# REPLY EXHIBIT 19

Reply Exhibit 19 – Theriva Biologics, Inc. Form 10-K filed March 12, 2026 (excerpts)

*Nejmeh v. Theriva Biologics, Inc.*, No. 3:26-cv-00705-ART-CSD (D. Nev.)

Source: SEC EDGAR, Accession No. 0001104659-26-026767.

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**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, DC 20549**

**FORM 10-K**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2025**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from to**

**Commission file number: 001-12584**

# THERIVA BIOLOGICS, INC.

*(Exact name of registrant as specified in its charter)*

| **Nevada** | **13-3808303** |
|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(I.R.S. Employer Identification No.)* |
| **9605 Medical Center Drive, Ste. 270**<br>**Rockville, MD** | **20850** |
| *(Address of principal executive offices)* | *(Zip Code)* |

**Registrant's telephone number, including area code:**
**(301) 417-4364**

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock | TOVX | NYSE American |

**Securities registered pursuant to Section 12(g) of the Act:**
***None***

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer, "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

| | | | |
|---|---|---|---|
| Large Accelerated Filer | ☐ | Accelerated Filer | ☐ |
| Non-accelerated Filer | ☒ | Smaller Reporting Company | ☒ |
| | | 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 provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive- based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2025, the last business day of the registrant's recently completed second fiscal quarter, was approximately $3.9 million based on $0.43, the closing price of the registrant's common stock as reported by the NYSE American on that date.

As of March 10, 2026, the registrant had 45,892,668 shares of common stock outstanding.

proposed SYN-004 (ribaxamase) Phase 3 clinical program entails a single, global, event-driven clinical trial with a fixed maximum number of approximately 4,000 patients for total enrollment and evaluates the potential efficacy and safety of ribaxamase in a broad patient population by enrolling patients with a variety of underlying infections treated with a range of IV beta-lactam antibiotics.

The proposed Phase 3 clinical trial incorporates co-primary safety and efficacy endpoints (mortality and the reduction in the incidence of CDI at one month after the last drug dose in the SYN-004 (ribaxamase) treatment group versus placebo, respectively). We expect the clinical development costs to complete this trial to be in excess of $80 million and anticipate initiating the Phase 3 clinical program only after securing additional potential financing via a strategic partnership.

*Acute Graft-Versus-Host-Disease in Allogeneic Hematopoietic Cell Transplant (allogeneic HCT) Recipients & SYN-004 (ribaxamase)*

In parallel with our clinical and regulatory efforts, we completed a Health Economics Outcomes Research ("HEOR") study, which was conducted to generate key insights on how we can expect Health Care Practitioners ("HCPs"), to evaluate patient access for SYN-004 (ribaxamase) while also providing a framework for potential reimbursement strategies. After evaluating findings from the study, we believe that there is significant potential value in exploring the development of SYN-004 (ribaxamase) in a narrower patient population where the incidence of the disease endpoint is high and the clinical development may be less costly.

We believe allogeneic hematopoietic cell transplant ("HCT") recipients, who have a very high risk of CDI, VRE colonization and potentially fatal bacteremia, and acute-graft-vs-host disease ("aGVHD"), represent such a patient population. Published literature has demonstrated a strong association between these adverse outcomes and microbiome damage caused by IV beta-lactam antibiotics in these patients. Approximately 80-90% of HCT recipients receive IV beta-lactam antibiotics to treat febrile neutropenia. Penicillins and cephalosporins are first-line therapies in the USA and EU, whereas carbapenems are first-line in China. Antibiotic-mediated damage to the gut microbiome is strongly associated with GVHD, bloodstream infections, VRE bacteremia, transplant relapse, and increased mortality in HCT recipients, raising concern over the spectrum of antibiotics used during HCT.

CDI occurs in up to 31% of HCT patients and is associated with aGVHD and increased mortality. aGVHD occurs in 30-60% of allogeneic HCT recipients and is recognized as a primary contributor to morbidity and mortality in this patient population. The most recent available data indicate approximately 8,000 reported allogeneic HCT procedures each year in the USA, 19,800 procedures in Europe, 12,700 in China, and 3,500 in Japan. First-line treatments for aGVHD fail in more than 50% of patients and 2-year survival in patients with steroid refractory aGVHD is only 20%. At least one U.S. study found allogeneic HCT recipients who developed aGVHD had 3-times higher in-hospital mortality and almost 2-fold higher median hospital costs than patients who did not develop aGVHD. It has been reported that in-patient costs for allogeneic HCT in the USA range from $180,000-$300,000 depending on the disease severity. VRE infection is a persistent problem in HCT patients and VRE colonization after HCT has been associated with decreased patient survival.

**Report of Independent Registered Public Accounting Firm**

Shareholders and Board of Directors
Theriva Biologics, Inc.
Rockville, Maryland

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of Theriva Biologics, Inc. (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive income, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

**Going Concern Uncertainty**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has not generated positive cash flows from operations which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

**Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which they relate.