UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): September 25, 2025

ORGANOGENESIS HOLDINGS INC.
(Exact Name of Registrant as specified in its charter)

Delaware	**001-37906**	**98-1329150**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

85 Dan Road **Canton, MA**	**02021**
(Address of principal executive offices)	**(Zip Code)**

(781) 575-0775
(Registrant's telephone number, including area code)

Not Applicable
(Registrant's name or former address, if change since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Class A Common Stock, $0.0001 par value	ORGO	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 25, 2025, Organogenesis Holdings Inc. (the "Company") issued a press release announcing an update on its second Phase 3 randomized controlled trial ("RCT") of ReNu, a cryopreserved amniotic suspension allograft ("ASA") for the management of symptoms associated with knee osteoarthritis ("OA"). A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by this reference.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in any such filing.

Item 8.01. Other Events.

As noted in Item 7.01 above, the Company announced an update on its second Phase 3 RCT of ReNu, a cryopreserved ASA for the management of symptoms associated with knee OA on September 25, 2025.

This second Phase 3 trial was a fully enrolled 594 patient trial and was a prospective, double-blind, multicenter, saline-controlled, parallel group, RCT of ReNu ASA, for the treatment of subjects with mild to severe symptomatic knee OA. Patients were randomized to receive a single intra-articular ("IA") injection of either saline control or ReNu.

This second Phase 3 RCT of ReNu did not achieve statistical significance for its primary endpoint, despite the ReNu results demonstrating a numerical improvement in baseline pain reduction over the first Phase 3 trial. Baseline pain reduction at six months for ReNu was -6.9 for the second Phase 3 study compared to -6.0 in the first Phase 3 study. Additionally, the ReNu results continued to demonstrate a favorable safety profile.

The primary endpoint for the study was the difference between ReNu and Saline groups in the reduction in knee pain at six months assessed by the Western Ontario and McMaster Universities Arthritis Index ("WOMAC") pain scale. The study data demonstrated a numerical improvement of -0.5 favoring ReNu (p=0.0393 one-sided p-value, compared to p=0.023 target threshold). The first Phase 3 trial achieved improvement of -0.7 favoring ReNu, which was statistically significant (p=0.0177, one sided p-value, compared to p=0.023 target threshold). Additional data from the Phase 3 RCTs is included as Exhibit 99.2 and is incorporated herein by reference.

The Company plans to request a pre-Biologics License Application ("BLA") meeting with the FDA by the end of October 2025 to discuss the BLA submission pathway, including potentially using the combined efficacy analysis from both Phase 3 studies of ReNu to support a BLA approval.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to expectations or forecasts of future events. Forward-looking statements may be identified by the use of words such as "intend," "seek," "anticipate," "believe," "expect," "estimate," "potential" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These statements concern, and these risks and uncertainties include, among others: the risks and uncertainties inherent in clinical development; the FDA may require additional evidence for ReNu before we can submit a BLA or get a BLA approved, which we may not be able to obtain; that other clinical trials of ReNu may produce different results; the likelihood and timing of possible regulatory approval and commercial launch of ReNu; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to develop or commercialize ReNu; ongoing regulatory obligations and oversight impacting ReNu; unforeseen safety issues resulting from the administration of ReNu in patients; competing products and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of ReNu and the impact of studies (whether conducted by us or others and whether mandated or voluntary) on the commercial success of ReNu; our ability to manufacture and manage supply components for ReNu; the availability and extent of reimbursement of ReNu from third-party payers, including private payer healthcare and insurance programs and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers, including local coverage determinations by Medicare Part A/B Medicare Administrative Contractors; new policies and procedures adopted by such payers; unanticipated expenses; the costs of developing, producing, and selling ReNu; our ability to meet our sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; and other risks and uncertainties described in the Company's filings with the Securities and Exchange Commission, including Item 1A (Risk Factors) of the Company's Form 10-K for the year ended December 31, 2024 and its subsequently filed periodic reports. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Although it may voluntarily do so from time to time, the Company undertakes no commitment to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable securities laws.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 25, 2025
99.2	Data from Phase 3 RCTs of ReNu dated September 25, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Organogenesis Holdings Inc.

By: /s/ Lori Freedman
Name: Lori Freedman
Title: Chief Administrative and Legal Officer

Date: September 25, 2025