

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): March 8, 2023

**THERIVA BIOLOGICS, INC.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of  
incorporation)

**001-12584**

(Commission File No.)

**13-3808303**

(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 4.02. Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.**

On March 8, 2023, the Audit Committee (the “Audit Committee”) of the Board of Directors of Theriva Biologics, Inc. (the “Company”) in consultation with management and BDO USA, LLP (“BDO USA”), the Company’s independent registered public accounting firm, met and concluded that the Company’s (i) unaudited consolidated interim financial statements as of and for the period ended June 30, 2022 included in the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and the (ii) unaudited consolidated interim financial statements as of and for the period ended September 30, 2022 included in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 (collectively, the “Specified Financial Statements”), should no longer be relied upon due to errors in such financial statements, and therefore a restatement of these Specified Financial Statements is required. The Company has not filed, and does not intend to file, an amendment to the Company’s previously filed Quarterly Reports on Form 10-Q for the quarters ended June 30, 2022 and September 30, 2022 but intends to restate the Specified Financial Statements, which restated financial statements will be included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022. These errors have no effect on the Company’s cash position, pre-tax income or the Company’s operating expenses and will result in a decrease in the net loss and loss per share for those periods.

During the preparation of its annual tax provision for the year ended December 31, 2022, the Company determined that a deferred tax asset related to net operating loss generated during the second and third quarters of 2022 at the Company’s subsidiary, VCN Biosciences S.L., should have been established. Further, because an existing deferred tax liability associated with an indefinite-lived intangible asset is considered a source of income for the future realization of the net operating loss deferred tax asset, the deferred tax asset was determined to be more likely than not recoverable. Since the deferred tax asset was determined to be more likely than not recoverable, it would have resulted in an income tax benefit during the interim periods thereby reducing the Company’s consolidated net loss and loss per share for the three- and six-months period ended June 30, 2022 and the three- and nine-month periods ended September 30, 2022.

The impact of this restatement on the Company’s second quarter 2022 unaudited condensed consolidated financial statements will be a \$532,000 decrease in deferred tax liabilities and a \$532,000 decrease in accumulated deficit as of June 30, 2022, and a \$532,000 increase in income tax benefit, a \$532,000 decrease in net loss, and a \$0.03 decrease in net loss per share for the three months ended June 30, 2022, and a \$532,000 increase in income tax benefit, a \$532,000 decrease in net loss and a \$0.03 decrease in net loss per share for the six months ended June 30, 2022.

The impact of this restatement on the Company’s third quarter 2022 unaudited condensed consolidated financial statements will be a \$867,000 decrease in deferred tax liabilities and a \$867,000 decrease in accumulated deficit as of September 30, 2022, and a \$335,000 increase in income tax benefit, a \$335,000 decrease in net loss and a \$0.02 decrease in net loss per share for the three months ended September 30, 2022, and a \$867,000 increase in income tax benefit, a \$867,000 decrease in net loss and a \$0.06 decrease in net loss per share for the nine months ended September 30, 2022.

Management has concluded that in light of the errors described above an additional material weakness in the Company’s internal controls over financial reporting existed. The material weakness identified relates to the effectiveness of the Company’s management review controls over the computation and disclosure of income taxes. Management has determined that, as a result of the errors described above, management’s assessment of the effectiveness of the Company’s disclosure controls and procedures as of June 30, 2022 and September 30, 2022 need to be modified to include a material weakness in its controls over financial reporting related to the accounting for deferred tax assets in addition to the previously disclosed weakness.

The Company’s remediation plan will be described in its Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

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## Item 8.01. Other Information

### Risk Factor Update

The Company is also filing this Current Report on Form 8-K to supplement the risk factors described in its Quarterly Report on Form 10-Q for the quarters ended June 30, 2022 and September 30, 2022, with the following additional risk factors.

***We have identified a material weakness in our internal controls, and we cannot provide assurances that this weakness will be effectively remediated or that additional material weaknesses will not occur in the future. In addition, we are not yet required to perform an assessment of internal controls for VCN.***

If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results, prevent fraud, or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a- 15(f) under the Exchange Act. During the preparation of our annual tax provision for the year ended December 31, 2022, we determined that a deferred tax asset related to our subsidiary, Theriva Biosciences S.L.(“VCN”), which deferred tax asset was related to an indefinite-lived net operating loss generated during the second and third quarters of 2022 should have been recorded resulting in an income tax benefit during the interim periods and errors in the unaudited condensed consolidated financial statements included in the Quarterly Report on Form 10-Q for the quarters ended June 30, 2022 and September 30, 2022. In addition, during the course of the review for the Quarterly Report for the quarter ended March 31, 2022, we identified a material weakness in our controls relating to accounting and disclosure controls for non-routine transactions. While we plan to take remedial action to address the material weaknesses, we cannot provide any assurance that such remedial measures, or any other remedial measures we take, will be effective. If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, detect or prevent fraud, or file our periodic reports in a timely manner, which may, among other adverse consequences, cause investors to lose confidence in our reported financial information and lead to a decline in our stock price. In addition, a material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are designed and operating effectively.

As permitted by the SEC, we have elected to exclude VCN from the assessment of internal control over financial reporting the year ending December 31, 2022. In conjunction with the acquisition of VCN, we are currently in the process of integrating VCN’s policies, processes, people, technology, and operations into the consolidated company, and integrating VCN’s operations into our system of internal control over financial reporting; however, we cannot assure you that such integration will be successful to enable us to identify or avoid material weaknesses in the future.

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Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
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: March 10, 2023

**THERIVA BIOLOGICS, INC.**

By: /s/ Steven A. Shallcross

Name: Steven A. Shallcross

Title: Chief Executive Officer and Chief Financial Officer

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