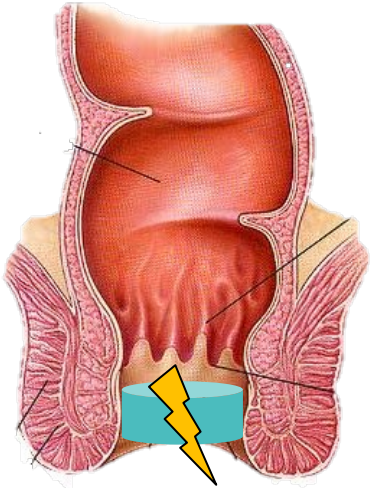
- **Like ICEF15, a defining characteristic is the application of electric stimuli to the pelvic floor to facilitate the engraftment of administered cells**

The cells are administered to the internal anal sphincters 12 times in a single procedure under supersonic guidance



The cells are administered using a needle guide

A pelvic floor electric stimulation device is used to apply electric stimuli twice a day (20 minutes each in the morning and evening) for a period of four weeks following the graft procedure

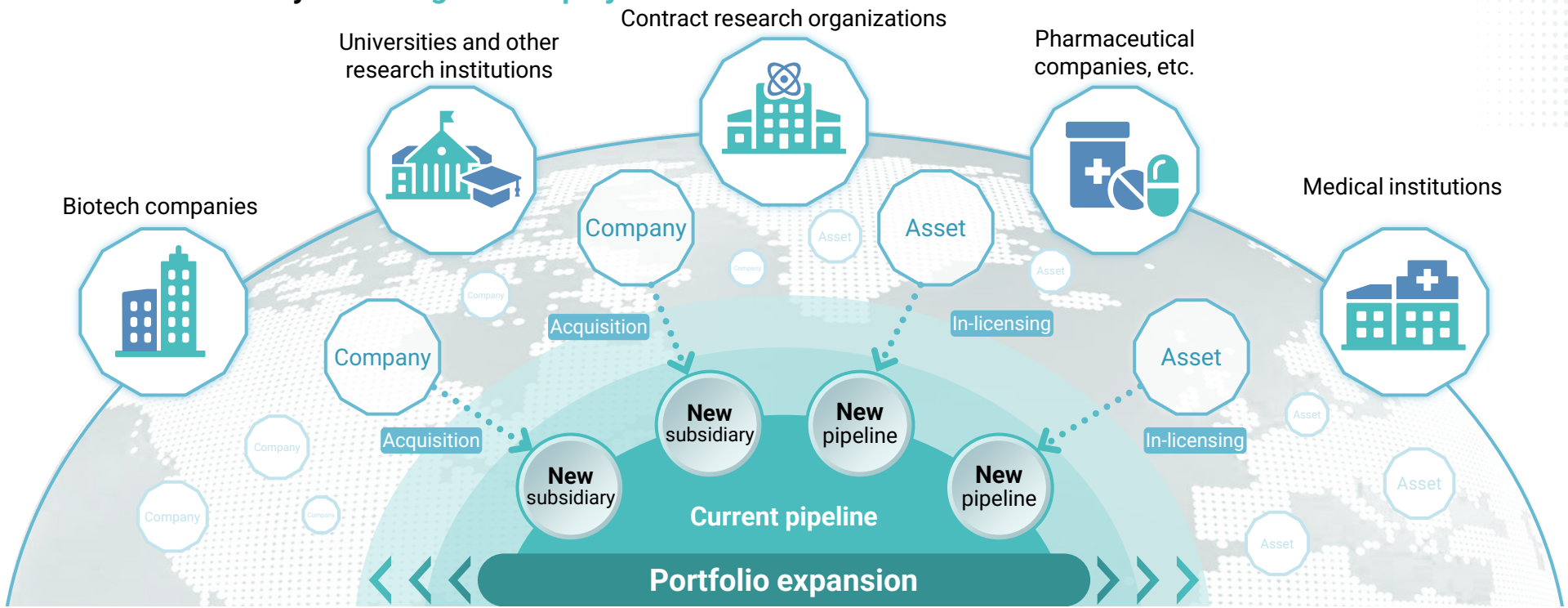


The stimuli are applied using an endorectal probe



Innovacell's Global Aggregation Model

- **Innovacell leverages its management resources to source, develop and commercialize product candidates to deliver medicines to patients worldwide**
- **We are currently reviewing several projects**



*Conceptual illustration of the Group's Global Aggregation Model and its aim to expand the portfolio by sourcing and commercializing product candidates. It does not represent or imply any specific future acquisition or in-licensing plans.

Other News (Disclosed during Q3 FY2026)

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- Other news in Q3 included disclosure of grant of a patent regarding ICEF16

Regarding ICEF15	• Announcement Regarding Completion of FDA IND Review and Approval to Include U.S. Sites and Patients in the ICEF15 Multi-Regional Phase III Trial (disclosed on July 2, 2026) • Announcement Regarding the Execution of a Product Commercialization Agreement with EVERSANA Life Science Services, LLC for the U.S. Market (disclosed on July 23, 2026) • Patient Enrollment Status of the ICEF15 Multi-Regional Phase III Clinical Trial (Fidelia) and Completion of Patient Recruitment in Japan and Europe (disclosed on August 6, 2026)
Patents	• Notice of Grant of a Japanese Patent for the Method for Obtaining Induced Smooth Muscle Cells (disclosed on August 27, 2026)
Other ***(Including those listed above)***	• Japanese news releases: 15 • English news releases: 14

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Summary of Consolidated P/L for Q3 FY2026

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- **Overall consolidated expenses were in line with the full-year forecast in Q3 FY2026**

(Millions of yen)

Item		(a) Q3 FY2026	(b) FY2026 full-year forecast	(a)/(b)	Notes
Operating Revenue		**16**	1,000	2%	Upfront revenue from the planned ICEF15 (Japan) co-promotion partnership is expected in Q4 FY2026
Operating Expenses	R&D	1,565			
	Others	633			
Operating Profit		**-2,181**	- 3,337	65%	
Ordinary Profit		**-2,395**	- 3,461	69%	One-time IPO-related expenses of approx. 74 million JPY recorded in non-operating expenses
Net Income		**-2,396**	- 3,463	69%	

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Key Progress Expected in FY2026

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- **In FY2026, we are achieving each milestone one by one: ICEF16 will become Innovacell's third pipeline product in human clinical development, while ICEF15 advances into commercialization preparation**

ICEF15	Multi-Regional Phase III clinical trial	✓ **Inclusion of the U.S. sites & patients (announced July 2026)** ● Last patient in (LPI)
	Commercialization preparation	✓ **Execution of the definitive agreement with the commercialization partner in the U.S. (announced July 2026)** ● Execution of the definitive agreement with a commercialization partner in the EU ● Execution of the definitive agreement with a co-promotion partner in Japan (with an associated upfront payment)
ICEF16		✓ **Submission of a Clinical Trial Application for the First-in-Human (FIH) Phase I Clinical Trial (announced in November 2026)**

Thank You!