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): October 23, 2023

THERIVA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-12584**	**13-3808303**
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

9605 Medical Center Drive, Suite 270
Rockville, Maryland 20850
(Address of principal executive offices and zip code)

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

N/A
(Former name or former address, if changed 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 (see General Instruction A.2. below):

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

¨ Soliciting material pursuant to Rule 14a-12(b) 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**
Common stock, par value $0.001 per share	TOVX	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter).

Emerging growth company ¨

If an emerging growth company, indicate by checkmark 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. ¨

Item 7.01. Regulation FD Disclosure.

On October 23, 2023, Theriva Biologics, Inc. (the "Company") issued a press release announcing the presentation of new clinical data from the Phase 1 investigator-sponsored study with the Institut Catala d'Oncologia (ICO) evaluating VCN-01 in combination with durvalumab for patients with recurrent/metastatic squamous cell carcinoma of the head and neck (R/M HNSCC). The poster titled "Survival Outcomes in Phase I Trial Combining VCN-01 and Durvalumab (MEDI4736) in Subjects with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma Refractory to Previous Immunotherapy Treatment" was presented at the European Society for Medical Oncology (ESMO) Congress, being held both virtually and in Madrid, Spain from October 20-24, 2023.

Key Takeaways from the presentation include: VCN-01 combined with durvalumab showed encouraging overall survival (OS) in patients who previously progressed on anti-PD(L)-1 therapy.

- **Survival**: VCN-01 induced upregulation of PD-L1, which correlated with enhanced patient survival.
  - In the concomitant (CS) cohort at the 3.3×10^{12} viral particles (vp) dose, overall survival (OS) was 10.4 months and progression free survival (PFS) was 1.7 months.
  - In the sequential (SS) cohort at the 3.3×10^{12}vp dose OS was 15.5 months and PFS was 3.7, whereas in the SS cohort at the 1×10^{13} vp dose OS was 17.3 months and PFS was 2.1 months.
- **VCN-01 induces changes in the immune status of tumors**
  - VCN-01 combined with durvalumab increased CD8 T cells, a marker of tumor inflammation and the expression of PD(L)-1 in tumors. An increase of PD(L)-1 CPS (8/11 at day 8; 8/10 at day 28) and CD8 T cells (7/11 at day 8; 5/10 at day 28) from baseline were found in tumor biopsies.
  - VCN-01 alone increased the CPS score of tumor biopsies at day 8 after administration by 62.5% in the sequential arm.
  - VCN-01 induced PD(L)-1 upregulation with enhanced patient survival. A statistical correlation was observed between CPS on day 8 and patient OS (p=0.005).
- **Pharmacodynamics and shedding of VCN-01**
  - PH20 expression from VCN-01 peaked on day 3-8 and remained elevated in some patients up to day 42. Quantification of VCN-01 genomes in stool demonstrated viral shedding that peaked at day 8.

A copy of the poster titled "Survival Outcomes in Phase I Trial Combining VCN-01 and Durvalumab (MEDI4736) in Subjects with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma Refractory to Previous Immunotherapy Treatment" is filed as Exhibit 99.2 to this Current Report on Form 8-K .

The information in this Item 7.01 and in the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended and shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The press release furnished as Exhibit 99.1 to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

Item 8.01. Other Events.

On October 23, 2023, the Company presented a poster at the European Society for Medical Oncology (ESMO) Congress, being held both virtually and in Madrid, Spain from October 20-24, 2023 with new clinical data from the Phase 1 investigator-sponsored study with the Institut Catala d'Oncologia (ICO) evaluating VCN-01 in combination with durvalumab for patients with recurrent/metastatic squamous cell carcinoma of the head and neck (R/M HNSCC.

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  - PH20 expression from VCN-01 peaked on day 3-8 and remained elevated in some patients up to day 42. Quantification of VCN-01 genomes in stool demonstrated viral shedding that peaked at day 8.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Theriva Biologics, Inc., dated October 23, 2023
99.2	Poster titled "Survival Outcomes in Phase I Trial Combining VCN-01 and Durvalumab (MEDI4736) in Subjects with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma Refractory to Previous Immunotherapy Treatment"
104	Cover Page Interactive Data File (embedded within the XBRL document)

SIGNATURES

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

Dated: October 23, 2023

THERIVA BIOLOGICS, INC.

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Title: Chief Executive Officer and Chief Financial Officer