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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES 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, Suite 270 **Rockville , MD**	**20850**
(Address of principal executive offices)	*(Zip Code)*

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

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

Indicate by check mark whether the registrant: (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 (§ 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

As of November 8, 2024, the registrant had 2,782,449 shares of common stock, $0.001 par value per share, outstanding.

THERIVA BIOLOGICS, INC.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In particular, statements contained in this Quarterly Report on Form 10-Q, including but not limited to, statements regarding the timing of our clinical trials, the development and commercialization of our pipeline products, the sufficiency of our cash, our ability to finance our operations and business initiatives and obtain funding for such activities and the timing of any such financing, our future results of operations and financial position, business strategy and plans prospects, or costs and objectives of management for future research, development or operations, are forward-looking statements. These forward-looking statements relate to our future plans, objectives, expectations and intentions and may be identified by words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “seeks,” “goals,” “estimates,” “predicts,” “potential” and “continue” or similar words. Readers are cautioned that these forward-looking statements are based on our current beliefs, expectations and assumptions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item 1A. “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q, and those identified under Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023 filed on March 25, 2024 (the “2023 Form 10-K”). Therefore, actual results may differ materially and adversely from those expressed, projected or implied in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

NOTE REGARDING COMPANY REFERENCES

Throughout this Quarterly Report on Form 10-Q, “Theriva Biologics,” the “Company,” “we,” “us” and “our” refer to Theriva Biologics, Inc. and our subsidiaries Theriva Biologics, S.L. (“VCN”, formerly known as VCN Biosciences, S.L.), Pipex Therapeutics, Inc. (“Pipex Therapeutics”), Effective Pharmaceuticals, Inc. (“EPI”), Solovax, Inc. (“Solovax”), CD4 Biosciences, Inc. (“CD4”), Epitope Pharmaceuticals, Inc. (“Epitope”), Healthmine, Inc. (“Healthmine”), Putney Drug Corp. (“Putney”) and Synthetic Biomics, Inc. (“SYN Biomics”).

NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

THERIVA BIOLOGICS, INC.

FORM 10-Q
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PART I–FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

Theriva Biologics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets
(In thousands except share and par value amounts)

	September 30, 2024	December 31, 2023
Assets		
Current Assets		
Cash and cash equivalents	$ 16,409	$ 23,177
Tax credit receivable	1,832	1,812
Prepaid expenses and other current assets	1,292	2,414
Total Current Assets	**19,533**	**27,403**
Non-Current Assets		
Property and equipment, net	314	422
Restricted cash	103	102
Right of use asset	1,428	1,759
In-process research and development	18,651	19,755
Goodwill	—	5,700
Deposits and other assets	79	78
Total Assets	**$ 40,108**	**$ 55,219**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 756	$ 770
Accrued expenses	3,754	2,995
Accrued employee benefits	1,291	1,517
Deferred research and development tax credit-current portion	916	906
Loans payable-current	65	63
Operating lease liability-current portion	541	487
Total Current Liabilities	**7,323**	**6,738**
Non-current Liabilities		
Non-current contingent consideration	6,788	6,274
Loan Payable - non-current	98	162
Non-current deferred research and development tax credit	229	906
Non-current operating lease liability	1,035	1,442
Total Liabilities	**15,473**	**15,522**
Commitments and Contingencies (Note 13)		
Temporary Equity; 10,000,000 authorized		
Series C convertible preferred stock, $ 0.001 par value; 0 issued and outstanding at September 30, 2024, and 275,000 issued and outstanding at December 31, 2023	—	2,006
Series D convertible preferred stock, $ 0.001 par value; 0 issued and outstanding at September 30, 2024 and 100,000 issued and outstanding at December 31, 2023	—	728
Stockholders' Equity:		
Common stock, $ 0.001 par value; 14,000,000 shares authorized, 2,646,272 issued and 2,617,462 outstanding at September 30, 2024 and 715,028 issued and 686,219 outstanding at December 31, 2023	3	1
Additional paid-in capital	355,333	346,536
Treasury stock at cost, 28,809 shares at September 30, 2024 and at December 31, 2023	(288)	(288)
Accumulated other comprehensive income	112	32
Accumulated deficit	(330,525)	(309,318)
Total Stockholders' Equity	**24,635**	**36,963**
Total Liabilities and Stockholders' Equity	**$ 40,108**	**$ 55,219**

All share numbers have been retrospectively adjusted for the one to twenty-five reverse stock split effective August 26, 2024

See accompanying notes to unaudited condensed consolidated financial statements.

Theriva Biologics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	For the Three months ended September 30,		For the Nine months ended September 30,	
	2024	2023	2024	2023
Operating Costs and Expenses:				
General and administrative	2,302	212	5,702	5,099
Research and development	2,734	4,006	9,145	10,115
In-process research and development impairment	1,325	—	1,325	—
Goodwill impairment	1,526	—	5,594	—
Total Operating Costs and Expenses	**7,887**	**4,218**	**21,766**	**15,214**
Loss from Operations	**(7,887)**	**(4,218)**	**(21,766)**	**(15,214)**
Other Income/Expense:				
Foreign currency exchange gain	3	6	1	7
Interest income	158	382	559	1,127
Total Other Income	**161**	**388**	**560**	**1,134**
Net Loss	**(7,726)**	**(3,830)**	**(21,206)**	**(14,080)**
Income tax benefit	—	527	—	1,216
Net Loss Attributable to Common Stockholders	**$ (7,726)**	**$ (3,303)**	**$ (21,206)**	**$ (12,864)**
Net Loss Per Share - Basic and Dilutive	**$ (6.81)**	**$ (4.85)**	**$ (24.47)**	**$ (20.38)**
Weighted average number of shares outstanding during the period - Basic and Dilutive	**1,134,391**	**681,708**	**866,529**	**631,387**
Net Loss	**(7,726)**	**(3,303)**	**(21,206)**	**(12,864)**
Gain (Loss) on foreign currency translation	821	(702)	80	(379)
Total comprehensive loss	**$ (6,905)**	**$ (4,005)**	**$ (21,126)**	**$ (13,243)**

All share numbers have been retrospectively adjusted for the one to twenty-five reverse stock split effective August 26, 2024

See accompanying notes to unaudited condensed consolidated financial statements.

Theriva Biologics, Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholder's Equity
(In thousands, except share and par value amounts)

	Common Stock $0.001 Par Value						
	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive income	Treasury Stock	Total Stockholders' Equity
Balance at December 31, 2023	**715,028**	**$ 1**	**$ 346,536**	**$ (309,318)**	**$ 32**	**$ (288)**	**$ 36,963**
Stock-based compensation	—	—	160	—	—	—	160
Foreign currency exchange gains (losses)	—	—	—	—	(569)	—	(569)
Net loss	—	—	—	(5,165)	—	—	(5,165)
Balance at March 31, 2024	**715,028**	**$ 1**	**$ 346,696**	**$ (314,483)**	**$ (537)**	**$ (288)**	**$ 31,389**
Stock-based compensation	—	—	172	—	—	—	172
Stock issued under "at-the-market" offering	174,282	—	1,839	—	—	—	1,839
Foreign currency exchange gains (losses)	—	—	—	—	(172)	—	(172)
Series C Preferred Stock conversion to Common	35,523	—	988	—	—	—	988
Net loss	—	—	—	(8,316)	—	—	(8,316)
Balance at June 30, 2024	**924,833**	**$ 1**	**$ 349,695**	**$ (322,799)**	**$ (709)**	**$ (288)**	**$ 25,900**
Stock-based compensation	—	—	177	—	—	—	177
Stock issued under "at-the-market" offering	395,000	1	1,763	—	—	—	1,764
Issuance of Common Stock and Warrants, net of issuance costs	918,600	1	1,952	—	—	—	1,953
Foreign currency exchange gains (losses)	—	—	—	—	821	—	821
Series C Preferred Stock conversion to Common	36,609	—	1,018	—	—	—	1,018
Series D Preferred Stock conversion to Common	26,230	—	728	—	—	—	728
Conversion of Pre-Funded Warrants to Common	345,000	—	—	—	—	—	—
Net loss	—	—	—	(7,726)	—	—	(7,726)
Balance at September 30, 2024	**2,646,272**	**$ 3**	**$ 355,333**	**$ (330,525)**	**$ 112**	**$ (288)**	**$ 24,635**

All share numbers have been retrospectively adjusted for theone to twenty-five reverse stock split effective August 26, 2024

See accompanying notes to unaudited condensed consolidated financial statements.

	Common Stock $0.001 Par Value		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive income	Treasury Stock	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2022	**634,069**	**$ 1**	**$ 343,765**	**$ (290,969)**	**$ (679)**	**$ (288)**	**$ 51,830**
Stock-based compensation	—	—	126	—	—	—	126
Translation gains	—	—	—	—	374	—	374
Net loss	—	—	—	(4,478)	—	—	(4,478)
Balance at March 31, 2023	**634,069**	**$ 1**	**$ 343,891**	**$ (295,447)**	**$ (305)**	**$ (288)**	**$ 47,852**
Stock-based compensation	—	—	146	—	—	—	146
Stock issued under "at-the-market" offering	76,709	—	2,156	—	—	—	2,156
Translation gains(loss)	—	—	—	—	(51)	—	(51)
Net loss	—	—	—	(5,084)	—	—	(5,084)
Balance at June 30, 2023	**710,778**	**$ 1**	**$ 346,193**	**$ (300,531)**	**$ (356)**	**$ (288)**	**$ 45,019**
Stock-based compensation	—	—	135	—	—	—	135
Stock issued under "at-the-market" offering	40	—	1	—	—	—	1
Translation gains(loss)	—	—	—	—	(702)	—	(702)
Net loss	—	—	—	(3,303)	—	—	(3,303)
Balance at September 30, 2023	**710,818**	**$ 1**	**$ 346,329**	**$ (303,834)**	**$ (1,058)**	**$ (288)**	**$ 41,150**

All share numbers have been retrospectively adjusted for the one to twenty-five reverse stock split effective August 26, 2024

See accompanying notes to unaudited condensed consolidated financial statements.

Theriva Biologics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	For the Nine Months Ended September 30,	
	2024	**2023**
Cash Flows From Operating Activities:		
Net loss	$ (21,206)	$ (12,864)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	509	407
Income tax benefit	—	(1,216)
In-process research and development impairment	1,325	—
Goodwill impairment	5,594	—
Change in fair value of contingent consideration	514	(999)
Non-cash lease expense	335	283
Depreciation	110	96
Deferred research and development tax credit	(669)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,124	1,524
Deposits and other assets	1	(54)
Accounts payable	(21)	(74)
Accrued expenses	724	883
Accrued employee benefits	(229)	(129)
Operating lease liability	(357)	(312)
Net Cash Used In Operating Activities	**(12,246)**	**(12,455)**
Cash Flows from Investing Activities		
Purchase of property and equipment	(1)	(146)
Net Cash Used in Investing Activities	**(1)**	**(146)**
Cash Flows from Financing Activities		
Payment of loans payable	(67)	(75)
Proceeds from issuance Common Stock and Warrants offering, net of issuance costs	1,953	—
Proceeds from issuance ATM offering, net of issuance costs	3,603	2,157
Net Cash provided by Financing Activities	**5,489**	**2,082**
Effects of exchange rate changes on cash and cash equivalents	(9)	(109)
Net decrease in cash and cash equivalents and restricted cash	(6,767)	(10,628)
Cash and cash equivalents and restricted at the beginning of this period	23,279	41,885
Cash and cash equivalents and restricted cash at the end of this period	**$ 16,512**	**$ 31,257**
Reconciliation of cash, cash equivalents, and restricted cash reported in the consolidated balance sheet		
Cash and cash equivalents	$ 16,409	$ 31,160
Restricted cash included in other long-term assets	103	97
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	**$ 16,512**	**$ 31,257**
Supplemental non-cash investing and financing activities:		
Conversion of Series C Preferred Stock to Common Shares	$ 2,005	$ —
Conversion of Series D Preferred Stock to Common Shares	$ 728	$ —
Right of use assets obtained in exchange for lease liabilities	$ —	$ 937

All share numbers have been adjusted for the one to twenty-five reverse stock split effective August 26, 2024

See accompanying notes to unaudited condensed consolidated financial statements.

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization, Nature of Operations and Basis of Presentation

Description of Business

Theriva Biologics, Inc. (the "Company" or "Theriva Biologics") is a diversified clinical-stage company developing therapeutics in areas of high unmet need. As a result of the acquisition in March 2022 of Theriva Biologics S.L. ("VCN", formerly known as VCN Biosciences, S.L.) (the "Acquisition"), described in more detail below, the Company transitioned its strategic focus to oncology through the development of VCN's new oncolytic adenovirus platform designed for intravenous and intravitreal delivery to trigger tumor cell death, to improve access of co-administered cancer therapies to the tumor, and to promote a robust and sustained anti-tumor response by the patient's immune system. Prior to the Acquisition, the Company's focus was on developing therapeutics designed to treat gastrointestinal (GI) diseases in areas which included its clinical development candidates: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the GI tract to prevent microbiome damage thereby preventing overgrowth and infection by pathogenic organisms such as *Clostridioides difficile* infection (CDI), and vancomycin resistant Enterococci (VRE), and reducing the incidence and severity of acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under cGMP conditions and intended to treat both local GI and systemic diseases.

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all the information and notes required by Accounting Principles Generally Accepted in the United States of America ("U.S. GAAP") for complete financial statements. The accompanying condensed consolidated financial statements include all adjustments, comprised of normal recurring adjustments, considered necessary by management to fairly state the Company's results of operations, financial position, and cash flows. The operating results for the interim periods are not necessarily indicative of results that may be expected for any other interim period or for the full year. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed on March 25, 2024 (the "2023 Form 10-K").

On August 15, 2024, the Board of Directors of the Company approved a reverse stock split of the Company's authorized, issued and outstanding shares of common stock, par value $ 0.001 per share (the "Common Stock"), at a ratio of one (1) share of Common Stock for twenty-five (25) shares of Common Stock (the "Reverse Stock Split"). The Reverse Stock Split was effective on August 26, 2024 (the "Effective Time").

As a result of the Reverse Stock Split, each twenty-five (25) pre-split shares of Common Stock outstanding automatically combined into one (1) new share of Common Stock without any action on the part of the holders, and the number of outstanding shares of common stock was reduced from 25,131,230 shares to 1,005,249 shares (subject to rounding of fractional shares) and the number of authorized shares of Common Stock was reduced from 350,000,000 share to 14,000,000 shares. Stockholders who otherwise were entitled to receive fractional shares because they held a number of pre-reverse stock split shares of Common Stock not evenly divisible by 25, received, in lieu of a fractional share, that number of shares rounded up to the nearest whole share. The Reverse Stock Split did not alter the par value of the Common Stock or modify any voting rights or other terms of the Common Stock. In addition, pursuant to their terms, a proportionate adjustment was made to the per share conversion exercise price and number of shares issuable under all of the Company's outstanding shares of convertible preferred stock and stock options and warrants to purchase shares of Common Stock, and the number of shares authorized and reserved for issuance pursuant to the Company's equity incentive plans was reduced proportionately.

All share amounts and exercise/conversion prices in the condensed consolidated financial statements and footnotes below have been adjusted retrospectively for the Reverse Stock Split.

The condensed consolidated financial statements are prepared in conformity with U.S. GAAP, which requires the use of estimates, judgments and assumptions that affect the amounts of assets and liabilities at the reporting date and the amounts of revenue and expenses in the periods presented. The Company believes that the accounting estimates employed are appropriate and the resulting balances are reasonable; however, due to the inherent uncertainties in making estimates, actual results may differ from the original estimates, requiring adjustments to these balances in future periods. As of September 30, 2024, the Company has one operating segment (which includes the legacy Company business and the VCN business) and therefore one reporting segment.

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

2. Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company continues to incur losses and, as of September 30, 2024, the Company had an accumulated deficit of approximately $ 330.5 million. These factors raise substantial doubt about the Company's ability to continue as a going concern. Since inception, the Company has financed its activities principally from the proceeds from the issuance of equity securities.

The Company's ability to continue as a going concern is dependent upon the Company's ability to raise additional debt and equity capital. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

The Company does not have sufficient capital to fund its operations beyond the date that is twelve months from the date of the filing of this Quarterly Report on Form 10-Q. In order to address the Company's capital needs, including its planned clinical trials, the Company is actively pursuing additional equity or debt financing in the form of either a private placement or a public offering. The Company has been in ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings. Such additional financing opportunities might not be available to the Company when and if needed, on acceptable terms or at all. If the Company is unable to obtain additional financing in sufficient amounts or on acceptable terms under such circumstances, the Company's operating results and prospects will be adversely affected.

At September 30, 2024, the Company had cash and cash equivalents of approximately $ 16.4 million. Based upon the Company's current business plans, management believes that the Company's current cash on hand will be sufficient to fully execute its plans into the third quarter of 2025. Commencement of planned future clinical trials is subject to the Company's successful pursuit of opportunities that will allow it to establish the clinical infrastructure and financial resources necessary to successfully initiate and complete its plan. The Company anticipates its current cash will allow it to cover overhead costs, manufacturing costs for near-term clinical supply and limited research efforts, including completing its funding requirements for its ongoing current trials for VCN-01. The Company will be required to obtain additional funding in order to continue the development of its current product candidates within the anticipated time periods (including initiation of its planned future clinical trials), if at all, and to continue to fund operations at the current cash expenditure levels. Currently, the Company does not have commitments from any third parties to provide it with capital. Potential sources of financing include strategic relationships, public or private sales of equity (including through its at the market offering sales agreement (the "ATM Sales Agreement")) or debt and other sources. The Company cannot assure that it will meet the requirements for use of the ATM Sales Agreement or that additional funding will be available on favorable terms at all. If the Company fails to obtain additional funding for its clinical trials, whether through the sale of securities or a partner or collaborator, and otherwise when needed, it will not be able to execute its business plan as planned and will be forced to cease certain development activities (including initiation of planned clinical trials) until funding is received and its business will suffer, which would have a material adverse effect on its financial position, results of operations and cash flows.

The actual amount of funds the Company will need to operate is subject to many factors, some of which are beyond its control. These factors include the following:

- the progress of its research activities;
- the number and scope of its research programs;
- the ability to recruit patients for clinical studies in a timely manner;
- the progress of its preclinical and clinical development activities;
- the progress of the development efforts of parties with whom the Company has entered into research and development agreements and amount of funding received from partners and collaborators;
- its ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

2. Going Concern – (continued)

- the Company's ability to achieve its milestones under licensing arrangements;
- the costs associated with manufacturing-related services to produce material for use in its clinical trials;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

The Company has based its estimates of funding requirements on assumptions that may prove to be wrong. The Company may need to obtain additional funds sooner or in greater amounts than it currently anticipates.

If the Company raises funds by selling additional shares of Common Stock or other securities convertible into Common Stock, the ownership interest of the existing stockholders will be diluted. If the Company is not able to obtain financing when needed, it may be unable to carry out its business plan. As a result, the Company may have to significantly limit its operations and its business, financial condition and results of operations would be materially harmed.

3. Summary of Significant Accounting Policies

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Such estimates and assumptions impact, among others, the following: the estimated useful lives for property and equipment, research and development costs, business combinations, contingent consideration, fair value of long-lived assets, valuation of goodwill and in process research and development, warrants, preferred stock and stock options granted for services or compensation, respectively, and the valuation allowance for deferred tax assets due to continuing and expected future operating losses.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of consolidated financial statements, which management considered in formulating its estimate could change in the near term due to one or more future confirming events. Accordingly, actual results could differ from those estimates.

There have been no new or material changes to the significant accounting policies discussed in the Company's audited financial statements and the notes thereto included in the 2023 Form 10-K.

In-Process Research and Development ("IPR&D")

IPR&D assets represent the fair value assigned to technologies that the Company acquired, which at the time of acquisition have not reached technological feasibility and have no alternative future use. IPR&D assets are considered to have indefinite-lives until the completion or abandonment of the associated research and development projects. If and when development is complete, which generally occurs upon regulatory approval and the ability to commercialize products associated with the IPR&D assets, these assets are then deemed to have definite lives and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

During the period that the assets are considered indefinite-lived, they are tested for impairment on an annual basis on October 1, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that could indicate an impairment. The impairment test consists of a comparison of the estimated fair value of the IPR&D with its carrying amount. If the carrying amount exceeds the fair value, an impairment charge is recognized in an amount equal to that excess. The key assumptions used to value IPR&D include estimates of future cash flows and to the discount rate applicable to the future cash flow periods.

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

3. Summary of Significant Accounting Policies – (continued)

Goodwill

The Company tests the carrying amounts of goodwill for recoverability on an annual basis on October 1 or more frequently if events or changes in circumstances indicate that the asset might be impaired. The Company performs a one-step test in its evaluation of the carrying value of goodwill if qualitative factors determine it is necessary to complete a goodwill impairment test. In the evaluation, the fair value of the relevant reporting unit is determined and compared to its carrying value. If the fair value is greater than the carrying value, then the carrying value is deemed to be recoverable, and no further action is required. If the fair value estimate is less than the carrying value, goodwill is considered impaired for the amount by which the carrying amount exceeds the reporting unit's fair value, and a charge is reported in impairment of goodwill in the Company's consolidated statements of operations. The key assumptions used to value the reporting unit include estimates of future cash flows, the discount rate applicable and those future cash flow periods, and the implied control premium.

Contingent Consideration

Consideration paid in a business combination may include potential future payments that are contingent upon the acquired business achieving certain milestones in the future ("contingent consideration"). Contingent consideration liabilities are measured at their estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded in the consolidated statements of operations. The Company estimates the fair value of the contingent consideration as of the acquisition date using the estimated future cash outflows based on the probability of meeting future milestones. Payments for amounts not in excess of original fair values established at acquisition date (including measurement period adjustments), and not paid within a period considered to be close to the transaction date, are reflected as financing activities in the statement of cash flows. Subsequent to the date of acquisition, the Company reassesses the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. The discounted cash flow is the method used to value the contingent consideration which includes inputs of not readily observable market data, which are level 3 inputs. Any adjustment to the contingent consideration liability will be recorded in the consolidated statements of operations. Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under long-term liabilities in the consolidated balance sheets. See Fair Value of Financial Instruments below.

Research and Development Tax Credits

The Company, through its Theriva S.L. subsidiary, participates in a Research and Development incentive program sponsored by the Spanish government. The program provides for reimbursement of certain expenses incurred in research and development efforts the Company incurs in Spain. The program provides for certain limits on the types and amounts of expenses and requires participants to complete a certification and apply for the refund annually. Subsequent to the period in which expenses are incurred, the program requires participants to maintain certain workforce levels and research and development expenditures over a 24-month period. The Company accounts for the reimbursement as a tax credit receivable related to amounts that had been approved by the Spanish government and a corresponding deferred research and development tax credit as it was determined that amounts became probable of being received upon the receipt of the approval. Additionally, the Company has elected to account for the tax credit as a contra-expense as this most appropriately reflects the nature of the transaction and will reduce future research and development expenditures as the Company continues to incur expenses in the upcoming 24-month period.

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

3. Summary of Significant Accounting Policies – (continued)

Recent Accounting Pronouncements and Developments

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This ASU amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and improves and amends the related earnings per share guidance for both Subtopics. The ASU is effective for annual reporting periods after December 15, 2023 and interim periods within those annual periods and early adoption is permitted in annual reporting periods ending after December 15, 2020. The Company adopted ASU 2020-06 on January 1, 2022. The ASU impacted the analysis of the accounting treatment for the issuance of Convertible Preferred Series C & D stock during the third quarter of 2022, specifically the cash conversion and beneficial conversion features.

In December 2023, the FASB issued final guidance in ASU No. 2023-09, Income Taxes (ASC 740): Improvements to Income Tax Disclosures requiring entities to provide additional information in the rate reconciliation and disclosures about income taxes paid. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The Company is not early adopting this ASU, and therefore, this ASU is not adopted in the current period. The Company does not expect this ASU to have a material impact on the consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures which requires public entities to disclose significant segment expenses regularly provided to the chief operating decision-maker. Public entities with a single reporting segment have to provide all disclosures required by ASC 280, including the significant segment expense disclosures. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The Company is not early adopting this ASU, and therefore has not adopted this ASU in the current period. The Company does not expect this ASU to have a material impact on the consolidated financial statements.

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

4. Goodwill and Intangibles

The following table provides the Company's Goodwill as of September 30, 2024.

	Goodwill (in thousands)
Balance at December 31, 2023	$ 5,700
Goodwill impairment	(5,594)
Effects of exchange rates	(106)
Balance at September 30, 2024	$ —

The following table provides the Company's in-process R&D as of September 30, 2024.

	In-process R&D (in thousands)
Balance at December 31, 2023	$ 19,755
In-process R&D impairment	(1,325)
Effects of exchange rates	221
Balance at September 30, 2024	$ 18,651

During the three and nine months ending September 30, 2024, the Company experienced a sustained decline in the quoted market price of the Company's Common Stock and the Company deemed this to be a triggering event for impairment. The Company performed an interim impairment analysis using both the replacement cost method and the "Income approach" that requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital. For the three and nine months ending September 30, 2024, the Company concluded that the in-process R&D with a carrying value of $ 19.8 million was impaired and was written down to its estimated fair value of $ 18.6 million and an impairment charge of $ 1.3 million was recorded. For the three and nine months ending September 30, 2024, the Company concluded that goodwill with a carrying value of $ 1.5 million was impaired and was written down to its estimated fair value of zero and an impairment charge of $ 1.5 million and $ 5.6 million, respectively, was recorded.

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

5. Fair Value of Financial Instruments

Accounting Standards Codification ("ASC") 820, *Fair Value Measurement*, defines fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are classified on a three-tier hierarchy as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 inputs: Inputs, other than quoted prices, that are observable either directly or indirectly; and
- Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

In many cases, a valuation technique used to measure fair value includes inputs from multiple levels of the fair value hierarchy described above. The lowest level of significant input determines the placement of the entire fair value measurement in the hierarchy.

The carrying amounts of the Company's short-term financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities, approximate fair value due to the relatively short period to maturity for these level 1 instruments.

As a result of the Acquisition of VCN the Company acquired interest-free or below-market interest rate loans extended by Spanish government. The carrying value of the loans payable approximate fair value and are classified under level 2.

In connection with the Acquisition of VCN, the Company agreed to pay up to $ 70.2 million in additional consideration upon the achievement of certain milestones, including regulatory filings completed. In August 2023, the Company initiated patient dosing in the U.S. in its Phase 2 clinical trial of VCN-01 in PDAC. As a result, payment was made in the third quarter 2023 in the amount of $ 3.25 million. The discounted cash flow method used to value this contingent consideration includes inputs of not readily observable market data, which are Level 3 inputs. The fair value of the contingent consideration was $ 6.8 million as of September 30, 2024 and is all reflected as non-current contingent consideration liability. During the three months ended September 30, 2024 and 2023, the Company recognized in operating expense a $ 587,000 increase and $ 1.6 million decrease, respectfully, fair value adjustment to contingent consideration. During the nine months ended September 30, 2024 and 2023, the Company recognized in operating expense a $ 514,000 increase and $ 1.0 million decrease, respectfully, fair value adjustment to contingent consideration. There were no transfers in or out of the level 3 liabilities during the nine months ended September 30, 2024 and 2023.

The following table summarizes the change in the fair value as determined by Level 3 inputs for the contingent consideration liabilities as of December 31, 2023 and September 30, 2024:

	(in thousands)
Balance at December 31, 2022	$ 10,184
Payment of contingent consideration	(3,250)
Change in fair value	(660)
Balance at December 31, 2023	$ 6,274
Contingent consideration, current portion	$ —
Contingent consideration, net of current portion	6,274
Balance at December 31, 2023	$ 6,274

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

5. Fair Value of Financial Instruments – (continued)

	(in thousands)
Balance at December 31, 2023	$ 6,274
Change in fair value	514
Balance at September 30, 2024	$ 6,788
Contingent consideration, current portion	$ —
Contingent consideration, net of current portion	6,788
Balance at September, 2024	$ 6,788

The fair value of financial instruments measured on a recurring basis is as follows:

	As of September 30, 2024			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Contingent consideration	$ 6,788	$ —	$ —	$ 6,788
Total liabilities	$ 6,788	$ —	$ —	$ 6,788

	As of December 31, 2023			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Contingent consideration	$ 6,274	$ —	$ —	$ 6,274
Total liabilities	$ 6,274	$ —	$ —	$ 6,274

The recurring Level 3 fair value measurements of contingent consideration for which a liability is recorded include the following significant unobservable inputs:

	As of September 30, 2024		
	Valuation Methodology	**Significant Unobservable Input**	**Weighted Average (range, if applicable)**
Contingent Consideration	Discounted Cash Flows	Milestone dates	2026-2028
		Discount rate	11.6 % to 11.9 %
		Weighted Average Discount rate	11.7 %
		Probability of Occurrence (periodic for each Milestone)	11.7 % to 92.0 %
		Probability of occurrence (cumulative through each Milestone)	5.3 % to 48.8 %

	As of December 31, 2023		
	Valuation Methodology	**Significant Unobservable Input**	**Weighted Average (range, if applicable)**
Contingent Consideration	Discounted Cash Flows	Milestone dates	2025-2028
		Discount rate	12.9 % to 13.6 %
		Weighted Average Discount rate	13.16 %
		Probability of Occurrence (periodic for each Milestone)	11.7 % to 92.0 %
		Probability of occurrence (cumulative through each Milestone)	5.3 % to 48.8 %

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

5. Fair Value of Financial Instruments – (continued)

The Company measures certain non-financial assets on a non-recurring basis, including goodwill and in-process R&D. As a result of those measurements, during the quarter ended September 30, 2024 in-process R&D with a carrying value of $ 19.8 million was written down to its estimated fair value of $ 18.6 million and an impairment charge of $ 1.3 million was recorded, and goodwill with a carrying value of $ 1.5 million was written down to its estimated fair value of zero and an impairment charge of $ 1.5 million was recorded. For the quarter ending June 30, 2024, goodwill with a carrying value of $ 5.5 million was written down to its estimated fair value of $ 1.5 million and an impairment charge of $ 4.0 million was recorded. This analysis requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital.

The fair value of the Company's reporting unit was determined using an income approach that utilizes a discounted cash flow model. The discounted cash flow models are dependent upon the Company's estimates of future cash flows and other factors. The Company's estimates of future cash flows are based on a comprehensive product by product forecast over a period which covers Phase 1 to approval and 15 years of commercialized revenue and involve assumptions concerning (i) future operating performance, including research and development costs through approval of the drug, the future addressable market, future sales, long-term growth rates, operating margins, allocation and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions, all which may differ from actual future cash flows.

Assumptions related to future operating performance are based on management's annual and ongoing budgeting, forecasting and planning processes and represent the Company's best estimate of the future results of its operations as of a point in time. These estimates are subject to many assumptions, such as the economic environments in which it operates, demand for the products and competitor actions. Estimated future cash flows are discounted to present value using a market participant, weighted average cost of capital, which considers the risk inherent in the probability adjusted future cash flows from each product. The financial and credit market volatility directly impacts certain inputs and assumptions used to develop the weighted average cost of capital such as the risk-free interest rate, industry beta, debt interest rate and the Company's market capital structure. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions could increase or decrease the Company's estimated discounted future cash flows, the resulting estimated fair values and the amounts of related goodwill impairments, if any.

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

6. Research and Development Tax Credits

The Company, through its Theriva S.L. subsidiary, participates in a Research and Development program sponsored by the Spanish government. The program provides for reimbursement of certain expenses incurred in research and development efforts the Company incurs in Spain. The reimbursements can be through either tax credits or direct refunds. The program provides for certain limits on the types and amounts of expenses for which reimbursement may be sought and requires participants to complete a certification and apply for the refund annually. Subsequent to the period in which expenses are incurred, the program requires participants to maintain certain workforce levels and research and development expenditures over a 24-month period.

In the quarter ended June 30, 2023, the Company completed the certification and applied for direct reimbursement, as opposed to a tax credit, for its qualifying research and development expenses incurred in the year ended December 31, 2022. The Company received approvals from the Spanish government in September and October 2023. During the quarter ended June 30, 2024, the Company completed the certification and applied for direct reimbursement for its qualifying research and development expenses incurred in the year ended December 31, 2023.

The Company evaluated the program and concluded that it qualified to be accounted for as government assistance. Accordingly, the Company, as allowed by U.S. GAAP, elected to account for the grant by analogizing to the guidance provided by International Accounting Standards ("IAS") 20, Accounting for Government Grants and Disclosure of Government Assistance. Accordingly, the Company recognized a tax credit receivable of $ 1.8 million related to amounts that had been approved by the Spanish government and a corresponding deferred research and development tax credit current portion of $ 916,000 and a deferred research and development tax credit non-current portion of $ 229,000 , as it was determined that amounts became probable of being received upon the receipt of the approval. Additionally, the Company has elected to account for the tax credit as a contra-expense as this most appropriately reflects the nature of the transaction and will reduce future research and development expenditures as the Company continues to incur expenses in the upcoming 24-month period. During the three and nine months ending September 30, 2024 the Company recorded $ 221,000 and $ 669,000 , respectively, as a reduction in research and development expense.

7. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands)

	September 30, 2024	December 31, 2023
Prepaid manufacturing expenses	$ 382	$ 491
Prepaid clinical research organizations	359	1,119
Prepaid consulting, subscriptions and other expenses	286	180
VAT receivable	170	128
Prepaid insurance	95	496
Total	$ 1,292	$ 2,414

Prepaid clinical research organizations (CROs) expense is classified as a current asset. The Company makes payments to the CROs based on agreed upon terms that include payments in advance of study services.

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

7. Selected Balance Sheet Information – (continued)

Property and equipment, net (in thousands)

	September 30, 2024	December 31, 2023
Computers and office equipment	$ 715	$ 902
Other property, plant and equipment	421	417
Leasehold improvements	94	94
Software	11	11
	1,241	1,424
Less: accumulated depreciation and amortization	(927)	(1,002)
Total	$ 314	$ 422

Accrued expenses (in thousands)

	September 30, 2024	December 31, 2023
Accrued clinical consulting services	$ 2,358	$ 1,700
Accrued manufacturing costs	820	843
Accrued vendor payments	576	452
Total	$ 3,754	$ 2,995

Accrued employee benefits (in thousands)

	September 30, 2024	December 31, 2023
Accrued bonus expense	$ 982	$ 1,307
Accrued compensation expense	181	127
Accrued vacation expense	128	83
Total	$ 1,291	$ 1,517

8. Stock-Based Compensation

Stock Incentive Plans

On November 2, 2010, the Board of Directors and stockholders adopted the 2010 Stock Incentive Plan ("2010 Stock Plan") for the issuance of up to 343 shares of Common Stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. From time to time the number of shares authorized for options was increased such that 16,000 were authorized as of September 5, 2019. The exercise price of stock options under the 2010 Stock Plan was determined by the compensation committee of the Board of Directors and could be equal to or greater than the fair market value of the Company's Common Stock on the date the option was granted. Options become exercisable over various periods from the date of grant and expire between five and ten years after the grant date. As of September 30, 2024, there were 7,843 options issued and outstanding under the 2010 Stock Plan. There are no shares available to be issued under this plan. Only options were issued under the plan.

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

8. Stock-Based Compensation – (continued)

On September 17, 2020, the stockholders approved and adopted the 2020 Stock Incentive Plan ("2020 Stock Plan") for the issuance of up to 16,000 shares of Common Stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. The number of shares authorized for awards under the 2020 Stock Plan was increased such that 280,000 shares were authorized as of December 31, 2022. As of September 30, 2024, there were 167,364 options issued and outstanding under the 2020 Stock Plan. Only options have been issued under the plan.

In the event of an employee's termination, the Company will cease to recognize compensation expense for that employee. Stock option forfeitures are recognized as incurred. The fair value of the stock-based payment is recognized over the stated vesting period.

The Company has applied fair value accounting for all stock-based payment awards since inception. The fair value of each option granted is estimated on the date of grant using the Black-Scholes option pricing model. During the three and nine months ended September 30, 2024, the Company granted 420 options to employees with an approximate fair value of $ 1,500 based upon the Black-Scholes option pricing model. There were no options granted during the three and nine months ended September 30, 2023.

Expected dividends—The Company has never declared or paid dividends on its Common Stock and has no plans to do so in the foreseeable future.

Expected volatility—Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The expected volatility assumption is derived from the historical volatility of the Company's Common Stock over a period approximately equal to the expected term.

Risk-free interest rate—The assumed risk-free rate used is a zero coupon U.S. Treasury security with a maturity that approximates the expected term of the option.

Expected life of the option—The period of time that the options granted are expected to remain unexercised. Options granted during the prior year have a maximum term of seven years. The Company estimates the expected life of the option term based on the weighted average life between the dates that options become fully vested and the maximum life of options granted.

The Company records stock-based compensation based upon the stated vesting provisions in the related agreements. The vesting provisions for these agreements have various terms as follows:

- immediate vesting,
- in full on the one-year anniversary date of the grant date,
- half vesting immediately and the remaining over three years,
- quarterly over three years,
- annually over three years,

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

8. Stock-Based Compensation – (continued)

- one-third immediate vesting and the remaining annually over two years,
- one-half immediate vesting and the remaining over nine months,
- one-quarter immediate vesting and the remaining over three years,
- one-quarter immediate vesting and the remaining over 33 months,
- monthly over one year, and
- monthly over three years.

A summary of stock option activity for the nine months ended September 30, 2024 and the year ended December 31, 2023 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2022	91,862	$ 90.47	6.44 years	$ —
Granted	87,801	14.75		
Expired	(4,181)	387.60		
Forfeited	(433)	27.79		
Balance - December 31, 2023	175,049	45.55	7.70 years	—
Granted	420	5.25		
Expired	(262)	2,267.32		
Forfeited	—	—		
Balance - September 30, 2024 - outstanding	175,207	$ 42.13	6.96 years	$ —
Balance - September 30, 2024 - exercisable	93,934	$ 65.71	5.97 years	$ —
Grant date fair value of options granted – nine months ended September 30, 2024		$ 1,526		
Weighted average grant date fair value – nine months ended September 30, 2024		$ 3.63		
Grant date fair value of options granted – year ended December 31, 2023		$ 873,140		
Weighted average grant date fair value – year ended December 31, 2023		$ 0.40		

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Notes to Condensed Consolidated Financial Statements

8. Stock-Based Compensation – (continued)

Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to employees for the three months ended September 30, 2024 and 2023 was $ 123,000 and $ 90,000 , respectively. Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to consultants for the three months ended September 30, 2024 and 2023 was $ 54,000 and $ 45,000 , respectively. Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to employees for the nine months ended September 30, 2024 and 2023 was $ 347,000 and $ 274,000 , respectively. Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to consultants for the nine months ended September 30, 2024 and 2023 was $ 161,000 and $ 133,000 , respectively.

As of September 30, 2024, total unrecognized stock-based compensation expense related to stock options was $ 758,000 , which is expected to be expensed through August 2026.

The FASB's guidance for stock-based payments requires cash flows from excess tax benefits to be classified as a part of cash flows from operating activities. Excess tax benefits are realized tax benefits from tax deductions for exercised options in excess of the deferred tax asset attributable to stock compensation costs for such options. The Company did not record any excess tax benefits during the three and nine months ended September 30, 2024 and 2023.

9. Stock Warrants

On September 27, 2024, the Company consummated a public offering (the "Offering") of an aggregate of (i) 918,600 shares (the "Shares") of Common Stock, (ii) pre-funded warrants ("Pre-Funded Warrants") to purchase up to 510,000 shares of Common Stock (the "Pre-Funded Warrant Shares"), and (iii) Common Stock purchase warrants ("Common Warrants") to purchase up to 1,428,600 shares of Common Stock (the "Common Warrant Shares"). Each Share and associated Common Warrant to purchase one (1) Common Warrant Share was sold at a combined public offering price of $ 1.75 . Each Pre-Funded Warrant and associated Common Warrant to purchase one (1) Common Warrant Share was sold at a combined public offering price of $ 1.7499 . The Company received aggregate gross proceeds from the Offering of approximately $ 2.5 million, before deducting placement agent fees and other offering expenses. The Company intends to use the proceeds of the Offering primarily for working capital and general corporate purposes, including research and development and manufacturing scale-up and may use a portion of the proceeds to invest in or acquire other products, businesses or technologies. Each Pre-Funded Warrant is immediately exercisable for one (1) Pre-Funded Warrant Shares at an exercise price of $ 0.0001 per share and will remain exercisable until the Pre-Funded Warrants are exercised in full. Each Common Warrant has an exercise price of $ 2.00 per share, is immediately exercisable for one (1) Common Warrant Share, and expires five (5) years from its issuance date. The Shares, Pre-Funded Warrants and accompanying Common Warrants were issued separately. The exercise price of the Common Warrants and the Pre-Funded Warrants and number of shares of Common Stock issuable upon exercise will adjust in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events. The Common Warrants may be exercised on a cashless basis if at the time of exercise thereof there is no effective registration statement registering, or the prospectus contained therein is not available for, the issuance of the Common Warrant Shares to the holder. The Pre-Funded Warrants may be exercised on a cashless basis at any time. A holder of the Common Warrants and the Pre-Funded Warrants (together with its affiliates) may not exercise any portion of the Common Warrant or Pre-Funded Warrant to the extent that the holder would own more than 4.99 % (or 9.99 %, at the election of the holder) of the outstanding shares of Common Stock immediately after exercise, except that upon at least 61 days ' prior notice from the holder to the Company, the holder may increase the amount of beneficial ownership of outstanding shares after exercising the holder's Common Warrants or Pre-Funded Warrants up to 9.99 % of the number of the Company's shares of Common Stock outstanding immediately after giving effect to the exercise. The Company has concluded that the Common Warrants and Pre-Funded Warrants are required to be equity classified. The Common Warrants were valued on the date of grant using Black Scholes model. During the nine months ended September 30, there were zero Common Warrants exercised and as of September 30, 2024, 345,000 Pre-Funded warrants were exercised.

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

9. Stock Warrants – (continued)

On October 15, 2018, the Company closed its underwritten public offering pursuant to which it received gross proceeds of approximately $ 18.6 million before deducting underwriting discounts, commissions and other offering expenses payable by the Company and sold (i) Class A Units (the "Class A Units"), consisting of an aggregate of 252,000 shares of the Common Stock, warrants to purchase an aggregate of 252,000 shares of Common Stock at an exercise price of $ 13.80 per share, which subsequently was reduced to $ 6.90 per share and then again to $ 1.22 (each a "Warrant" and collectively, the "Warrants") and (ii) Class B Units (the "Class B Units", and together with the Class A Units, the "Units"), consisting of an aggregate of 15,723 shares of the Company's Series B Convertible Preferred Stock (the "Series B Preferred Stock"), with a stated value of $ 1,000 and convertible into shares of Common Stock at the stated value divided by a conversion price of $ 11.50 per share, with all shares of Series B Preferred Stock convertible into an aggregate of 1,367,218 shares of Common Stock, and issued with a warrant to purchase an aggregate of 1,367,218 shares of Common Stock. The Warrants were valued on the date of grant using Monte Carlo simulations. There were no Warrants exercised during the year ended December 31, 2023. The Warrants expired in October 2023 and are no longer outstanding. Upon expiration, the balance in additional paid - in capital related to the warrants was transferred to the additional paid - in capital balance related to Common Stock with no effect on additional paid - in capital.

A summary of all warrant activity for the Company for the nine months ended September 30, 2024 and the year ended December 31, 2023 is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Balance at December 31, 2022	634,426	$ 1.22	0.78 years
Granted	—	—	
Exercised	—	—	
Forfeited	(634,426)	1.22	
Balance at December 31, 2023	—	$ —	—
Granted	1,938,600	1.47	4.99 years
Exercised	(345,000)	0.0001	
Forfeited	—	—	—
Balance at September 30, 2024	1,593,600	1.79	4.99 years

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10. Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding including the effect of common share equivalents. Diluted net loss per share assumes the issuance of potential dilutive common shares outstanding for the period and adjusts for any changes in income and the repurchase of common shares that would have occurred from the assumed issuance, unless such effect is anti-dilutive. Net loss attributable to common stockholders for the three and nine months ended September 30, 2024 was $ 7.7 million and $ 21.2 million, respectively. Net loss per share attributable to common stockholders for the three and nine months ended September 30, 2024 includes 510,000 of pre-funded warrants. Net loss attributable to common stockholders for the three and nine months ended September 30, 2023 was $ 3.3 million and $ 12.9 million, respectively. The number of options and warrants for the purchase of Common Stock that were excluded from the computations of net loss per common share for the three and nine months ended September 30, 2024 were 175,207 and 1,428,600 , respectively, and for the three and nine months ended September 30, 2023 were 2,284,336 and 634,426 , respectively, because their effect is anti-dilutive

11. Common and Preferred Stock

Series C and D Preferred Stock

On July 29, 2022, the Company closed a private placement offering pursuant to the terms of a Securities Purchase Agreement dated as of July 28, 2022 entered into with MSD Credit Opportunity Master Fund, L.P.(the “Securities Purchase Agreement”), pursuant to which the Company issued and sold 275,000 shares of the Company’s Series C Convertible Preferred Stock, par value $ 0.001 per share (the “Series C Preferred Stock”), and 100,000 shares of the Company’s Series D Convertible Preferred Stock, par value $ 0.001 per share (the “Series D Preferred Stock,” and together with the Series C Preferred Stock, the “Preferred Stock”), at an offering price of $ 8.00 per share, for gross proceeds of approximately $ 3.0 million in the aggregate, before the deduction of discounts, fees and offering expenses. The shares of Preferred Stock are convertible, at a conversion price (the “Conversion Price”) of $ 30.50 per share (subject in certain circumstances to adjustments), into an aggregate of 2,459,016 shares of the Company’s Common Stock, at the option of the holders of the Preferred Stock and, in certain circumstances, by the Company. The Securities Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing.

The Company included certain shareholder proposals at its 2022 annual meeting of stockholders, including (i) an amendment to the Company’s Articles of Incorporation, as amended (the “Charter”), to change the name of the Company to “Theriva Biologics, Inc.” (the “Name Change”), (ii) an amendment to the Articles of Incorporation, as amended to increase the number of authorized shares of Common Stock from 20,000,000 t o 350,000,000 (the “Authorized Common Stock Increase”) and (iii) to adjourn any meeting of stockholders called for the purpose of voting on the Authorized Common Stock Increase (collectively, the “Stockholder Items”). The purchaser of the Preferred Stock agreed in the Securities Purchase Agreement to (i) not transfer, offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of the shares of the Preferred Stock until the earlier of the date that the Authorized Common Stock Increase is effected or October 26, 2022 (which could have been extended to December 31, 2022 if certain conditions were met), and (ii) vote the shares of the Series C Preferred Stock purchased in the offering in favor of the Stockholder Items.

Pursuant to the Securities Purchase Agreement, the Company filed certificates of designation (the “Certificates of Designation”) with the Secretary of the State of Nevada designating the rights, preferences and limitations of the shares of Series C Preferred Stock and Series D Preferred Stock. The Certificate of Designation for the Series C Preferred Stock provides, in particular, that the Series C Preferred Stock will have no voting rights other than the right to vote as a class on the Stockholder Items and the right to cast votes on an as converted to Common Stock basis on the Stockholder Items. The Certificate of Designation for the Series D Preferred Stock provides, in particular, that the Series D Preferred Stock will have no voting rights other than the right to vote as a class on the Stockholder Items and the right to cast 20,000 votes per share of Series D Preferred Stock on the Stockholder Items and to vote the shares of the Series D Preferred Stock purchased in the offering in the same proportion as shares of Common Stock and any other shares of capital stock of the Company that are entitled to vote thereon (excluding any shares of Common Stock that are not voted) on the Stockholder Items.

The holders of Preferred Stock will be entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock. The Conversion Price may be adjusted pursuant to the Certificates of Designation for stock dividends and stock splits, subsequent rights offering, pro rata distributions of dividends or the occurrence of a fundamental transaction (as defined in the applicable Certificate of Designation).

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

11. Common and Preferred Stock – (continued)

The Series C Preferred Stock and Series D Preferred Stock are classified as temporary equity as a result of the deemed liquidation provision. Transaction expenses paid to third parties will be charged to temporary equity and will not be accreted as deemed dividends until redemption becomes probable.

During three and nine months ending September 30, 2024, the Company issued 36,609 and 72,132 , respectively, shares of its Common Stock upon the conversion effected on such dates by the holder of 139,569 and 275,000 , respectively, shares of its Series C convertible Preferred Stock at a conversion price of $ 30.50 per share. As a result of the conversions during the three and nine months ending September 30, 2024, the Company reduced the Series C Preferred Stock $ 1.0 million and $ 2.0 million, respectively, and increased Common Stock $ 37 and $ 72 , respectively and Additional Paid in Capital $ 1.0 million and $ 2.0 million, respectively. There are no shares of Series C Preferred Stock outstanding as of September 30, 2024.

During three and nine months ending September 30, 2024, the Company issued 26,230 shares of its Common Stock upon the conversion effected on such dates by the holder of 100,000 shares of its Series D convertible Preferred Stock at a conversion price of $ 30.50 per share. As a result of the conversion during the three and nine months ending September 30, 2024 the Company reduced the Series D Preferred Stock $ 728,000 and increased Common Stock $ 26 respectively and Additional Paid in Capital $ 728,000 . There are no shares of Series D Preferred stock outstanding as of September 30, 2024.

At Market Issuance Sales Agreement

On May 2, 2024, the Company and A.G.P./Alliance Global Partners ("AGP") entered into Amendment No. 2 ("Amendment No. 2") to that certain Amended and Restated Sales Agreement among the Company, AGP and FBR Capital Markets & Co. (now known as B. Riley Securities) dated as of February 9, 2021, as amended by Amendment No. 1 thereto dated May 3, 2021 (the "Sales Agreement"), pursuant to which the Company may offer and sell, from time to time, at its option, shares of the Common Stock through A.G.P./Alliance Global Partners, as sales agent, in an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended (the "Securities Act"). Sales in the "at the market offering" may occur under the Company's current effective registration statement on Form S-3 (File No. 333-255726) utilizing a prior prospectus and related prospectus supplements thereto or a newly filed registration statement on Form S-3 which was filed on May 2, 2024 (File No. 333-279077) and declared effective on September 25, 2024. In addition, on May 1, 2024, the Company and B. Riley Securities, Inc. mutually agreed to enter into a notice of termination whereby B. Riley Securities, Inc. would no longer be a party to the Sales Agreement. During the three and nine months ended September 30, 2024, the Company sold through the Sales Agreement approximately 395,000 and 569,000 , respectively, shares of the Company's Common Stock and received net proceeds of approximately $ 1.8 million and $ 3.6 million, respectively. During the three and nine months ended September, 2023, the Company sold through the At Market Issuance Sales Agreement and the Amended and Restated Sales Agreement approximately 40 and 77,000 shares, respectively, of the Company's Common Stock and received net proceeds of approximately $ 1,000 and $ 2.2 million.

12. Loans Payable

As a result of the Acquisition of VCN, the Company acquired interest-free or below-market interest rates loans (0 %- 1 %) extended by Spanish governmental institutions of Ministerio de Ciencia, Innovacion y Universidades (RETOS loan) and ACC10 Generalitat de Catalunya (NEBT loan). The maturities of these loans are between 2024 and 2028. As a result of the VCN Acquisition, the Company maintains a restricted cash collateral account of $ 103,000 relating to the RETOS loan, which is reflected as a non-current asset on the balance sheet.

	September 30, 2024 Current	September 30, 2024 Non-current	December 31, 2023 Current	December 31, 2023 Non-current
NEBT Loan	8	$ 17	8	24
RETOS 2015	57	81	55	138
	$ 65	$ 98	$ 63	$ 162

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

12. Loans Payable – (continued)

A maturity analysis of the debt as of September 30, 2024 is as follows *(amounts in thousands of dollars)*:

2025	65
2026	54
2027	34
2028	10
Total	163

13. Commitments and Contingencies

The Company's existing leases as of September 30, 2024 for its U.S. and Spanish facilities are classified as operating leases. During the quarter ended June 30, 2021, the Company renewed its Rockville, MD facility lease by entering into a Second Lease Amendment which extends the lease term for 63 months beginning on September 1, 2022 and ending on December 31, 2027 at stated rental rates and including a 3-month rent abatement. The Second Amendment also has options for a Tenant Improvement Allowance and a Second Extension Term. The Second Extension Term is offered at market rates and there is no economic incentive for the lessee, therefore the Company has determined that it is not part of the original lease term.

The Company also leases research and office facilities in Barcelona, Spain for its 100 percent owned Theriva S.L. subsidiary. The lease that was in existence from December 2021 to December 2022 was a short term agreement with a 90-day termination notice provision that can be exercised by either party. On the closing date of the Acquisition, a sublease was executed for Theriva S.L. to lease research and office facilities at a new location in Parets del Valles (Barcelona) from the former owner of Theriva S.L. This lease was executed for an initial term to begin in January 2023 until October 2026, with an option to renew for an additional five years . On January 15, 2023, Theriva S.L. moved into the facilities and the new lease commenced and the prior lease terminated.

Operating lease costs are presented as part of general and administrative expenses in the condensed consolidated statements of operations, and for the three and nine months ended September 30, 2024 approximated $ 158,000 and $ 474,000 , respectively and $ 156,000 and $ 454,000 for the three and six months ended September 30, 2023, respectively. For the Barcelona lease, the day one non-cash addition of right of use assets due to adoption of ASC 842 was $ 937,000 .

A maturity analysis of the Company's operating leases as of September 30, 2024 is as follows *(amounts in thousands of dollars)*:

Future undiscounted cash flow for the years ending December 31,	
2024	166
2025	673
2026	588
2027	369
Total	1,796
Discount factor	(220)
Operating lease liability	1,576
Operating lease liability – current	(541)
Operating lease liability – long term	$ 1,035

Theriva Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements

13. Commitments and Contingencies – (continued)

Risks and Uncertainties

The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values could impact the Company's business in the future. The Company and its third-party contract manufacturers, contract research organizations, and clinical sites may also face disruptions in procuring items that are essential to the Company's research and development activities, including, for example, medical and laboratory supplies used in its clinical trials or preclinical studies, in each case, that are sourced from abroad or for which there are shortages. Further, although the Company has not experienced any material adverse effects on business due to increasing inflation, it has raised operating costs for many businesses and, in the future, could impact demand or pricing manufacturing of its drug candidates or services providers, foreign exchange rates or employee wages. The Company is actively monitoring the effects that these disruptions and increasing inflation could have on its operations.

Through the VCN Acquisition, the Company has operations in Spain related to conducting research and development, manufacturing, and clinical trials in Western European countries. The invasion of Ukraine by Russia, the war in the Middle East, and the retaliatory measures that have been taken, or could be taken in the future, by the United States, NATO, and other countries have created global security concerns that could result in a regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could disrupt the Company's supply chain, and despite the fact that it currently does not plan any clinical trials in Eastern Europe, may adversely impact the cost and conduct of R&D, manufacturing, and international clinical trials of its product candidates.

14. Related Party

On December 14, 2023 the Company approved the retention of Mary Ann Shallcross for compensation of $ 152,000 , a bonus of $ 70,000 and the grant of an option to purchase 3,000 shares of Common Stock having a value of $ 30,000 . During the three and nine months ended September 30, 2024, the company paid compensation to Ms. Shallcross of $ 38,000 and $ 114,000 , respectively.

15. Subsequent events

On October 31, 2024, the Company held its 2024 Annual Meeting of Stockholders. At the Annual Meeting, the Company's stockholders approved an amendment ("Amendment No. 2") to the Company's 2020 Stock Incentive Plan (the "2020 Stock Incentive Plan") to (a) increase the number of shares of Common Stock that we will have authority to grant under the 2020 Stock Incentive Plan from 280,000 shares of Common Stock to 2,500,000 shares of Common Stock and (b) to amend the annual non-employee director grant limit to 250,000 shares of Common Stock; and approved an amendment to our Articles of Incorporation to increase the number of authorized shares of Common Stock to 350,000,000 shares.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion should be read in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q, and our audited consolidated financial statements and notes thereto for the year ended December 31, 2023 included in our 2023 Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See "Note Regarding Forward-Looking Statements" for a discussion of the uncertainties, risks and assumptions associated with these statements. Our actual results and the timing of events could differ materially from those expressed or implied by the forward-looking statements due to important factors and risks including, but not limited to, those set forth below under "Risk Factors" and elsewhere herein, and those identified under Part I, Item 1A of our 2023 Form 10-K.

All share amounts and exercise or conversion prices in this Quarterly Report on Form 10-Q have been adjusted retrospectively for our 1-for-25 reverse stock split, which was effective on August 26, 2024.

Overview

We are a diversified clinical-stage company developing therapeutics designed to treat cancer and related diseases in areas of high unmet need. As a result of the acquisition in March 2022 of Theriva Biologics, S.L. ("VCN", formerly named VCN Biosciences, S.L.), described in more detail below (the "Acquisition"), we began transitioning our strategic focus to oncology, which is now our primary focus, through the development of VCN's new oncolytic adenovirus platform designed for intravenous and intravitreal delivery to trigger tumor cell death, to improve access of co-administered cancer therapies to the tumor, and to promote a robust and sustained anti-tumor response by the patient's immune system. Our lead product candidate, VCN-01, a clinical stage oncolytic human adenovirus that is modified for tumor-selective replication and to express an enzyme, PH20 hyaluronidase, is currently being evaluated in a Phase 2 clinical study for the treatment of pancreatic cancer ("VIRAGE"), and has recently been used to treat patients in a Phase 1 clinical study for the treatment of retinoblastoma, and Phase 1 clinical studies for the treatment of other solid tumors including head and neck squamous cell carcinoma.

Prior to the Acquisition, our focus was on developing therapeutics designed to treat gastrointestinal (GI) diseases which included our clinical development candidates: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the GI tract to prevent microbiome damage, thereby preventing overgrowth and infection by pathogenic organisms such *Clostridioides difficile* infection (CDI) and vancomycin resistant Enterococci (VRE), and reducing the incidence and severity of acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under cGMP conditions and intended to treat both local GI and systemic diseases. As part of our strategic transformation into an oncology focused company, we are exploring value creation options for our SYN-004 and SYN-020 assets, including out-licensing or partnering.

Recent Developments

Reverse Stock Split

On August 15, 2024, our Board of Directors approved a reverse stock split of our authorized, issued and outstanding shares of Common Stock, at a ratio of one (1) share of Common Stock for twenty-five (25) shares of Common Stock (the "Reverse Stock Split"). The Reverse Stock Split was effective on August 26, 2024. Any share amounts and exercise or conversion prices in this Quarterly Report on Form 10-Q have been adjusted retrospectively for the Reverse Stock Split.

Public Offering

On September 27, 2024, we consummated a public offering (the "Offering") of an aggregate of (i) 918,600 shares (the "Shares") of Common Stock, (ii) pre-funded warrants ("Pre-Funded Warrants") to purchase up to 510,000 shares of Common Stock (the "Pre-Funded Warrant Shares"), and (iii) Common Stock purchase warrants ("Common Warrants") to purchase up to 1,428,600 shares of Common Stock (the "Common Warrant Shares"). Each Share and associated Common Warrant to purchase one (1) Common Warrant Share was sold at a combined public offering price of $1.75. Each Pre-Funded Warrant and associated Common Warrant to purchase one (1) Common Warrant Share was sold at a combined public offering price of $1.7499. We received aggregate gross proceeds from the Offering of approximately $2.5 million, before deducting placement agent fees and other offering expenses. We intend to use the proceeds of the Offering primarily for working capital and general corporate purposes, including for research and development and manufacturing scale-up and may use a portion of the proceeds to invest in or acquire other products, businesses or technologies. Each Pre-Funded Warrant is immediately exercisable for one (1) Pre-Funded Warrant Shares at an exercise price of $0.0001 per share and will remain exercisable until the Pre-Funded Warrants are exercised in full. Each Common Warrant has an exercise price of $2.00 per share, is immediately exercisable for one (1) Common Warrant Share, and expires five (5) years from its issuance date. The Shares, Pre-Funded Warrants and accompanying Common Warrants were issued separately. The exercise price of the Common Warrants and the Pre-Funded Warrants and number of shares of Common Stock issuable upon exercise will adjust in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events. The Common Warrants may be exercised on a cashless basis if at the time of exercise thereof there is no effective registration statement registering, or the prospectus contained therein is not available for, the issuance of the Common Warrant Shares to the holder. The Pre-Funded Warrants may be exercised on a cashless basis at any time. A holder of the Common Warrants and the Pre-Funded Warrants (together with its affiliates) may not exercise any portion of the Common Warrant or Pre-Funded Warrant to the extent that the holder would own more than 4.99% (or 9.99%, at the election of the holder) of the outstanding shares of Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to the Company, the holder may increase the amount of beneficial ownership of outstanding shares after exercising the holder's Common Warrants or Pre-Funded Warrants up to 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise. As of October 3, 2024, all of the Pre-Funded Warrants were exercised.

Preferred Shares Conversion

On September 6, 2024, we received a notice of conversion from the holder of 4,138 shares of our Series C Convertible Preferred Stock and 100,000 shares of our Series D Convertible Preferred Stock to convert the 4,138 shares of Series C Convertible Preferred Stock into 1,086 shares of our Common Stock at a conversion price of $30.50 per share and to convert the 100,000 shares of Series D Convertible Preferred Stock into 26,230 shares of Common Stock at a conversion price of $30.50 per share. On September 6, 2024, we issued an aggregate of 27,316 shares of Common Stock upon conversion of such shares of Series C Convertible Preferred Stock and Series D Convertible Preferred Stock. Upon such conversion there are no shares of Series C Convertible Preferred Stock or Series D Convertible Preferred Stock outstanding.

On July 30, 2024, we received a notice of conversion from the holder of shares of our Series C Convertible Preferred Stock to convert 135,431 shares of Series C Convertible Preferred Stock into 35,523 shares of Common Stock at a conversion price of $30.50 per share.

Other Financial Developments

On September 16, 2024, we announced that THERICEL project has been awarded funding of €2.28 million ($2.54 million) from the National Knowledge Transfer Program of the Spanish government's Ministry of Science, Innovation & Universities to support a collaboration between us and the Universitat Autònoma de Barcelona ("UAB") to advance our suspension cell platform for the clinical manufacture of adenovirus- and adeno-associated virus ("AAV") therapies. Under the award, we will receive an unsecured loan of €1.33 million ($1.48 million) as a lump sum payment in the fourth quarter of 2024 which shall bear interest at a rate of 4.015% and be repaid over 7 years commencing three years from the date of award, and UAB will receive a grant of €0.95 million ($1.06 million) dedicated to the THERICEL project and paid in annual installments over the next 3 years.

2024 Annual Stockholder's Meeting

On October 31, 2024, we held our 2024 Annual Meeting of Stockholders (the "Annual Meeting"). At the Annual Meeting, our stockholders (i) elected Jeffrey J. Kraws, John Monahan, Steven A. Shallcross and Jeffery Wolf as directors; (ii) ratified the appointment of BDO USA P.C. as our independent registered public accounting firm for the year ending December 31, 2024; (iii) approved an amendment ("Amendment No. 2") to our 2020 Stock Incentive Plan (the "2020 Stock Incentive Plan") to (a) increase the number of shares of Common Stock that we will have authority to grant under the 2020 Stock Incentive Plan from 280,000 shares of Common Stock to 2,500,000 shares of Common Stock and (b) to amend the annual non-employee director grant limit to 250,000 shares of Common Stock; and (iv) approved an amendment to our Articles of Incorporation to increase the number of authorized shares of Common Stock to 350,000,000 shares.

On November 1, 2024, we filed a Certificate of Change to our Articles of Incorporation with the Secretary of State of the State of Nevada (the "Certificate of Change") that was effective on such date that increased the number of our authorized shares of Common Stock, from 14,000,000 shares to $350,000,000 shares.

Our Current Product Pipeline

Based on management's current beliefs and expectations

allo-HCT allogeneic hematopoietic cell transplant. **CSR** clinical study report. **HNSCC** head and neck squamous cell carcinoma. **IV** intravenous. **IVit** intravitreal. For other abbreviations see the text.

[1]Additional products with preclinical proof-of-concept include SYN-006 (carbapenemase) to prevent aGVHD, CDI, and microbiome damage in patients treated with carbapenem antibiotics and SYN-007 (ribaxamase) DR to prevent antibiotic associated diarrhea with oral β-lactam antibiotics.

[2]Depending on funding/partnership. SYN-004 may enter a U.S. Food and Drug Administration ("FDA")-agreed Phase 3 clinical trial for the treatment of CDI.

Recent Clinical and Regulatory Developments

On October 16, 2024, we announced that the European Commission has adopted the European Medicines Agency (EMA) recommendation to grant orphan medicinal product designation to lead clinical candidate VCN-01for the treatment of retinoblastoma. The United States Food and Drug Administration (FDA) has previously granted orphan drug designation and rare pediatric disease designation to VCN-01 for the treatment of retinoblastoma. The EMA recommends orphan designation for products intended to treat, prevent or diagnose a disease that is life-threatening or chronically debilitating and either the prevalence of the condition in the European Union (EU) does not exceed 5 in 10,000 or it is unlikely that marketing of the product would generate sufficient returns to justify the investment needed for its development. Additionally, there should be no authorizable method of diagnosis, prevention or treatment of the condition, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. Orphan designation is designed to provide drug developers with various benefits to support the development of novel therapies, including 10 years of market exclusivity once they receive marketing authorization in the EU, protocol assistance, administrative and procedural assistance, and reduced fees for regulatory activities.

On October 3, 2024, we announced a positive outcome from the Data and Safety Monitoring Committee (“DSMC”) review of results from the second Cohort of our Phase 1b/2a randomized, double-blinded, placebo-controlled clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (“HCT”) recipients for the prevention of acute graft-versus-host-disease. Based on a review of the safety and pharmacokinetic data, the DSMC has recommended that the study may proceed to enroll Cohort 3 in which study drug (SYN-004 or Placebo) will be administered in combination with the IV beta-lactam antibiotic cefepime. We are pursuing additional funding to enable the conduct of the third cohort.

The Phase 1b/2a study is on-going and remains blinded; however, key findings from blinded data for Cohort 2 are included below:

- Adverse events (“AEs”) and serious adverse events (“SAEs”) observed in Cohort 2 were typical of those observed in allo-HCT patients and no AEs or SAEs were determined by the investigators to be related to study drug treatment.
- A total of 15 SAEs were reported among 10 patients, with the most common SAE being infections and infestations, including sepsis.
- No patients died within the 30-day follow-up period after the last dose of study drug; 1 patient died 95 days and another 211 days after the last dose of study drug due to cancer relapse and pneumonia respectively (not related to study drug).

- Consistent with the findings from Cohort 1 and previous studies of SYN-004 in healthy volunteers, no patient blood samples were positive for SYN-004 at any timepoint.
- The pharmacokinetics of piperacillin, which can be metabolized by SYN-004, were as expected for this patient population.

On September 23, 2024, we announced that we have achieved our target patient enrollment of 92 evaluable patients in the VIRAGE Phase 2b clinical trial evaluating the Company’s lead product candidate VCN-01 plus standard-of-care (“SoC”) chemotherapy (gemcitabine/nab-paclitaxel) as a first line therapy for patients with metastatic pancreatic ductal adenocarcinoma (“PDAC”). The trial enrolled 46 or more patients in each of the control and VCN-01 treatment arms across 15 sites in Spain and the USA within 21 months.VCN-01 has been granted Orphan Drug Designation and Fast Track Designation by the U.S. Food and Drug Administration (“FDA”) for the treatment of PDAC. Patients in the VCN-01 treatment arm of the VIRAGE trial are treated with two separate IV VCN-01 doses ($1x10^{13}$ vp/patient) administered approximately 3 months apart: the first VCN-01 dose is administered 7-days prior to initiation of the 1st gemcitabine/nab-paclitaxel SoC chemotherapy cycle; the second VCN-01 dose is administered 7-days prior to initiation of the 4th gemcitabine/nab-paclitaxel SoC chemotherapy cycle. The VCN-01 dose used in the VIRAGE trial was determined in a previously reported Phase 1 dose-escalation study where patients administered a single dose of VCN-01 ($1x10^{13}$ vp/patient) 7-days prior to initiation of gemcitabine/nab-paclitaxel SoC chemotherapy cycles (n=6) showed an overall response rate of 83%, with a median progression free survival of 6.3 months and median overall of 20.8 months. A total of 26 patients were administered different doses of VCN-01 in the Phase 1 study, and the most common treatment-related adverse events were dose-dependent and reversible pyrexia, flu-like symptoms, and increases in liver transaminases.

On July 30, 2024, we received notice from the FDA that we had been granted Rare Pediatric Drug Designation (RPDD) for VCN-01 for the treatment of retinoblastoma. The FDA grants RPDD for rare diseases (fewer than 200,000 affected persons in the United States) that are serious and life-threatening and primarily affect children ages 18 years or younger. If a Biologics License Application for VCN-01 for the treatment of retinoblastoma is approved by the FDA, Theriva may be eligible to receive a Priority Review Voucher. Previously, the FDA granted orphan drug designation to VCN-01 for treatment of retinoblastoma.

Our Current Oncology-Focused Pipeline

Oncolytic Viruses

Our oncology platform is based on oncolytic virotherapy ("OV therapy"), which exploits the ability of certain viruses to kill tumor cells and trigger an anti-tumor immune response. This novel class of anticancer agents has unique mechanisms of action compared to other cancer drugs. Oncolytic viruses ("OV") exploit the fact that cancer cells contain mutations that cause them to lose growth control and form tumors. Once inside a tumor cell, oncolytic viruses exploit the tumor cell machinery to generate thousands of additional copies of the virus, which then kill the tumor cell and spread to neighboring cells, causing a chain reaction of cell killing. This infection and tumor cell killing by OVs also alerts the immune system, which can then attack the virus infected tumor cells to help destroy the tumor in some instances.

Our OV product candidates are engineered to efficiently infect and selectively replicate to a high extent in tumor cells versus normal host cells, which enables intravenous delivery. By contrast, many other oncolytic viruses in clinical development today are administered by direct injection into the tumor. Intravenous delivery has the potential to expand the therapeutic effect of OVs because the virus can infect both the primary tumor and tumor metastases throughout the body.

Our first product candidate, VCN-01, is a clinical stage oncolytic human adenovirus that is modified to express an enzyme, PH20 hyaluronidase, that degrades hyaluronan in the tumor stroma, which helps the virus and other molecules to penetrate and spread throughout the tumor. VCN-01 can be used alone or in combination with other cancer therapies, such as chemotherapy and immunotherapy, for difficult to treat cancers. An expanding intellectual property portfolio supports our oncology programs, and because our products are characterized as biologics with Orphan Drug designation in our target indications, they will be further protected by data and/or market exclusivity in major markets.

VCN-01 has been administered to 142 patients across multiple Phase 1 clinical trials and the Phase 2 VIRAGE trial, including patients with pancreatic cancer, head and neck squamous cell carcinoma, ovarian cancer, colorectal cancer, and retinoblastoma.

Current clinical and Regulatory update

We are currently conducting a Phase 2 trial of intravenous VCN-01 with or without nab-paclitaxel plus gemcitabine in patients with PDAC. Additional on-going investigator sponsored studies comprise a Phase 1 trial combining VCN-01 with huCART-meso cells in patients with pancreatic or serous epithelial ovarian cancer, and a Phase 1 trial evaluating the intravenous administration of VCN-01 in patients prior to surgical resection of high-grade brain tumors. Additionally, the Clinical Study Reports (CSRs) are being prepared for the Phase 1 Trial of intravenous VCN-01 in combination with durvalumab in subjects with recurrent/ metastatic squamous cell carcinoma of the head and neck (mSCCHN) and the Phase 1 trial evaluating intravitreal VCN-01 in patients with retinoblastoma.

Phase 1 Clinical Trials in PDAC

The safety, tolerability, and potential dosing regimens for VCN-01 in patients with PDAC or colorectal cancer were evaluated in Phase 1 clinical trials evaluating intratumoral (n=8; NCT02045589) and intravenous (n= 42; NCT02045602) VCN-01 either alone or in combination with gemcitabine ± nab-paclitaxel (published in J. Immunother. Cancer 2021 Nov;9(11):e003254 and J. Immunother. Cancer 2022 Mar;10(3):e003255, respectively). Intravenous VCN-01 was found to have an acceptable safety/tolerability profile in PDAC and colorectal cancer patients and demonstrated compelling biochemical and clinical outcomes that enabled the advancement of VCN-01 into Phase 2 clinical trial in patients with metastatic PDAC.

Phase 2 Trial of intravenous VCN-01 with or without nab-paclitaxel plus gemcitabine in patients with PDAC

In January 2023, we dosed the first patients in VIRAGE, the Phase 2b randomized, open-label, placebo-controlled, multicenter clinical trial of systemically administered VCN-01 in combination with standard-of-care (SoC) chemotherapy (gemcitabine/nab-paclitaxel) as a first line therapy for patients with newly-diagnosed metastatic pancreatic ductal adenocarcinoma. The study is expected to be conducted at approximately 17 sites in the US and EU. Two doses of VCN-01 are included in the treatment arm: the 1st dose is administered on day 1, then one week later 3 cycles of gemcitabine and nab-paclitaxel as standard of care is administered. The second VCN-01 dose is administered 7 days before the 4th cycle of chemotherapy (approximately 90 days after the first VCN-01 dose), followed by additional cycles of gemcitabine/nab-paclitaxel chemotherapy.

Patient dosing was initiated in the U.S. in July 2023 and on September 23, 2024, we announced that we have achieved our target patient enrollment of 92 evaluable patients in the VIRAGE Phase 2b clinical trial. Thirty patients have received their second doses of intravenous VCN-01, which were well tolerated and demonstrated the expected VCN-01 safety profile.

On May 10, 2024, we presented data demonstrating enhanced anti-tumor effects in human pancreatic cancer xenograft-bearing mice treated with lead product candidate VCN-01 and liposomal irinotecan. These data support the potential synergy of VCN-01 and first-line pancreatic cancer chemotherapy regimens

On May 23, 2024, we announced that the FDA granted Fast Track Designation (FTD) to lead clinical candidate VCN-01 in combination with gemcitabine and nab-paclitaxel to improve progression-free survival and overall survival in patients with metastatic pancreatic adenocarcinoma.

On June 1, 2024, we presented the design of VIRAGE trial in a poster at the American Society of Clinical Oncology (ASCO) Annual Meeting 2024 Congress held and in Chicago (Illinois) from May 31- June 4, 2024. The poster discussed the objectives, endpoints and key inclusion and exclusion criteria included in the trial protocol, together with the treatment schedule for each arm of the study.

On September 23, 2024, we announced that we have achieved our target patient enrollment of 92 evaluable patients in the VIRAGE Phase 2b clinical trial. Thirty patients have received their second doses of intravenous VCN-01, which were well tolerated and demonstrated the expected VCN-01 safety profile.

According to the IDMC's assessment of clinical data from patients enrolled across 6 sites open in the U.S. and 9 sites open in Spain, the ongoing Phase 2b trial will continue without any changes to the protocol. No safety concerns were raised based on the evaluation of data presented at the IDMC meeting. Intravenous VCN-01 has been well tolerated and demonstrated a safety profile consistent with prior clinical trials. Importantly, no additional toxicities were observed in patients receiving a second dose of VCN-01, providing the first clinical evidence of the feasibility of repeated systemic dosing.

Retinoblastoma

Phase 1 Trial of intravitreal VCN-01 in patients with retinoblastoma

During the third quarter of 2017, VCN entered into a Clinical Trial Agreement with Hospital Sant Joan de Déu (Barcelona, Spain) to conduct an investigator sponsored Phase 1 clinical study evaluating the safety and tolerability of two intravitreal injections of VCN-01 in patients with intraocular retinoblastoma refractory to systemic, intra-arterial or intravitreal chemotherapy, or radiotherapy, in whom enucleation was the only recommended treatment (NCT03284268). Patients received two intravitreal injections of VCN-01, 14 days apart, at a dose of either 2 x 10^9 vp/eye (n=1) or 2 x 10^{10} vp/eye (n=8). Enrollment, dosing and safety follow-up in this study have been completed and the clinical study report is being prepared. On April 23, 2024, we announced positive topline data from this study, with agreement by the study Monitoring Committee that the study had a positive outcome.

- VCN-01 was well tolerated after intravitreal administration at the 2 doses and the most frequently reported treatment-related adverse events were Grade 1 or 2. There were no dose limiting toxicities and no ocular or systemic toxicities equal to or greater than Grade 3 during the evaluation period.

- Some degree of ocular inflammation and associated turbidity was observed after VCN-01 injection. Inflammation was managed, and vitreous haze improved in some cases, by local and systemic administration of anti-inflammatory drugs.

- VCN-01 does not appear to change the retinal function, and selective VCN-01 replication in retinoblastoma cells has been observed by immunohistochemical analysis.
- Replication within retinoblastoma tumors over time was detected
- Intravitreal VCN-01 demonstrated promising antitumor activity:
    - Four patients presented a response characterized by unequivocal improvement in vitreous seed density.
    - Eye enucleation was avoided in 3 patients to date, one of whom has retained their eye after 4 years of follow-up.

Per the terms of the clinical trial agreement, the determination by the study Monitoring Committee that the study had a positive outcome means we will receive an exclusive, worldwide technology license, and related patents from Hospital Sant Joan de Déu for the treatment of pediatric patients with advanced retinoblastoma and we will pay to Hospital Sant Joan de Déu the amount of three hundred twenty thousand Euros (€320,000) or $345,000.

A pre-Investigational New Drug ("IND") meeting with the FDA was held on December 19, 2023 to discuss the path forward for VCN-01 as an adjunct to chemotherapy in pediatric patients with advanced retinoblastoma. The FDA provided some guidance on the potential endpoints and patient population for an advanced clinical trial and encouraged submission of a formal protocol under a US IND in order to provide more detailed commentary.

On April 23, 2024, we announced positive topline data from the investigator sponsored Phase 1 Trial of intravitreal VCN-01 in pediatric patients with refractory retinoblastoma. Safety and clinical outcomes support the therapeutic potential of VCN-01 in retinoblastoma and emphasize VCN-01's potential for use in diverse cancer. The Monitoring Committee determined that the trial results were positive, and therefore, the Company will receive an exclusive, worldwide license, and related patents from Sant Joan de Déu-Barcelona Children's Hospital for the treatment of pediatric patients with advanced retinoblastoma.

On July 30, 2024, we received notice from the FDA that we had been granted Rare Pediatric Drug Designation (RPDD) for VCN-01 for the treatment of retinoblastoma. Previously, the FDA granted orphan drug designation to VCN-01 for treatment of retinoblastoma.

Phase 1 Trial of intravenous VCN-01 in Combination with Durvalumab in Subjects with Recurrent/ Metastatic SCCHN

In February 2019, VCN entered into a Clinical Trial Agreement with Catalan Institute of Oncology (ICO) (Spain) to conduct an investigator sponsored Phase 1 clinical study to evaluate the safety, tolerability and RP2D of a single intravenous injection of VCN-01 combined with durvalumab in two administration regimens: VCN-01 concomitantly with durvalumab, or sequentially with durvalumab starting two weeks after VCN-01 administration (NCT03799744). The study is also designed to evaluate whether VCN-01 treatment can re-sensitize PD-(l)-1 refractory tumors to subsequent anti-PD-L1 therapy. Durvalumab is a human monoclonal antibody (mAb) of the immunoglobulin G (IgG) 1 kappa subclass that inhibits binding of PD-L1. It is marketed as IMFINZI® by AstraZeneca/MedImmune, who supplied the product for its use in the clinical study. This Phase I trial is a multicenter, open label, dose escalation study in patients with histologically confirmed head and neck squamous cell carcinoma from specific sites: oral cavity, oropharynx, larynx or hypopharynx that is recurrent/metastatic (R/M) and not amenable to curative therapy by surgery or radiation. In addition, all patients should have undergone prior exposure to anti-PD-(L) 1 and progressed. Patients are entered at each dose level, according to a planned dose escalation schedule. The treatment is a single intravenous VCN-01 dose combined with concomitant intravenous durvalumab (MEDI4736) 1500 mg Q4W (Arm I) or durvalumab starting two weeks after VCN-01 administration ("sequential schedule"; Arm II). Patient recruitment into Arm I and Arm II was performed concurrently. Intravenous VCN-01 was administered to each patient only once during the trial at the VCN-01 dose level to which they were randomized. Durvalumab was administered Q4W until disease progression, unacceptable toxicity, withdrawal of consent, or another discontinuation criterion. Patient recruitment into the study was completed in February 2022 with a total of 18 patients enrolled. On September 05, 2022 we announced a presentation of initial data from this study in a poster at the European Society for Medical Oncology (ESMO) Congress. The poster reported that treatment with VCN-01 had an acceptable safety profile when administered with durvalumab in the sequential schedule and the most common treatment-related adverse events were dose-dependent and reversible pyrexia, flu-like symptoms and increases in liver transaminases. Sustained blood levels of VCN-01 viral genomes and increased serum hyaluronidase levels were maintained for over six weeks and analysis of tumor samples showed an increase in CD8 T cells (a marker of tumor inflammation); upregulation of PD-L1; and downregulation of matrix-related pathways after VCN-01 administration. The last patients in this study are currently being followed for overall survival and patent samples are being analyzed to evaluate potential VCN-01 pharmacodynamic effects.

On October 16, 2023, we presented additional data from this study in a poster at the European Society for Medical Oncology (ESMO) 2023 Congress held 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 a global objective response rate for the trial of 5.5%, most of the patients appeared to benefit from subsequent treatment, with 2 patients showing complete responses to palliative chemotherapy and at least one patient still alive 4 years after entering the study.
- 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.
    - There was a statistically significant correlation between OS observed in patients and CPS on day 8 (p=0.005).

- *Phase 1 Trial evaluating the safety and feasibility of huCART-meso cells when given in combination with VCN-01*

- In July 2021, VCN entered into a Clinical Trial Agreement with the University of Pennsylvania (Philadelphia) to conduct an investigator sponsored Phase 1 clinical study to evaluate the safety, tolerability and feasibility of intravenous administration of VCN-01 in combination with lentiviral transduced huCART-meso cells (developed by the laboratory of Dr. Carl June) in patients with histologically confirmed unresectable or metastatic pancreatic adenocarcinoma and serous epithelial ovarian cancer (NCT05057715). This is a Phase I study evaluating the combination of VCN-01 when given in combination with huCART-meso cells in a dose-escalation design in two cohorts (N = 3-6), where patients receive VCN-01 as a single IV infusion (at $3.3x10^{12}$ or $1x10^{13}$ vp) on Day 0, followed by a single dose of $5x10^{7}$ huCART-meso cells on Day 14 via IV infusion. huCART-meso cells are modified T-cells targeting the mesothelin antigen, which is frequently expressed in multiple tumor types, particularly in pancreatic and ovarian cancers. Dr. June's previous clinical studies have shown that huCART-meso cells encounter significant challenges in the tumor microenvironment, including immunosuppressive cells and soluble factors as well as metabolic restrictions. Initial VCN-01 clinical data from the studies described above suggest that administration of VCN-01 may increase tumor immunogenicity and improve access of the huCART-meso cells to tumor cells. This Phase I study will evaluate the safety and tolerability of the VCN-01 huCART-meso cell combination and test the hypothesis that administration of VCN-01 may enhance the potential antitumor effects of the co-administered huCART-meso cells.

- On July 8, 2022, we were notified that the first patient to be dosed with VCN-01 had passed the safety evaluation period in this study. On June 22, 2023, at their Cellicon Valley conference, and again at the Society for Immunotherapy of Cancer (SITC) meeting in San Diego, CA on November 03, 2023, and the International Oncolytic Virotherapy Conference (IOVC2023) in Calgary on November 13 2023, University of Pennsylvania investigators presented preliminary clinical safety and pharmacokinetic data from this study highlighting the feasibility of administering VCN-01 in sequence with huCART-meso cells in pancreatic and ovarian cancer patients. VCN-01 persistence was suggestive of tumor infection and active replication. The peak and duration of huCART-meso T cells in the peripheral blood as well as duration of stable disease in evaluable patients showed encouraging trends.

- The study is ongoing and may test higher doses of VCN-01 and interrogate tumor biopsies to gain further insights. The results will inform and guide optimization of the combination of CAR T cells with oncolytic virus.

Phase 1 Trial evaluating the intravenous administration of VCN-01 in patients prior to surgical resection of high-grade brain tumors

In the second quarter of 2021, VCN entered into a Clinical Trial Agreement with the University of Leeds (UK) to sponsor a proof-of-concept Phase 1 clinical study to evaluate whether intravenously administered VCN-01 can cross the blood-brain barrier and infect the target brain tumor. This is an open-label, non-randomized, single center study of VCN-01 given intravenously at a dose of $1x10^{13}$ virus particles to patients prior to planned surgery for recurrent high-grade primary or metastatic brain tumors. We believe that the intravenous delivery of anti-cancer therapy to brain tumors, if effective, may enable the treatment of systemically disseminated brain metastases and may allow for reduction in the need to use neurosurgery to administer the drugs. This study aims to assess the presence of VCN-01 within the resected surgical specimen after systemic VCN-01 delivery and determine the safety of intravenous VCN-01 in patients with recurrent high-grade glioma or brain metastases. By confirming the presence of VCN-01 in high grade brain tumors following intravenous delivery, this study may pave the way for larger trials to study VCN-01 efficacy, both as a monotherapy and in combination with PD-1/PD-L1 blockade. This trial has already received approval from Medicines & Healthcare Products Regulatory Agency (MHRA) from UK Government.

On January 9, 2023, we issued a press release announcing that the first patient was dosed in this study and recruitment is on-going.

Our Current Gastrointestinal (GI) and Microbiome-Focused Pipeline

Our SYN-004 (ribaxamase) and SYN-020 clinical programs are focused on the gastrointestinal tract (GI) and the gut microbiome, which is home to billions of microbial species and composed of a natural balance of both “good” beneficial species and potentially “bad” pathogenic species. When the natural balance or normal function of these microbial species is disrupted, a person’s health can be compromised. All of our programs are supported by our growing intellectual property portfolio. We are maintaining and building our patent portfolio through: prosecuting existing applications; and licensing and acquiring new patents and patent applications. We are exploring value creation options for our SYN-004 assets, including out-licensing or partnering.

SYN-004 (ribaxamase) — Prevention of antibiotic-mediated microbiome damage, thereby preventing overgrowth and infection by pathogenic organisms such as Clostridioides difficile infection (CDI) and vancomycin resistant Enterococci (VRE), and reducing the incidence and severity of acute graft-versus-host disease (aGVHD) in allogeneic HCT recipients

SYN-004 (ribaxamase) is a proprietary oral capsule prophylactic therapy designed to degrade certain IV beta-lactam antibiotics excreted into the GI tract and thereby maintain the natural balance of the gut microbiome. Preventing beta-lactam damage to the gut microbiome has a range of potential therapeutic outcomes, including prevention of CDI, suppression of the overgrowth of pathogenic species (particularly antimicrobial-resistant organisms) and potentially reducing the incidence and/or severity of aGVHD in allogeneic hematopoietic cell transplant (HCT) patients. SYN-004 (ribaxamase) 75 mg capsules are intended to be administered orally while patients are administered certain IV beta-lactam antibiotics. The capsule dosage form is designed to release the SYN-004 (ribaxamase) enzyme into proximal small intestine, where it has been shown to degrade beta-lactam antibiotics in the GI tract without altering systemic antibiotic levels. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics.

Clostridioides difficile Infection

Clostridioides difficile (formerly known as *Clostridium difficile* and often called *C. difficile* or CDI) is a leading type of hospital acquired infection and is frequently associated with IV beta-lactam antibiotic treatment. The Centers for Disease Control and Prevention (CDC) identified *C. difficile* as an “urgent public health threat,” particularly given its resistance to many drugs used to treat other infections. CDI is a major unintended risk associated with the prophylactic or therapeutic use of IV antibiotics, which may adversely alter the natural balance of microflora that normally protect the GI tract, leading to *C. difficile* overgrowth and infection. Other risk factors for CDI include hospitalization, prolonged length of stay (estimated at 7 days), underlying illness, and immune-compromising conditions including the administration of chemotherapy and advanced age. According to a paper published in BMC Infectious Diseases (Desai K et al. BMC Infect Dis. 2016; 16: 303) the economic cost of CDI was approximately $5.4 billion in 2016 ($4.7 billion in healthcare settings; $725 million in the community) in the U.S., mostly due to hospitalizations.

Phase 1b/2a Clinical Study in Allogeneic HCT Recipients

In August 2019, we entered into a Clinical Trial Agreement (CTA) with the Washington University School of Medicine (Washington University) to conduct a Phase 1b/2a clinical trial of SYN-004 (ribaxamase). Under the terms of this agreement, we serve as the sponsor of the study and supply SYN-004 (ribaxamase). Dr. Erik R. Dubberke, Professor of Medicine and Clinical Director, Transplant Infectious Diseases at Washington University and a member of the SYN-004 (ribaxamase) steering committee serves as the principal investigator of the clinical trial in collaboration with his Washington University colleague Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia.

The Phase 1b/2a clinical trial is a single center, randomized, double-blinded, placebo-controlled clinical trial of oral SYN-004 (ribaxamase) in up to 36 evaluable adult allogeneic HCT recipients. The goal of this study is to evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of oral SYN-004 (ribaxamase; 150 mg four times daily) administered to allogeneic HCT recipients who receive an IV carbapenem or beta-lactam antibiotic to treat fever. Study participants are enrolled into three sequential cohorts administered a different study-assigned IV antibiotic. Each cohort seeks to complete eight evaluable participants treated with SYN-004 (ribaxamase) and four evaluable participants treated with placebo. Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee, which will make a recommendation on whether to proceed to the next IV antibiotic cohort. The study will also evaluate potential protective effects of SYN-004 on the gut microbiome as well as generate preliminary information on potential therapeutic benefits and patient outcomes of SYN-004 in allogeneic HCT recipients.

To date, we have completed 2 of 3 cohorts (Cohorts 1 and 2) in this study. On September 27, 2022, we issued a press release announcing positive outcomes from the Data and Safety Monitoring Committee (“DSMC”) review of results from the first Cohort and their recommendation that the study may proceed to enroll Cohort 2 in which study drug (SYN-004 or Placebo) is administered in combination with the IV beta-lactam antibiotic piperacillin/tazobactam.

On October 3, 2024, we announced a positive outcome from the Data and Safety Monitoring Committee (“DSMC”) review of results from the second Cohort of our Phase 1b/2a randomized, double-blinded, placebo-controlled clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (“HCT”) recipients for the prevention of acute graft-versus-host-disease. Based on a review of the safety and pharmacokinetic data, the DSMC has recommended that the study may proceed to enroll Cohort 3 in which study drug (SYN-004 or Placebo) will be administered in combination with the IV beta-lactam antibiotic cefepime. Based upon our current available funding and our focus on our clinical development of VCN-01 we do not anticipate that enrollment for the third cohort will commence unless we obtain grant funding, or find a licensee or partner for the SYN-004 development program.

On February 16, 2023 and April 13, 2023, we announced the presentation of safety and pharmacokinetic data from Cohort 1 of the Phase 1b/2a Clinical Trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant recipients at the 2023 Tandem Meetings: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR and at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID), respectively.

SYN-020 — Oral Intestinal Alkaline Phosphatase (IAP)

SYN-020 is a quality-controlled, recombinant version of bovine Intestinal Alkaline Phosphatase (IAP) produced under cGMP conditions and formulated for oral delivery. The published literature indicates that IAP functions to diminish GI and systemic inflammation, tighten the gut barrier to diminish “leaky gut,” diminish fat absorption, and promote a healthy microbiome. Despite its broad therapeutic potential, a key hurdle to commercialization has been the high cost of IAP manufacture which is commercially available for as much as $10,000 per gram. We believe we have developed technologies to traverse this hurdle and now have the ability to produce more than 3 grams per liter of SYN-020 and anticipate a cost of roughly a few hundred dollars per gram at commercial scale. Based on the known mechanisms as well as our own supporting animal model data, we intended to initially develop SYN-020 to mitigate the intestinal damage caused by radiation therapy that is routinely used to treat pelvic cancers. While we believe SYN-020 may play a pivotal role in addressing acute and long-term complications associated with radiation exposure to the GI tract, we have also begun planning for potential development of SYN-020 in large market indications with significant unmet medical needs. Such indications include celiac disease, non-alcoholic fatty liver disease (“NAFLD”), and indications to treat and prevent metabolic and inflammatory disorders associated with aging.

On June 30, 2020, we submitted an IND application to the FDA in support of an initial indication for the treatment of radiation enteropathy secondary to pelvic cancer therapy. On July 30, 2020, we announced that we received a study-may-proceed letter from the FDA to conduct a Phase 1a single-ascending-dose ("SAD") study in healthy volunteers designed to evaluate SYN-020 for safety, tolerability and pharmacokinetic parameters (NCT04815993). On June 29, 2021, we announced that enrollment, patient dosing and observation had been completed in the Phase 1, open-label, SAD study of SYN-020. The SAD study enrolled 6 healthy adult volunteers into each of four cohorts with SYN-020 given orally as single doses ranging from 5 mg to 150 mg. The data demonstrated that SYN-020 maintained a favorable safety profile, was well tolerated at all dose levels, and no adverse events were attributed to the study drug. No serious adverse events were reported.

During the third quarter of 2021 we initiated a Phase 1 clinical study evaluating multiple ascending doses ("MAD") of SYN-020 (NCT05045833). The placebo-controlled, blinded study enrolled 32 healthy adult volunteers into four cohorts with SYN-020 administered orally in doses ranging from 5 mg to 75 mg twice daily for 14 days with a follow-up evaluation at day 35. Each cohort included six subjects who received SYN-020 and two who received placebo. On May 10, 2022, we announced positive safety data from the Phase 1 MAD study demonstrating that SYN-020 maintained a favorable safety profile and was well-tolerated across all dose levels. There were a few treatment-related adverse events, and all were mild (grade 1) and resolved without medical intervention. The most common adverse event, constipation, occurred in three out of 24 subjects in the treatment arm and in one out of eight subjects in the placebo arm. No adverse event led to discontinuation of the study drug and there were no serious adverse events. Additionally, fecal SYN-020 analyses verified intestinal bioavailability while plasma levels of SYN-020 were below the limit of quantitation in all samples at all timepoints verifying that SYN-020 was not absorbed into the systemic circulation.

During the second quarter of 2020, we announced that we entered into an agreement with Massachusetts General Hospital ("MGH") granting us an option for an exclusive license to intellectual property and technology related to the use of IAP to maintain GI and microbiome health, diminish systemic inflammation, and treat age-related diseases, which option was later amended liver fibrosis in select diseases, including NAFLD. The option expired unexercised on July 1, 2024.

The Phase 1 data from our SAD and MAD studies are intended to support the development of SYN-020 in multiple clinical indications including radiation enteritis, NAFLD, celiac disease, and diseases associated with aging. With our transition to an oncology focused Company, we are exploring strategic opportunities to enable advancement of this potentially valuable asset.

Research Programs

VCN-01 + Topoisomerase Inhibitors

On May 10, 2024, we presented non-clinical describing enhanced anti-tumor effects in human pancreatic cancer xenograft-bearing mice treated with lead product candidate VCN-01 and liposomal irinotecan in a poster at the 27th American Society of Gene and Cell Therapy (ASGCT) 2024 Congress held in Baltimore (Maryland) from May 7-11, 2024. These data support the potential synergy of VCN-01 and additional first-line pancreatic cancer chemotherapy regimens FOLFIRINOX and NALIRIFOX. Key finding reported in the poster include:

- The combination of VCN-01 + topoisomerase I (topo1) inhibitors, such as liposomal irinotecan, has a tolerable toxicity profile and may improve efficacy in the treatment of human pancreatic cancer.
- Viral protein expression was increased in human pancreatic cancer cell lines when they were exposed to topo1 inhibiting chemotherapeutics, irinotecan, its active metabolite, SN-38, and topotecan.
- Synergy of VCN-01 plus liposomal irinotecan was observed in animals bearing subcutaneous human pancreatic tumors.
    - In human pancreatic mouse xenograft models, treatment with VCN-01 at a dose of 4x1010 vp or liposomal irinotecan alone (at both the 10 mg/kg and 5 mg/kg doses) resulted in significant tumor growth inhibition compared to saline.
    - Combination therapy with VCN-01 + liposomal irinotecan at either dose displayed significantly reduced tumor growth compared to each treatment alone.
    - qPCR analyses performed on tumors collected at end of study confirmed the presence of viral genomes, indicating ongoing transcriptional activity of VCN-01, which is consistent with viral replication for several days after administration.

VCN-X Next Generation OVs and Albumin Shield™ Technology

In parallel with VCN-01 clinical development, we are developing next-generation oncolytic adenoviruses (termed VCN-X) with novel therapeutic payloads and structural modifications to increase tumor cell killing and improve systemic virus pharmacokinetics. Preclinical proof-of-concept has been established with VCN-11, which has been engineered to contain all of the features of VCN-01 as well as an additional modification to include an albumin binding domain (ABD) in the virus capsid. The virus capsid is the target for neutralizing antibodies (NAbs) that are generated by the host immune system to destroy circulating viruses. The presence of an ABD, however, blocks the binding of most neutralizing antibodies, which allows the virus to reach the tumor following intravenous administration. This "Albumin Shield" works because human blood contains a large amount of albumin to coat the ABD-containing virus. Importantly, this coating of albumin appears to be displaced after the virus reaches tumor cells to infect them. In pre-clinical mouse studies to test the functionality of the "Albumin Shield", mice pre-immunized with virus are able to completely neutralize an unmodified OV because they have a large concentration of neutralizing antibodies in their blood. By contrast, viruses such as VCN-11 that contain the ABD are not neutralized and retain their ability to infect and destroy tumor cells. We believe the results with VCN-11 support the application of the Albumin Shield technology in our VCN-X program to advance treatments for tumors in which rapid multi-dosing may be beneficial.

In March 2021, preclinical data obtained with VCN-11 was published (J Control Release. 2021 Apr 10;332:517-528), showing that the ABD-containing virus induced 450 times more cytotoxicity in tumor cells than in normal cells. Hyaluronidase production was confirmed by measuring the activity of the PH20 enzyme with a hyaluronic acid-degradation assay, and by measuring PH20 activity in VCN-11 infected tumors in vivo. The ABD-containing virus evaded NAbs from different sources and tumor levels of virus were demonstrated in the presence of high levels of NAbs in vivo, whereas the control virus without ABD was neutralized. VCN-11 showed a low toxicity profile in athymic nude mice and Syrian hamsters, allowing treatments with high doses and fractionated administrations without major toxicities (up to $1.2x10^{11}$vp/mouse and $7.5x10^{11}$vp/hamster). ALT levels were increased on day 3 within an acceptable range that returned to normal levels by day 9. Fractionated intravenous administration of the ABD-containing virus (splitting the dose into two portions administered 4 h apart) appeared to improve virus circulation kinetics and increase tumor levels. Antitumor efficacy was observed in the presence of NAbs against Ad5 and the ABD-containing virus.

In May 2022, we presented data at the 25th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT). The presentation included preclinical results showcasing the potential of the Albumin Shield Technology to effectively target tumors after intravenous re-administration, even in the presence of high level NAbs, with no major toxicities observed. Our internal VCN-X discovery programs are currently evaluating new oncolytic viruses that contain the Albumin Shield technology and may expand the potential efficacy of Theriva's oncolytic viruses.

Intellectual Property

All of our programs are supported by growing patent estates. In total, Theriva Biologics has over 175 U.S. and foreign patents and over 60 U.S. and foreign patents pending. VCN, through assignment or exclusive licenses, controls over 50 U.S. and foreign patents and over 15 U.S. and foreign patents pending.

The SYN-004 (ribaxamase) program is supported by intellectual property ("IP") that is assigned to Theriva Biologics, namely U.S. and foreign patents (in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others) and U.S. and foreign patents pending (in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others). For instance, U.S. Patent Nos. 8,894,994 and 9,587,234, which include claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including SYN-004 (ribaxamase), have patent terms to at least 2031. Further, U.S. Patent 9,301,995 and 9,301,996, both of which will expire in at least 2031, cover various uses of beta-lactamases, including SYN-004 (ribaxamase), in protecting the microbiome, and U.S. Patent Nos. 9,290,754, 9,376,673, 9,404,103, 9,464,280, and 9,695,409 which will expire in at least 2035, covers further beta-lactamase compositions of matter related to SYN-004 (ribaxamase).

The SYN-020 (oral intestinal alkaline phosphatase (IAP)) program is supported by IP that is assigned to Theriva Biologics, namely U.S. and foreign patents and patent applications (in many major markets, e.g. Europe, China, Japan, Korea, Canada, and Australia). These patents and patent applications, which cover various formulations, medical uses and manufacture of SYN-020, are expected to expire in 2038-2040, without taking potential patent term extensions or patent term adjustment into account.

The VCN-01 and Albumin Shield programs are supported by U.S. and foreign patents and patent applications that are assigned to VCN or exclusively licensed from Fundació Privada Institut d'Investigacio Biomedica de Bellvitge (IDIBELL), Institut Catala d'Oncologia (ICO), and Hospital Sant Joan de Déu in Barcelona. The patents and patent applications include U.S. patents and foreign patents (in most major markets, e.g. Europe, China, Japan, Korea, Canada, Israel, Mexico, Russia, and Australia) and U.S. and foreign patents pending (in most major markets, e.g. Europe, China, Korea, Canada, Mexico, and India). The patents and patent applications cover compositions of matter and pharmaceutical compositions of oncolytic adenoviruses and various medical uses of the same. For instance, U.S. Patent No. 10,316,065, which expires in 2030 without taking potential patent term extensions or patent term adjustment into account, provides composition of matter and pharmaceutical composition coverage for a genus of engineered oncolytic adenovirus suitable for the treatment of solid tumors. Other patents and patent applications, if granted, will provide protection to 2037 without taking potential patent term extensions or patent term adjustment into account.

Our goal is to (i) obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies, (ii) preserve our trade secrets, and (iii) operate without infringing on the proprietary rights of other parties worldwide. We seek, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents.

Critical Accounting Estimates

The preparation of our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) which requires the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses in the periods presented. We believe that the accounting estimates employed are appropriate and resulting balances are reasonable; however, due to inherent uncertainties in making estimates, actual results may differ from the original estimates, requiring adjustments to these balances in future periods.

There are accounting policies, each of which requires significant judgments and estimates on the part of management, that we believe are significant to the presentation of our consolidated financial statements. The most significant accounting estimates relate to goodwill and IPR&D, research and development costs, contingent consideration, and impairment of long-lived assets.

Goodwill and IPR&D

We classify intangible assets into two categories: (1) intangible assets with indefinite lives not subject to amortization and (2) goodwill. Intangible assets that are deemed to have indefinite lives, including goodwill, are reviewed for impairment annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired. The impairment test for indefinite-lived intangibles, other than goodwill, consists of a comparison of the fair value of the intangible asset with their carrying amount. If the carrying amount exceeds the fair value, an impairment charge is recognized in an amount equal to that excess. Indefinite-lived intangible assets, such as goodwill, are not amortized. We test the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate evidence a potential impairment exists, using a fair value-based test. If a reporting unit's carrying value exceeds its fair value, then we will record a goodwill impairment charge for the excess amount.

IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. IPR&D assets represent the fair value assigned to technologies that we acquire, which at the time of acquisition have not reached technological feasibility and have no alternative future use. During the period that the assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if we become aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval and the ability to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, we may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

Goodwill represents the excess of the purchase price paid when we acquired VCN in March 2022, over the fair values of the acquired tangible or intangible assets and assumed liabilities. We conduct an impairment test of goodwill on an annual basis as of October 1 of each year and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce our fair value below our net equity value.

Contingent Consideration

Consideration paid in a business combination may include potential future payments that are contingent upon the acquired business achieving certain milestones in the future ("contingent consideration"). Contingent consideration liabilities are measured at their estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded in the consolidated statements of operations. We estimate the fair value of the contingent consideration as of the acquisition date using the estimated future cash outflows based on the probability of meeting future milestones. The milestone payments will be made upon the achievement of clinical and commercialization milestones. Subsequent to the date of acquisition, we reassess the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. Any adjustment to the contingent consideration liability will be recorded in the consolidated statements of operations. Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under long term liabilities in the consolidated balance sheets.

Research and Development Costs

We expense research and development costs associated with developmental products not yet approved by the FDA to research and development expense as incurred. Research and development costs consist primarily of license fees (including upfront payments), milestone payments, manufacturing costs, salaries, stock-based compensation and related employee costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of our product candidates. Research and development expenses include external contract research organization ("CRO") services. Additionally, the grant income is used to offset research and development costs. We make payments to the CROs based on agreed upon terms and may include payments in advance of study services. We review and accrue CRO expenses based on services performed and rely on estimates of those costs applicable to the stage of completion of study as provided by the CRO. Accrued CRO costs are subject to revisions as such studies progress to completion. At September 30, 2024 and 2023, we have accrued CRO expenses of $2.4 million and $1.4 million, respectively, that are included in accrued expenses. As of September 30, 2024 and 2023, we have prepaid CRO costs of $0.4 million and $1.2 million, respectively, that are included in prepaid expenses.

Results of Operations

Three Months Ended September 30, 2024 and 2023

General and Administrative Expenses

General and administrative expenses increased to $2.3 million for the three months ended September 30, 2024, from $212,000 for the three months ended September 30, 2023. This increase of 986% is primarily related to a $1.5 million decrease in contingent consideration during the three months ended September 30, 2023, resulting in a reduction of prior period expenses and a $0.5 million increase in contingent consideration during the three months ended September 30, 2024. Additionally, there was a decrease in investor relations expenses, Theriva S.L. expenses, and lower director and officer insurance, offset by increased audit and registration fees. The charge related to stock-based compensation expense was $118,000 for the three months ended September 30, 2024, compared to $95,000 for the three months ended September 30, 2023.

Research and Development Expenses

Research and development expenses decreased to $2.7 million for the three months ended September 30, 2024, from approximately $4.0 million for the three months ended September 30, 2023. This decrease of 32% is primarily the result of lower clinical trial expenses related to our VIRAGE Phase 2 clinical trial of VCN-01 in PDAC, lower expenses related to our Phase 1a clinical trial of SYN-020 which has completed, and lower expenses to our Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients. We anticipate research and development expense to increase as we continue our VIRAGE Phase 2 clinical trial of VCN-01 and plan for our Phase 3 clinical trial of VCN-01 in PDAC, advance our VCN-01 program in retinoblastoma, expand GMP manufacturing activities for VCN-01, and continue supporting our other preclinical and discovery initiatives. The charge related to stock-based compensation expense was $59,000 for the three months ended September 30, 2024, compared to $40,000 related to stock-based compensation expense for the three months ended September 30, 2023.

The following table sets forth our research and development expenses directly related to our product candidates for the three months ended September 30, 2024 and 2023. These direct expenses were external costs associated with preclinical studies and clinical trials. Indirect research and development expenses related to employee costs, facilities, stock-based compensation and research and development support services that are not directly allocated to specific product candidates.

Therapeutic Areas	September 30, 2024	September 30, 2023
VCN-01	$ 1,418	$ 2,593
Ribaxamase	177	226
SYN-020	41	85
Other therapeutic areas	72	190
Total direct costs	1,708	3,094
Total indirect costs	1,026	912
Total Research and Development	$ 2,734	$ 4,006

IPRD and Goodwill Impairment

During the three months ended September 30, 2024, we experienced a sustained decline in the quoted market price of our Common Stock and we deemed this to be a triggering event for impairment. We performed an interim impairment analysis using the "Income approach" that requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of our development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital. We concluded that the in-process R&D with a carrying value of $19.8 million was written down to its estimated fair value of $18.6 million and an impairment charge of $1.3 million was recorded, and goodwill with a carrying value of $1.5 million was written down to its estimated fair value of zero and an impairment charge of $1.5 million was recorded during the quarter. The decrease in the valuation was primarily driven by an increase in the discount rate which was impacted by an increase in the company specific risk premium, and not by material changes to the clinical and administrative operations of the business.

Other Income/Expense

Other income was $161,000 for the three months ended September 30, 2024 compared to other income of $388,000 for the three months ended September 30, 2023. Other income for the three months ended September 30, 2024 is primarily comprised of interest income of $158,000 and an exchange gain of $3,000. Other income for the three months ended September 30, 2023 is primarily comprised of interest income of $382,000 and an exchange gain of $6,000.

Net Loss Attributable to Common Stockholders

Our net loss attributable to common stockholders was approximately $7.7 million, or $6.81 per basic and diluted common share, for the three months ended September 30, 2024, compared to a net loss of approximately $3.3 million, or $4.85 per basic and diluted common share, for the three months ended September 30, 2023.

Nine Months Ended September 30, 2024 and 2023

General and Administrative Expenses

General and administrative expenses increased to $5.7 million for the nine months ended September 30, 2024, compared to $5.1 million for the nine months ended September 30, 2023. This increase of 12% is primarily comprised of the contingent consideration adjustment of $1.5 million and registration fees, offset by a decrease in compensation costs, consulting, legal fees, audit fees and lower director and officer insurance. The charge related to stock-based compensation expense was $335,000 for the nine months ended September 30, 2024, compared to $288,000 for the nine months ended September 30, 2023.

Research and Development Expenses

Research and development expenses decreased to $9.1 million for the nine months ended September 30, 2024, from approximately $10.1 million for the nine months ended September 30, 2023. This decrease of 10% is primarily the result of lower clinical trial expenses related to our VIRAGE Phase 2 clinical trial of VCN-01 in PDAC, lower expenses related to our Phase 1a clinical trial of SYN-020, offset by increased expenses related to the Phase 1 trial of intravitreal VCN-01 in patients with retinoblastoma, and increased expenses related to our Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients. We anticipate research and development expense to increase as we continue our VIRAGE Phase 2 clinical trial of VCN-01and plan for our Phase 3 clinical trial of VCN-01 in PDAC, advance our VCN-01 program in retinoblastoma, expand GMP manufacturing activities for VCN-01, and continue supporting our other preclinical and discovery initiatives. The charge related to stock-based compensation expense was $175,000 for the nine months ended September 30, 2024, compared to $119,000 related to stock-based compensation expense for the nine months ended September 30, 2023.

The following table sets forth our research and development expenses directly related to our product candidates for the nine months ended September 30, 2024 and 2023. These direct expenses were external costs associated with preclinical studies and clinical trials. Indirect research and development expenses related to employee costs, facilities, stock-based compensation and research and development support services that are not directly allocated to specific product candidates.

Therapeutic Areas	September 30, 2024	September 30, 2023
VCN-01	$ 4,657	$ 5,907
Ribaxamase	719	634
SYN-020	109	229
Other therapeutic areas	288	347
Total direct costs	5,773	7,117
Total indirect costs	3,372	2,998
Total Research and Development	$ 9,145	$ 10,115

IPRD and Goodwill Impairment

During the nine months ended September 30, 2024, we experienced a sustained decline in the quoted market price of our Common Stock and we deemed this to be a triggering event for impairment. We performed an interim impairment analysis using the “Income approach” that requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital. We concluded that the in-process R&D with a carrying value of $19.8 million was written down to its estimated fair value of $18.6 million and an impairment charge of $1.3 million was recorded, and goodwill with a carrying value of $5.6 million was written down to its estimated fair value of zero and an impairment charge of $5.6 million was recorded during the nine months ended September 30, 2024. The decrease in the valuation was primarily driven by an increase in the discount rate which was impacted by an increase in the company specific risk premium, and not by material changes to the clinical and administrative operations of the business.

Other Income/Expense

Other income was $560,000 for the nine months ended September 30, 2024 compared to other income of $1.1 million for the nine months ended September 30, 2023. Other income for the nine months ended September 30, 2024 is primarily comprised of interest income of $559,000 and an exchange gain of $1,000. The income for the nine months ended September 30, 2023 is primarily comprised of interest income of $1.1 million and an exchange gain of $7,000.

Net Loss Attributable to Common Stockholders

Our net loss attributable to common stockholders was approximately $21.2 million, or $24.47 per basic and diluted common share, for the nine months ended September 30, 2024, compared to a net loss of approximately $12.9 million, or $20.38 per basic and diluted common share, for the nine months ended September 30, 2023.

Liquidity and Capital Resources

As of September 30, 2024, we have a significant accumulated deficit, and with the exception of the three months ended June 30, 2010 and the three months ended December 31, 2017, the Company has experienced significant losses and incurred negative cash flows since inception. We have incurred an accumulated deficit of $330.5 million as of September 30, 2024, and expect to continue to incur losses in the foreseeable future with the recognition of revenue being contingent on successful phase 3 clinical trials and requisite approvals by the FDA or foreign equivalents.

Our cash and cash equivalents totaled $16.4 million as of September 30, 2024, a decrease of $6.8 million from December 31, 2023. During the year ended December 31, 2023 and nine months ended September 30, 2024, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $18.3 million and $21.2 million for the year ended December 31, 2023 and the nine months ended September 30, 2024, respectively.

With our cash position of approximately $14.1 million in early November 2024, we believe we will be able to fund our operations into the third quarter of 2025. Following the anticipated completion of our ongoing Phase 1 and Phase 2 clinical trials for VCN-01, and preclinical studies supporting VCN-01 and our discovery initiatives, we will need to obtain additional funds for future clinical trials. We anticipate that our future clinical trials will be much larger in size and require larger cash expenditures than the aforementioned clinical programs. We do not have any committed sources of financing for future clinical trials at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. Management believes its plan, which is focused on the advancement of VCN-01 will allow us to meet our financial obligations, further advance key products, and maintain our planned operations. Based on our current plans, our cash and cash equivalents will be sufficient to complete our planned clinical trials of VCN-01 (in PDAC and retinoblastoma), but may not be sufficient for additional trials of VCN-01, SYN-020 or SYN-004, or to complete the last cohort of the Phase 1a/2a clinical trial of SYN-004, which are expected to require significant cash expenditures. Based upon our current available funding and our focus on our clinical development of VCN-01 we do not anticipate that enrollment for the third cohort will commence unless we obtain grant funding, or find a licensee or partner for the SYN-004 development program. However, the amount of additional capital needed by us will also depend upon the costs to advance our VCN-01 clinical programs and whether we continue to develop SYN-004 internally, or out-license or partner such development. If necessary, we may attempt to utilize the at the market sales facility (the “ATM”) or seek to raise additional capital in other financing transactions, neither of which is guaranteed. Use of the ATM is limited by certain restrictions and management’s plan does not rely on additional capital from either of these sources. If we are not able to obtain additional capital (which is not assured at this time), our long-term business plan may not be accomplished, and we may be forced to cease certain development activities. More specifically, the completion of any later stage clinical trial will require significant financing or a significant partnership.

Historically, we have financed our operations primarily through public and private sales of our securities, and we expect to continue to seek and obtain additional capital in a similar manner. During the year ended December 31, 2023, our only source of cash was from sales of our Common Stock through the ATM pursuant to which we sold 81,000 shares of our Common Stock for net proceeds of $2.2 million. During the nine months ended September 30, 2024, our only source of cash was from sales of our Common Stock through the Amended and Restated ATM Sales Agreement pursuant to which we sold 569,000 shares of our Common Stock for net proceeds of $3.6 million and from the sale of our securities in our public offering of 918,600 shares of Common Stock in combination with accompanying warrants to purchase an aggregate of 1,428,600 shares of the Common Stock for gross proceeds of $2.5 million (net proceeds of $2.0 million, after deducting underwriting discounts and estimated expenses).

There can be no assurance that we will be able to continue to raise funds through the sale of shares of Common Stock through the ATM or other equity financings. If we raise funds by selling additional shares of Common Stock or other securities convertible into Common Stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain funding for future clinical trials when needed, we will be unable to carry out our business plan and we will be forced to delay the initiation of future clinical trials until such time as we obtain adequate financing and may need to abandon some of our development programs.

We have spent, and expect to continue to spend, a substantial amount of funds in connection with implementing our business strategy, including our planned product development efforts, preparation for our planned clinical trials, performance of clinical trials and our research and discovery efforts. Based on our current plans, our cash and cash equivalents will not be sufficient to enable us to meet our near term or long-term expected plans as it is anticipated that we will not have enough cash to continue our operations for the next twelve months from the date of the filing of this Quarterly Report on Form 10-Q. We will be required to obtain additional funding in order to continue the development of certain product candidates within the anticipated time periods (including initiation of planned clinical trials), if at all, and to continue to fund operations at the current cash expenditure levels. We do anticipate that our current cash of approximately $14.1 million as of early November 2024 will allow us to cover overhead costs, manufacturing costs for near-term clinical supply, manufacturing costs of VCN-01 for clinical trail use and limited research efforts, including completing our funding requirements for our ongoing Phase 1b/2a clinical study (cohort II) of SYN-004 (ribaxamase) in allogeneic HCT recipients for the prevention of aGVHD, our ongoing Phase 1 and Phase 2 clinical trials for VCN-01, preclinical studies supporting VCN-01 and our ongoing discovery initiatives, and to fund our committed obligations under the terms of the VCN Share Purchase Agreement (the “VCN Purchase Agreement”) related to the VCN Acquisition into the third quarter of 2025. Our independent registered public accounting firm has issued a report for the year ended December 31, 2023 that includes an explanatory paragraph referring to our recurring losses from operations (anticipated continued losses in the future) and net capital deficiency that raise substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Our notes to the consolidated financial statements contain an explanatory paragraph referring to our recurring and continuing losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. We cannot provide any assurance that we will be able to obtain the required funding to achieve our current business plan, obtain the required regulatory approvals for our product candidates or complete additional corporate partnering or acquisition transactions in order to commercialize such product candidates once regulatory approval is received. If we fail to obtain additional funding for our clinical trials, whether through the sale of securities or a partner or collaborator, and otherwise when needed, we will not be able to execute our business plan as planned and will be forced to cease certain development activities (including initiation of planned clinical trials) until funding is received and our business will suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

Our ability to continue as a going concern is dependent upon our ability to raise additional capital. Our cash and cash equivalents will not be sufficient to enable us to meet our near term or long-term expected plans, including initiation or completion of future registrational studies for VCN-01, any potential future trials of SYN-004 including Phase 3 clinical programs of SYN-004 (ribaxamase) for prevention of CDI or the Phase 1b/2a clinical study of SYN-004 (ribaxamase) in allogeneic HCT recipients, or later-stage clinical trials of SYN-020. Therefore, we do not intend to commence future new studies of VCN-01, SYN-004 (ribaxamase) or SYN-020 until we are confident that we have funding necessary to complete such trials. We are actively pursuing additional equity or debt financing, in the form of either a private placement or a public offering and have been in ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings. However, we do not currently have commitments from any third parties to provide us with capital. Potential sources of financing that we are pursuing include strategic relationships, public or private sales of our equity (including through the ATM) or debt and other sources. Such additional financing opportunities might not be available to us when and if needed, on acceptable terms or at all. We cannot assure that we will meet the requirements for use of the ATM especially in light of the fact that we are currently limited by rules of the Securities and Exchange Commission (the “SEC”) as to the number of shares of Common Stock that we can sell pursuant to the ATM due to the market value of our Common Stock held by non-affiliates. Even if we meet the requirements for use of the ATM, there can be no assurance that we will be able to raise funds through the sale of shares of Common Stock through the ATM. Additionally, we may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. If we are unable to obtain additional capital (which is not assured at this time), our long-term business plan may not be accomplished and we may be forced to cease certain development activities. More specifically, the completion of future Phase 3 and/or registrational clinical studies will require significant financing or a significant partnership. If we raise funds by selling additional shares of Common Stock or other securities convertible into Common Stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain funding for future clinical trials when needed, we will be unable to carry out our business plan and we will be forced to delay the initiation of future clinical trials until such time as we obtain adequate financing and our operating results and prospects will be adversely affected.

Cash Flows

Cash Used in Operating Activities

Net cash used in operating activities was $12.2 million and $12.5 million during the nine months ended September 30, 2024 and 2023, respectively, which was primarily due to the use of funds in our operations related to the development of VCN-01 our product candidate. Cash used in operating activities for the nine months ended September 30, 2024 decreased compared to the same period in 2023 due primarily to the decrease in net loss in 2024.

Cash Used In Investing Activities

Cash used in investing activities during the nine months ended September 30, 2024 and 2023 was $1,000 and $146,000 for equipment purchases.

Cash Provided by Financing Activities

Cash provided by financing activities was $5.5 million during the nine months ended September 30, 2024 compared to $2.1 million during the nine months ended September 30, 2023.Cash provided by financing activities during the nine months ended September 30, 2024 included at the market offering proceeds of $3.6 million from sales of 569,000 shares of our Common Stock offset by payments related to loans extended by certain Spanish institutions of $67,000 and net proceeds of $2.0 million from the sale of our securities in our public offering of 918,600 shares of Common Stock in combination with accompanying warrants to purchase an aggregate of 1,428,600 shares. Cash provided by financing activities during the nine months ended September 30, 2023 included at the market offering proceeds of $2.2 million from sales of 81,000 shares of our Common Stock which was offset by $75,000 of debt payments.

Off-Balance Sheet Arrangements

During the nine months ended September 30, 2024, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Contractual Obligations

Leases

At the inception of a contract we determine if the arrangement is, or contains, a lease. Right of use (“ROU”) assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term.

We have made certain accounting policy elections whereby we (i) do not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combine lease and non-lease elements of our operating leases. As of September 30, 2024, we did not have any material finance leases.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of September 30, 2024 our cash and cash equivalents consisted primarily of investments in treasury securities. We do not engage in any hedging activities against changes in interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio. We may, however, require additional financing to fund future obligations and no assurance can be given that the terms of future sources of financing will not expose us to material market risk.

ITEM 4. CONTROLS AND PROCEDURES.

(a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer who also serves as our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. We have adopted and maintain disclosure controls and procedures (as defined Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. The Company’s disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Due to the material weaknesses in internal control over financial reporting as described below, our Chief Executive Officer who also serves as our Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were not effective.

Based on its assessment, management has concluded that the Company did not maintain effective internal control over financial reporting as of September 30, 2024, due to the following previously reported material weaknesses that continued to exist:

- Management did not design and maintain effective review controls at a sufficient level of precision with certain financial statement areas and over unusual transactions involving complex accounting and related disclosure requirements.

- Management did not maintain effective information technology general controls over user access, program change management, and segregation of duties, within certain key information systems supporting the Company’s accounting and financial reporting processes. Additionally, many of the Company’s business process controls dependent upon the information derived from these information systems were also ineffective, as management did not design and implement controls to validate the completeness and accuracy of underlying data utilized in the operation of those controls.

Management's Plan for Remediation

In response to the material weaknesses, management, with oversight of the Audit Committee of the Board of Directors, has identified and begun to implement steps to remediate the material weaknesses. We have hired a third party consultant during 2024 to assist with the remediation efforts. While we have made progress during 2024, the remediation efforts are ongoing, as additional time is needed to complete the remediation and allow for the internal controls to be tested by management. Our continued internal control remediation efforts include the following:

- Enhancing existing policies and procedures to facilitate more efficient operations and improve the timely execution of key controls by company personnel.
- Enhancing program change management, user access provisioning, and monitoring controls to ensure changes to key applications are appropriately reviewed and approved and to enforce appropriate system access and segregation of duties.
- Improving the design of key controls to ensure reports used in the performance of such controls are complete and accurate as part of the controls execution.

We are committed to ensuring that our internal controls over financial reporting are designed and operating effectively. Management believes the efforts taken to date and the planned remediation will improve the effectiveness of our internal control over financial reporting. While these remediation efforts are ongoing, the controls must be operating effectively for a sufficient period of time and be tested by management in order to consider them remediated and conclude that the design is effective to address the risks of material misstatement.

Changes in Internal Control Over Financial Reporting

Except for the material weaknesses described above, there has been no change in the Company's internal control over financial reporting during the Company's most recent quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II–OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 1A. RISK FACTORS.

The following information updates, and should be read in conjunction with, the information disclosed in Part I, Item 1A, “Risk Factors,” contained in our 2023 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2023 Form 10-K.

RISKS RELATING TO OUR BUSINESS

There is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

Our consolidated unaudited financial statements as of September 30, 2024 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our management concluded that our recurring losses from operations and the fact that as of September 30, 2024 we have an accumulated deficit of approximately $330.5 and working capital of $12.2 million raise substantial doubt about our ability to continue as a going concern for the next twelve months after issuance of our financial statements. As of September 30, 2024, we had a cash and cash equivalents and restricted cash balance of approximately $16.5 million. At December 31, 2023, we had an accumulated deficit of $309.3 million and working capital of $20.7 million. As of December 31, 2023, we had a cash and cash equivalents and restricted cash balance of approximately $23.3 million consisting of cash and investments in highly liquid U.S. money market funds. We expect to continue to incur losses from expenses related to the development of our product candidates and related administrative activities for the foreseeable future. We expect that our current cash will be able to fund operations into the third quarter of 2025 but will not be sufficient to fund operations for twelve months from the date of the filing of this Quarterly Report on Form 10-Q and we will need to seek additional capital to fulfill our operating and capital requirement for the next 12 months to advance our clinical development program to later stages of development and commercialize our clinical product candidate. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Although management has been successful in raising capital in the past, there can be no assurance that we will be successful or that any needed financing will be available in the future at terms acceptable to us. As such, we cannot conclude that such plans will be effectively implemented within one year after the date that the financial statements included in this Quarterly Report on Form 10-Q are filed with the SEC and there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

We will need to raise additional capital to operate our business and our failure to obtain funding when needed may force us to delay, reduce or eliminate certain of our development programs or commercialization efforts.

During the nine months ended September 30, 2024, our operating activities used net cash of approximately $12.2 million and our cash and cash equivalents were approximately $16.4 million as of September 30, 2024. With the exception of the three months ended June 30, 2010 and the three months ended December 31, 2017, we have experienced significant losses since inception and have a significant accumulated deficit. As of September 30, 2024, our accumulated deficit totaled approximately $330.5 million on a consolidated basis. Pursuant to the VCN Purchase Agreement, we have agreed to use reasonable efforts to commercialize VCN-01 and we agreed as a post- closing covenant to commit to fund VCN's research and development programs, including but not limited to VCN-01 PDAC phase 2 clinical trial, VCN-01 RB trial and necessary G&A within a budgetary plan of approximately $27.8 million over three years. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. With the exception of the quarter ended June 30, 2010, and limited laboratory revenues from Adeona Clinical Laboratory, which we sold in March 2012, we have generated very minimal revenues. We do not expect to derive revenue from any source in the near future until we or our potential partners successfully commercialize our products. We expect our expenses to increase in connection with our anticipated activities, particularly as we continue research and development, initiate and conduct clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing and collaboration fees and grants, if any.

We will need to raise additional capital to fund our operations and meet our current timelines and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. Based on our current plans, our cash and cash equivalents will be sufficient to complete our planned clinical trials of VCN-01 (in PDAC and retinoblastoma), but may not be sufficient for additional trials of VCN-01, SYN-020 or SYN-004, or to complete the last cohort of the Phase 1a/2a clinical trial of SYN-004, which are expected to require significant cash expenditures. In addition, based on the significant anticipated cost of a Phase 3 clinical program in a broad indication for SYN-004, we expect it will not be feasible for us to initiate and complete this trial at this time without a partner given the capital constraints tied to our current market cap and share price. We intend to focus our capital on our VCN-01 clinical trials and do not intend to provide further funding for our development of VCN-004 internally but intend to our license or partner further development ofSYN-004. Further development of VCN's product candidates will require additional funding. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business and also have a dilutive effect on our stockholders. A failure otherwise to secure additional funds when needed in the future whether through an equity or debt financing or a sufficient amount of capital without a strategic partnership could result in us being unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Our ability to raise capital through the sale of securities may be limited by the rules of the SEC and NYSE American that place limits on the number and dollar amount of securities that may be sold. There can be no assurances that we will be able to raise the funds needed, especially in light of the fact that our ability to sell securities registered on our registration statement on Form S-3 will be limited until such time the market value of our voting securities held by non-affiliates is $75 million or more. We also may be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available.

We expect to seek to raise additional capital in the future, which may be dilutive to stockholders or impose operational restrictions.

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity or of debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as consideration for acquisitions or part of license issue fees to our licensors, compensate consultants or settle outstanding payables using equity that may be dilutive. We are authorized to issue 350,000,000 shares of Common Stock, of which 2,782,449 shares of Common Stock were outstanding as of November 8, 2024. If all of the unissued authorized shares were issued stockholders ownership percentage will be diluted.

In order to raise additional capital, we may in the future offer additional shares of our Common Stock or other securities convertible into or exchangeable for our Common Stock at prices that may not be the same as the price per share paid by existing stockholders, thereby subjecting such stockholders to dilution. Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our Common Stock.

We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our Common Stock, or securities convertible or exchangeable into Common Stock, in future transactions may be higher or lower than the price per share paid by existing stockholders.

We have identified material weaknesses in our internal controls, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future

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. Based on our assessment, we have concluded that as of September 30, 2024 we did not maintain effective review controls at a sufficient level of precision with certain financial statement areas and over unusual transactions involving complex accounting and related. disclosure requirements. We also did not maintain effective information technology general controls over user access, program change management, and segregation of duties, within certain key information systems supporting our accounting and financial reporting processes. Additionally, many of our business process controls dependent upon the information derived from these information systems were also ineffective, as we did not design and implement controls to validate the completeness and accuracy of underlying data utilized in the operation of those controls. 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. Although management believes that the material weaknesses will be remediated by the end of the fiscal year there can be no assurance that the deficiencies will be remediated at such time or that the internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

We cannot assure you that our Common Stock will be liquid or that it will remain listed on the NYSE American.

Our Common Stock is listed on the NYSE American. The NYSE American's listing standards generally mandate that we meet certain requirements relating to stockholders' equity, stock price, market capitalization, aggregate market value of publicly held shares and distribution requirements

We cannot assure you that we will be able to maintain the continued listing standards of the NYSE American. The NYSE American requires companies to meet certain continued listing criteria including a minimum stockholders' equity of $6.0 million if an issuer has sustained losses from continuing operations and/or net losses in its five most recent years, as outlined in the NYSE American Company Guide and trading of the stock above $0.10 per share. The NYSE American Company Guide also states that the NYSE normally will not consider removing from listing securities of an issuer if it is in compliance with all of the following: a total value of market capitalization of at least $50.0 million; 1,100,000 publicly-held shares; a market value of publicly held shares of at least $15.0 million; and 400 round lot shareholders. In addition, the NYSE American has informed us that it can commence delisting proceedings and immediately suspend trading in the event that our Common Stock trades at levels viewed to be abnormally low and no longer suitable for listing pursuant to Section 1003(f)(v) of the NYSE American Company Guide. Generally the NYSE American views trading at or below a price of $0.10 to be abnormally low.

As stated above, in the event that we were to fail to meet the requirements of NYSE American per share price requirement the NYSE American could commence delisting proceedings and immediately suspend trading of our Common Stock o the NYSE American or if we fail to meet other requirements such as the stockholders' equity requirement and we could not timely cure such deficiency, our listing could become subject to NYSE American continued listing evaluation and follow-up procedures, which could result in delisting procedures.

We previously received notification from the NYSE American citing failure to comply with the minimum stockholders' equity continued listing standard as set forth in Part 10, Section 1003 of the Company Guide. Although in the past we have been able to cure previously cited deficiencies, there can be no assurance that we will continue to meet the NYSE American continued listing requirements.

In addition, in the future we may not be able to ensure that our Common Stock trades at levels not viewed to be abnormally low and no longer suitable for listing or maintain minimum stockholders' equity and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE American. If we are delisted from the NYSE American then our Common Stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our Common Stock could depress our stock price, substantially limit liquidity of our Common Stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the NYSE American could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. We cannot assure you that our Common Stock will be liquid or that it will remain listed on the NYSE American. A failure to regain compliance with the NYSE American stockholders' equity requirements or failure to continue to meet the other listing requirements could result in a de-listing of our Common Stock.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

(a) Unregistered Sales of Equity Securities

We did not sell any equity securities during the three months ended September 30, 2024 in transactions that were not registered under the Securities Act other than as previously disclosed in our filings with the SEC.

(b) Use of Proceeds

Not applicable.

(c) Issuer Purchases of Equity Securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

During the three months ended September 30, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "nonRule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

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 thereunto duly authorized.

THERIVA BIOLOGICS, INC.

By: /s/ Steven A. Shallcross
Steven A. Shallcross
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Date: November 12, 2024

EXHIBIT INDEX

Exhibit Number	Exhibit Title
1.1	Placement Agency Agreement, dated as of September 26, 2024, by and between Theriva Biologics, Inc. and A.G.P./Alliance Global Partners, as placement agent (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed September 30, 2024, File No. 001-12584.)
3.1	Certificate of Incorporation, as amended (Incorporated by reference to (i) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 16, 2008, File No. 001-12584, (ii) Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001 filed August 14, 2001, File No. 001-12584; and (iii) Exhibits 3.1, 4.1 and 4.2 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1998 filed August 14, 1998, File No. 001-12584.)
3.2	Articles of Merger (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.3	Certificate of Merger filed with the Secretary of State of Delaware (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.4	Articles of Incorporation filed with the Nevada Secretary of State (Incorporated by reference to Exhibit 3.3 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.5	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed February 16, 2012, File No. 001-12584.)
3.6	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed May 18, 2015, File No. 001-12584.)
3.7	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 8, 2017, File No. 001-12584.)
3.8	Certificate of Designations for Series A Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 12, 2017, File No. 001-12584.)
3.9	Certificate of Change Pursuant to NRS 78. 209 (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed August 13, 2018, File No. 001-12584.)
3.10	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 26, 2018, File No. 001-12584.)
3.11	Certificate of Designations for Series B Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 15, 2018, File No. 001-12584.)
3.12	Certificate of Amendment to Certificate of Designation for Series B Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 15, 2018, File No. 001-12584.)
3.13	Certificate of Amendment to the Certificate of Designation for the Series A Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K/A filed on February 1, 2021 File No. 001-12584.)
3.14	Certificate of Designation for Series C Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed July 29, 2022, File No. 001-12584.)
3.15	Certificate of Designation for Series D Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed July 29,2022, File No. 001-12584.)

3.16	Second Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed August 11, 2023, File No. 001-12584.)
3.17	Certificate of Change filed with the Secretary of State of the State of Nevada on August 22, 2024 (effective as of August 26, 2024) (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed August 26, 2024, File No. 001-12584.)
3.18	Certificate of Change to the Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed November 1, 2024, File No. 001-12584.)
4.1	Form of Common Warrant (Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed September 30, 2024, File No. 001-12584.)
4.2	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed September 30, 2024, File No. 001-12584.)
10.1	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed September 30, 2024, File No. 001-12584.)
10.2	Amendment No. 2 to the Theriva Biologics, Inc. 2020 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed November 1, 2024, File No. 001-12584.)
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)*
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase*
104	Cover Page Interactive Data File (formatted in XBRL in Exhibit 101)

*Filed herewith.

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven A. Shallcross, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Theriva Biologics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFCIER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Theriva Biologics, Inc. (the "Registrant") hereby certifies, to such officer's knowledge, that:

(1) the accompanying Quarterly Report on Form 10-Q of the Registrant for the quarter ended September 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 12, 2024

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)