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 16, 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 16, 2023, Theriva Biologics, Inc. (the "Company") issued a press release announcing the presentation of survival outcomes in Phase 1 study evaluating VCN-01 in combination with durvalumab in patients with recurrent/ metastatic squamous cell carcinoma of the head and neck. These data will be featured in a poster presentation at the European Society for Medical Oncology (ESMO) Congress, being held both virtually and in Madrid, Spain from October 20-24, 2023.

Key data and conclusions featured in the ESMO presentation include:

- 20 patients were enrolled with a median of 4 prior lines of therapy, from which six in the concomitant (CS) (single dose of VCN-01 in combination with durvalumab on day 1) and 12 in the sequential (SS) (single dose of VCN-01 on day -14 and durvalumab on day 1) were evaluable for response.
    - In the CS cohort at the 3.3×10^{12} viral particles (vp) dose, overall survival (OS) was 10.4 months.
    - In the SS cohort at the 3.3×10^{12}vp dose OS was 15.5 months, whereas in the SS cohort at the 1×10^{13} vp dose OS was 17.3 months.
    - 11 patients (61.1%) were alive >12 months (2 in CS; 5 in SS at 3.3×10^{12}vp, 4 in SS at 1×10^{13} vp).
    - In spite of the advanced stage of the disease and objective response rate of 0%, most of the patients appeared to benefit from subsequent treatment.
- **Biological activity**: Patients showed VCN-01 replication and increased serum hyaluronidase levels were maintained for over six weeks.
    - Observed an increase in CD8 T cells, a marker of tumor inflammation and an upregulation of PD-L1 in tumors.
        - Increase of PDL1-CPS (16/21; p=0.013) and CD8 T-cells (12/21; p=0.007) from baseline were found in tumor biopsies.
        - CPS score of tumor biopsies was increased by administration of VCN-01 at day 8 after administration in the sequential group.
        - A statistical correlation was observed between CPS on day 8 and patient OS (p=0.005).

A copy of the abstract titled "Survival outcomes in Phase 1 trial combining VCN-01 and Durvalumab (MED14736) 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 16, 2023, the Company presented survival outcomes in Phase 1 study evaluating VCN-01 in combination with durvalumab in patients with recurrent/ metastatic squamous cell carcinoma of the head and neck These data will be featured in a poster presentation at the European Society for Medical Oncology (ESMO) Congress, being held both virtually and in Madrid, Spain from October 20-24, 2023.

Key data and conclusions featured in the ESMO presentation include:

- 20 patients were enrolled with a median of 4 prior lines of therapy, from which six in the concomitant (CS) (single dose of VCN-01 in combination with durvalumab on day 1) and 12 in the sequential (SS) (single dose of VCN-01 on day -14 and durvalumab on day 1) were evaluable for response.
    - In the CS cohort at the 3.3×10^{12} viral particles (vp) dose, overall survival (OS) was 10.4 months.
    - In the SS cohort at the 3.3×10^{12}vp dose OS was 15.5 months, whereas in the SS cohort at the 1×10^{13} vp dose OS was 17.3 months.
    - 11 patients (61.1%) were alive >12 months (2 in CS; 5 in SS at 3.3×10^{12}vp, 4 in SS at 1×10^{13} vp).
    - In spite of the advanced stage of the disease, and objective response rate of 0%, most of the patients appeared to benefit from subsequent treatment.
- **Biological activity**: Patients showed VCN-01 replication and increased serum hyaluronidase levels were maintained for over six weeks.
    - Observed an increase in CD8 T cells, a marker of tumor inflammation and an upregulation of PD-L1 in tumors.
        - Increase of PDL1-CPS (16/21; p=0.013) and CD8 T-cells (12/21; p=0.007) from baseline were found in tumor biopsies.
        - CPS score of tumor biopsies was increased by administration of VCN-01 at day 8 after administration in the sequential group.
        - A statistical correlation between OS observed in patients and CPS on day 8 (p=0.005).

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Theriva Biologics, Inc., dated October 16, 2023
99.2	Abstract titled "Survival outcomes in Phase 1 trial combining VCN-01 and Durvalumab (MED14736) in Subjects With Recurrent/ Metastatic Head and Neck Squamous Cell Carcinoma refractor 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 17, 2023

THERIVA BIOLOGICS, INC.

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