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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 June 30, 2023

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 August 2, 2023, the registrant had 17,042,765 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, 2022 filed on March 30, 2023 (the “2022 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

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

	June 30, 2023	December 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	$ 34,248	$ 41,786
Prepaid expenses and other current assets	3,717	3,734
Total Current Assets	37,965	45,520
Non-Current Assets		
Property and equipment, net	301	345
Restricted cash	100	99
Right of use asset	1,956	1,199
In-process research and development	19,483	19,150
Goodwill	5,621	5,525
Deposits and other assets	23	23
Total Assets	**$ 65,449**	**$ 71,861**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 741	$ 915
Accrued expenses	1,826	1,496
Accrued employee benefits	1,070	1,403
Contingent consideration, current portion	4,978	2,973
Loans payable-current	67	57
Operating lease liability	452	216
Total Current Liabilities	9,134	7,060
Non-current Liabilities		
Non-current contingent consideration	5,773	7,211
Loan Payable - Long term	153	221
Deferred tax liabilities, net	952	1,618
Operating lease liability - Long term	1,684	1,187
Total Liabilities	17,696	17,297
Commitments and Contingencies		
Temporary Equity		
Series C convertible preferred stock, $0.001 par value; 10,000,000 authorized;275,000 issued and outstanding	2,006	2,006
Series D convertible preferred stock, $0.001 par value; 10,000,000 authorized;100,000 issued and outstanding	728	728
Stockholders' Equity:		
Common stock, $0.001 par value; 350,000,000 shares authorized, 17,762,010 issued and 17,041,777 outstanding at June 30, 2023 and 15,844,294 issued and 15,124,061 outstanding at December 31, 2022	18	16
Additional paid-in capital	346,176	343,750
Treasury stock at cost, 720,233 shares at June 30, 2023 and at December 31, 2022	(288)	(288)
Accumulated other comprehensive loss	(356)	(679)
Accumulated deficit	(300,531)	(290,969)
Total Stockholders' Equity	45,019	51,830
Total Liabilities Temporary Equity, and Stockholders' Equity	**$ 65,449**	**$ 71,861**

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 June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
Operating Costs and Expenses:				
General and administrative	2,687	1,541	4,888	3,196
Research and development	3,133	3,485	6,110	6,082
Total Operating Costs and Expenses	5,820	5,026	10,998	9,278
Loss from Operations	(5,820)	(5,026)	(10,998)	(9,278)
Other Expense:				
Exchange loss	(4)	(9)	1	(31)
Interest income	381	26	745	27
Total Other Income (Expense)	377	17	746	(4)
Net Loss	(5,443)	(5,009)	(10,252)	(9,282)
Income tax benefit	359	532	689	532
Net Loss Attributable to Common Stockholders	**$ (5,084)**	**$ (4,477)**	**$ (9,563)**	**$ (8,750)**
Net Loss Per Share - Basic and Dilutive	$ (0.34)	$ (0.28)	$ (0.63)	$ (0.59)
Weighted average number of shares outstanding during the period - Basic and Dilutive	15,166,209	15,844,061	15,145,252	14,837,832
Net Loss	**(5,084)**	**(4,477)**	**(9,563)**	**(8,750)**
Gain(Loss) on foreign currency translation	**(51)**	**(1,442)**	**323**	**(1,261)**
Total comprehensive loss	**$ (5,135)**	**$ (5,919)**	**$ (9,240)**	**$ (10,011)**

See accompanying notes to unaudited condensed consolidated financial statements.

Theriva Biologics, Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders Equity (Deficit)
(In thousands, except share and par value amounts)

	Common Stock $0.001 Par Value						
	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive income	Treasury Stock	Total Stockholders' Equity
Balance at December 31, 2022	**15,844,061**	**$ 16**	**$ 343,750**	**$ (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	**15,844,061**	**$ 16**	**$ 343,876**	**$ (295,447)**	**$ (305)**	**(288)**	**$ 47,852**
Stock-based compensation	—	—	146	—	—	—	146
Stock issued under "at-the-market" offering	1,917,716	2	2,154	—	—	—	2,156
Translation gains(loss)	—	—	—	—	(51)	—	(51)
Net loss	—	—	—	(5,084)	—	—	(5,084)
Balance at June 30, 2023	**17,761,777**	**18**	**346,176**	**(300,531)**	**(356)**	**(288)**	**45,019**

	Common Stock $0.001 Par Value					
	Shares	Amount	APIC	Accumulated Deficit	Accumulated Other Comprehensive income	Total Stockholders' Equity
Balance at December 31, 2021	13,204,531	$ 13	$ 336,679	$ (271,284)	$ —	$ 65,408
Stock-based compensation	—	—	112	—	—	112
Issuance of Common Stock for VCN Acquisition	2,639,530	3	6,596	—	—	6,599
Translation gains (losses)	—	—	—	—	181	181
Net loss	—	—	—	(4,273)	—	(4,273)
Balance at March 31, 2022	**15,844,061**	**$ 16**	**$ 343,387**	**$ (275,557)**	**$ 181**	**$ 68,027**
Stock-based compensation	—	—	113	—	—	113
Translation gains (losses)	—	—	—	—	(1,442)	(1,442)
Net loss	—	—	—	(4,477)	—	(4,477)
Balance at June 30, 2022	**15,844,061**	**$ 16**	**$ 343,500**	**$ (280,034)**	**$ (1,261)**	**$ 62,221**

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 Six Months Ended June 30,	
	2023	**2022**
Cash Flows From Operating Activities:		
Net loss	$ (9,563)	$ (8,750)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	272	225
Income tax benefit	(689)	(532)
Change in fair value of contingent consideration	568	(442)
Non-cash lease expense	181	90
Depreciation	64	36
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	53	518
Accounts payable	(181)	(295)
Accrued expenses	335	265
Accrued employee benefits	(337)	(272)
Operating lease liability	(205)	(101)
Net Cash Used In Operating Activities	(9,502)	(9,258)
Cash Flows from Investing Activities		
Purchase of property and equipment	(17)	(14)
Cash paid for business combination, net of cash acquired	—	(3,863)
Pre-acquisition loan to VCN	—	(417)
Net Cash Used in Investing Activities	(17)	(4,294)
Cash Flows from Financing Activities		
Payment of debt	(75)	(1,376)
Proceeds from issuance ATM offering, net of issuance costs	2,156	—
Net Cash Provided by (used in) Financing Activities	2,081	(1,376)
Effects of exchange rate changes on cash and cash equivalents	(98)	(35)
Net decrease in cash and cash equivalents and restricted cash	(7,536)	(14,963)
Cash and cash equivalents and restricted at the beginning of this period	41,884	67,325
Cash and cash equivalents and restricted cash at the end of this period	**$ 34,348**	**$ 52,362**
Reconciliation of cash, cash equivalents, and restricted cash reported in the consolidated balance sheet		
Cash and cash equivalents	$ 34,248	$ 52,266
Restricted cash included in other long-term assets	100	96
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	**$ 34,348**	**$ 52,362**
Supplemental non-cash investing and financing activities:		
Right of use assets obtained in exchange for lease liabilities	$ 937	$ —
Fair value of contingent consideration in a business combination	$ —	$ 12,158
Fair value of equity issued as consideration in a business combination	$ —	$ 6,599
Effective settlement of pre-closing VCN financing	$ —	$ 417
Goodwill measurement period adjustment	$ —	$ 277

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 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 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 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. On October 12, 2022, the Company changed its name to Theriva Biologics, Inc. In connection with the name change, its common stock began trading on the NYSE American LLC under the new ticker symbol "TOVX" effective as of the opening of trading hours on October 13, 2022. Effective November 15, 2022, our acquired subsidiary VCN Biosciences, S.L. rebranded to Theriva Biologics, S.L. without other changes to its corporate structure.

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 2022 Form 10-K. The interim results for the six months ended June 30, 2023 are not necessarily indicative of results for the full year.

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 June 30, 2023 the Company has one operating segment (which includes the legacy Company business and the VCN business) and therefore one reporting segment.

Liquidity

As of June 30, 2023, the Company has 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. The Company expects to continue incurring losses for 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.

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

1. Organization, Nature of Operations and Basis of Presentation – (continued)

Our cash and cash equivalents totaled $34.2 million as of June 30, 2023, a decrease of $7.5 million from December 31, 2022. During the three and six months ended June 30, 2023, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $5.1 million and $9.6 million for three and six months ended June 30, 2023, respectively. With our cash position of $32.8 million in early August 2023, we believe we will be able to fund our operations through the third quarter and into the fourth quarter of 2024. Management believes its plan, which includes the additional testing of SYN-004 (ribaxamase) and the advancement of VCN-01 will allow us to meet our financial obligations, further advance key products, and maintain our planned operations for at least one year from the issuance date of these consolidated financial statements. 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 ATM or seek to raise additional capital on the open market, 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.

2. Summary of Significant Accounting Policies

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 Fiscal 2022 Form 10-K.

Business Combination

The Company accounts for acquisitions using the acquisition method of accounting, which requires that all identifiable assets acquired, and liabilities assumed be recorded at their estimated fair values. The excess of the fair value of purchase consideration over the fair values of identifiable assets and liabilities is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions. Critical estimates in valuing certain intangible assets include but are not limited to future expected cash flows from acquired patented technology. Management's estimates of fair value are based upon assumptions believed to be reasonable, but are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates.

As a result of the acquisition of VCN (see Note 3), the Company recorded two intangible assets: in-process research and development ("IPR&D") and goodwill. The IPR&D and goodwill are deemed to have indefinite lives and therefore not amortized.

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.

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

2. 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.

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. The payments include milestone payments to be made upon the achievement of clinical and commercialization milestones as well as single low digit royalty payments and payments upon receipt of sublicensing income. 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. 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.

Long-Lived Assets

Long-lived assets include property, equipment, and right-of-use assets. Management reviews the Company's long-lived assets for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be fully recoverable. The Company determines the extent to which an asset may be impaired based upon its expectation of the asset's future usability as well as whether there is reasonable assurance that the future cash flows associated with the asset will be in excess of its carrying amount. If the total of the expected undiscounted future cash flows is less than the carrying amount of the asset, a loss is recognized for the difference between the fair value and the carrying value of the asset. No impairment charges were recorded during the three and six months ended June 30, 2023 and 2022.

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

3. BUSINESS COMBINATION

Summary

On March 10, 2022, the Company completed the acquisition of all the outstanding shares of Theriva Biologics, S.L, which at the time was known as VCN Biosciences, S.L.(the "VCN Shares") from the shareholders of VCN. VCN is a clinical-stage biopharmaceutical company developing new oncolytic adenoviruses for the treatment of cancer. Theriva's lead product candidate, VCN-01, is being studied in a Company sponsored Phase 2 clinical trial for pancreatic cancer with additional investigator sponsored trials in indications including head and neck squamous cell carcinoma (HNSCC), retinoblastoma, brain tumors and pancreatic and ovarian cancers. VCN-01 is designed to be administered systemically, intratumorally or intravitreally, either as a monotherapy or in combination with standard of care chemotherapies or immunotherapies, to treat a wide variety of cancer indications. VCN-01 is designed to replicate selectively and aggressively within tumor cells, and to degrade the tumor stroma barrier that serves as a significant physical and immunosuppressive barrier to cancer treatment. Degrading the tumor stroma has been shown to improve access to the tumor by the virus and additional therapies such as chemo- and immuno-therapies. Importantly, degrading the stroma exposes tumor antigens, turning "cold" tumors "hot" and enabling a sustained anti-tumor immune response. Theriva has the exclusive rights to four patent families for proprietary technologies, as well as technologies developed in collaboration with the Virotherapy Group of the Catalan Institute of Oncology (ICO-IDIBELL) and with Hospital Sant Joan de Deu (HSJD), with a number of additional patents pending. As consideration for the purchase of the VCN Shares and pursuant to the terms of a purchase agreement that the parties entered into (the "Purchase Agreement"), the Company paid $4,700,000 to Grifols Innovation and New Technologies Limited ("Grifols"), the owner of approximately 86% of the equity of VCN, and issued to the remaining sellers and certain key VCN employees and consultants of VCN an aggregate of 2,639,530 shares of its common stock, $0.001 par value per share (the "Common Stock"). In addition to the consideration described above, under the terms of the purchase agreement that the parties entered into, the Company assumed up to $2,390,000 of existing liabilities of VCN and has agreed to make cash payments of up to $70.2 million to Grifols upon the achievement of certain clinical and commercialization milestones. In September 2022, the Company received approval from the FDA to proceed with the Phase 2 clinical trial of VCN-01 in PDAC. Due to this approval, the Company paid Grifols $3.0 million in the fourth quarter of 2022.

In anticipation of the Acquisition, prior to the Closing, the Company loaned VCN $417,000 to help finance the costs of certain of VCN's research and development activities. At the Closing, VCN and Grifols entered into a sublease agreement for the sublease by VCN of laboratory and office space as well as a transitional services agreement. As a post-Closing covenant, the Company has agreed to commit to fund VCN's research and development programs, including but not limited to VCN-01 in a pancreatic ductal adenocarcinoma PDAC Phase 2 trial, VCN-01 in a retinoblastoma (RB) Phase 2/3 trial and necessary G&A within a budgetary plan of approximately $27.8 million.

Total purchase consideration including cash, common shares and contingent consideration was valued at approximately $22.8 million, as follows (in thousands):

Cash paid at Closing	$	4,700
Receivable from VCN "effectively settled"		417
Fair value of common shares issued		6,599
Fair value of contingent consideration		11,093
	$	22,809

As of June 30, 2023 and December 31, 2022, the fair value of the contingent consideration was approximately $10.8 million and 10.2 million, respectively. During the three and six months ended June 30, 2023, the Company recognized in operating expense a $432,000 and 568,000, respectively, fair value adjustment increase to contingent consideration. During the three months ended June 30, 2022 the Company recognized fair value adjustment decrease to contingent consideration of $432,000.

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

3. BUSINESS COMBINATION - (continued)

The allocation of the fair value of the VCN acquisition updated for measurement period and other adjustments is shown in the table below.

	Estimated fair value ($in thousands)
Cash and cash equivalents	$ 837
Receivables	1,889
Property and equipment	216
In-process research and development intangible asset	19,742
Goodwill	5,696
Deferred tax assets (liabilities), net	(3,209)
Accounts payable	(522)
Accrued expenses	(113)
Accrued employee benefits	(90)
Loan Payable-current	(67)
Other long-term liabilities	(1,570)
Total purchase consideration	$ 22,809

The net assets were recorded at their estimated fair value. In valuing acquired assets and liabilities, fair value estimates were based primarily on future expected cash flows, market rate assumptions for contractual obligations, and appropriate discount rates. In connection with the Acquisition, we recognized $19.7 million of indefinite-lived in-process research and development intangible assets.

Goodwill is considered an indefinite-lived asset and relates primarily to intangible assets that do not qualify for separate recognition, such as the assembled workforce and synergies between the entities. Goodwill of $5.7 million was established as a result of the Acquisition and is not tax deductible.

Theriva Biologics, S.L. operations recorded a net loss of $8.3 million from the date of Acquisition through June 30, 2023.

During the year ended December 31, 2022, the Company recognized the following measurement period adjustments:

- estimate of acquired liabilities resulting in a $277,000 reduction in accrued expenses and goodwill,
- estimate in the receivable from the prior owner resulting in a $176,000 increase in other receivables and reduction in goodwill.
- estimated fair value of its in-process R&D resulting in a $810,000 increase in in-process R&D, an increase of $202,000 in deferred tax liabilities and a decrease of $607,000 in goodwill.

The cumulative impact of the re-measurements as of the year ended December 31, 2022, was a reduction in accrued liabilities of $277,000, and increase in other receivables or $176,000, an increase in in-process R&D of $810,000; an increase in deferred tax liabilities of $202,000 and a decrease in goodwill of $1,061,000.

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

3. BUSINESS COMBINATION - (continued)

Pro Forma Consolidated Financial Information (unaudited)

The following unaudited pro forma consolidated financial information summarizes the results of operations for the periods indicated as if the VCN Acquisition had been completed as of January 1, 2022 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Net revenues	$ —	$ —	—	$ —
Net loss	$ (5,084)	$ (4,967)	(9,563)	$ (9,763)

Transaction Costs

In conjunction with the Acquisition, the Company incurred approximately $0.2 million in transaction costs during the three and six months ended June, 2022, which were expensed as general, and administrative expense in the consolidated statements of operations. There were no acquisition costs incurred during the three and six months ended June 31, 2023.

4. Goodwill and Intangibles

The following table provides the Company's Goodwill as of June 30, 2023.

	Goodwill (in thousands)
Balance at December 31, 2021	$ —
Goodwill from Acquisition of VCN	6,757
Goodwill impairment loss	—
Measurement Period Adjustments	(1,061)
Effects of exchange rates	(171)
Balance at December 31, 2022	5,525
Effects of exchange rates	96
Balance at June, 2023	$ 5,621

The following table provides the Company's in-process R&D as of June 30, 2023.

	In-process R&D (in thousands)
Balance at December 31, 2021	$ —
Acquired IPR&D	18,932
Measurement Period Adjustments	810
Effects of exchange rates	(592)
Balance at December 31, 2022	19,150
Effects of exchange rates	333
Balance at June 30, 2023	$ 19,483

During the quarter ended September 30, 2022, and the quarter ended December 31, 2022, 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 trigger event for impairment. The Company performed an impairment analysis and concluded that the Goodwill and IPR&D was not impaired as of September 30, 2022, and December 31, 2022. There was no trigger event during the three and six months ended June 30, 2023.

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 rates 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 will be required pay up to $70.2 million in additional consideration upon the achievement of certain milestones, including regulatory filings completed noted in Note 3. In September 2022, the Company received approval from the FDA to proceed with the Phase 2 clinical trial of VCN-01 in PDAC. Due to this approval the Company paid Grifols Innovation and New Technologies Limited ("Grifols") $3.0 million in Q4 2022. 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 $10.8 million as of June 30, 2023 and is reflected as current accrued contingent consideration of $5.0 million and non-current contingent consideration liability of $5.8 million in the consolidated balance sheet. During the three and six months ended June 30, 2023 the Company recognized in operating expense a $432,000 and $568,000, respectively, fair value adjustment increase to contingent consideration. During the three months ended June 30, 2022 the Company recognized in operating expense a $432,000 fair value adjustment decrease to contingent consideration. There were no transfers in or out of the level 3 liabilities during the three and six months ended June 30, 2023 and 2022.

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

	As of June 30, 2023			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Contingent consideration	$ 10,751	$ —	$ —	$ 10,751
Loans payable	220	—	220	—
Total liabilities	$ 10,971	$ —	$ 220	$ 10,751

	As of December 31, 2022			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Contingent consideration	$ 10,184	$ —	$ —	$ 10,184
Loans payable	278	—	278	—
Total liabilities	$ 10,462	$ —	$ 278	$ 10,184

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

5. Fair Value of Financial Instruments – (continued)

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

	As of June 30, 2023		
	Valuation Methodology	**Significant Unobservable Input**	**Weighted Average (range, if applicable)**
Contingent Consideration	Discounted Cash Flows	Milestone dates	2023-2028
		Discount rate	12.2% to 13.4%
		Weighted Average Discount rate	12.05%
		Probability of Occurrence (periodic for each Milestone)	11.7% to 95.0%
		Probability of occurrence (cumulative through each Milestone)	6.9% to 95.0%

	As of December 31, 2022		
	Valuation Methodology	**Significant Unobservable Input**	**Weighted Average (range, if applicable)**
Contingent Consideration	Discounted Cash Flows	Milestone dates	2023-2028
		Discount rate	13.4% to 14.1%
		Weighted Average Discount rate	13.6%
		Probability of Occurrence (periodic for each Milestone)	11.7% to 95.0%
		Probability of occurrence (cumulative through each Milestone)	6.9% to 95.0%

6. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands)

	June 30, 2023	**December 31, 2022**
Prepaid clinical research organizations	$ 2,065	$ 2,293
Prepaid manufacturing expenses	859	418
Prepaid insurance	321	637
Prepaid consulting, subscriptions and other expenses	182	155
Receivable from prior owner	146	144
VAT receivable	144	87
Total	$ 3,717	$ 3,734

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. Receivable from prior VCN owner includes amounts due related to research and development tax rebates, VAT and corporate taxes.

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

6. Selected Balance Sheet Information – (continued)

Property and equipment, net (in thousands)

	June 30, 2023	December 31, 2022
Computers and office equipment	$ 901	$ 897
Other Property, Plant and Equipment	225	208
Leasehold improvements	94	94
Software	11	11
	1,231	1,210
Less: accumulated depreciation and amortization	(930)	(865)
Total	$ 301	$ 345

Accrued expenses (in thousands)

	June 30, 2023	December 31, 2022
Accrued clinical consulting services	$ 961	$ 807
Accrued manufacturing costs	443	197
Accrued vendor payments	422	492
Total	$ 1,826	$ 1,496

Accrued employee benefits (in thousands)

	June 30, 2023	December 31, 2022
Accrued bonus expense	$ 606	$ 1,216
Accrued compensation expense	350	87
Accrued vacation expense	114	100
Total	$ 1,070	$ 1,403

7. Stock-Based Compensation

Stock Incentive Plans

On March 20, 2007, the Company's Board of Directors approved the 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 7,143 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. This plan was approved by the stockholders on November 2, 2007. The exercise price of stock options under the 2007 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 is granted. As of June 30, 2023, there were 86 options issued and outstanding under the 2007 Stock Plan.

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

7. Stock-Based Compensation – (continued)

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 8,572 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 400,000 were authorized as of September 5, 2019. The exercise price of stock options under the 2010 Stock Plan is determined by the compensation committee of the Board of Directors and may be equal to or greater than the fair market value of the Company's common stock on the date the option is 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 June 30, 2023, there were 202,095 options issued and outstanding under the 2010 Stock Plan. There are no shares available to be issued under this plan.

On September 17, 2020, the stockholders approved and adopted the 2020 Stock Incentive Plan ("2020 Stock Plan") for the issuance of up to 400,000 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 options was increased such that 7,000,000 were authorized as of June 30, 2023. As of June 30, 2023, there were 2,082,155 options issued and outstanding under the 2020 Stock Plan. In the event of an employee's termination, the Company will cease to recognize compensation expense for that employee. Stock 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. There were no options granted during the three and six months ended June 30, 2023 and 2022.

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 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,
- one-third immediate vesting and the remaining annually over two years,

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

7. Stock-Based Compensation – (continued)

- 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 six months ended June 30, 2023 and the year ended December 31, 2022 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2021	625,565	$ 16.12	5.58 years	$ —
Granted	1,728,000	0.58		
Exercised	—	—		
Expired	(43,126)	67.81		
Forfeited	(14,541)	3.61		
Balance - December 31, 2022	2,295,898	3.53	6.44 years	—
Granted	—	—		
Exercised	—	—		
Expired	(715)	615.30		
Forfeited	(10,847)	1.11		
Balance – June 30, 2023 - outstanding	2,284,336	$ 3.35	5.67 years	$ 720,766
Balance – June 30, 2023 - exercisable	941,501	$ 7.02	4.65 years	$ 197,514
Grant date fair value of options granted – six months ended June 30, 2023		$ —		
Weighted average grant date fair value – six months ended June 30, 2023		$ —		
Grant date fair value of options granted – year ended December 31, 2022		$ 706,264		
Weighted average grant date fair value – year ended December 31, 2022		$ 0.41		

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Notes to Condensed Consolidated Financial Statements

7. Stock-Based Compensation – (continued)

Stock-based compensation expense included in general and administrative expenses relating to stock options issued to employees for the three and six months ended June 30, 2023 was $73,000 and $126,000, respectively, and $39,000 and $78,000 for the three and six months ended June 30, 2022, respectively. Stock-based compensation expense included in research and development expenses relating to stock options issued to employees for the three and six months ended June 30, 2023 was $29,000 and $58,000, respectively, and $21,000 and $41,000 for the three and six months ended June 30, 2022, respectively.

Stock-based compensation expense included in general and administrative expenses relating to stock options issued to consultants for the three and six months ended June 30, 2023 was $33,000 and $66,000, respectively, and $46,000 and $93,000 for the three and six months ended June 30, 2022, respectively. Stock-based compensation expense included in research and development expenses relating to stock options issued to consultants for the three and six months ended June 30, 2023 was $11,000 and $21,000, respectively, and $7,000 and $14,000 for the three and six months ended June 30, 2022, respectively.

As of June 30, 2023, total unrecognized stock-based compensation expense related to stock options was $673,000, which is expected to be expensed through June 2025.

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 six months ended June 30, 2023 and 2022.

8. Stock Warrants

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, and five-year warrant 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.

On November 16, 2020, the exercise price of the Warrants was reduced from $13.80 per Warrant per full share of the Company's Common Stock, to $6.90 per Warrant per full share of Common Stock in accordance with the antidilution terms of the Warrant. The reduction was the result of the issuance of shares of Common Stock by the Company through its "at the market offering" facility. The effect of the change in the exercise price of the Warrants as a result of the triggering of the down round protection clause in the Warrants was recorded as a deemed dividend of $0.9 million during the year ended December 31, 2020, which reduces the income available to common stockholders. In addition, pursuant to the underwriting agreement that the Company had entered into with A.G.P./Alliance Global Partners (the "Underwriters"), as representative of the underwriters, the Company granted the Underwriters a 45 day option (the "Over-allotment Option") to purchase up to an additional 242,883 shares of Common Stock and/or additional Warrants to purchase an additional 242,883 shares of Common Stock. The Underwriters partially exercised the Over-allotment Option by electing to purchase from the Company additional Warrants to purchase 180,783 shares of Common Stock.

If, at the time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance of the shares of Common Stock to the holder, then the Warrants may only be exercised through a cashless exercise. No fractional shares of Common Stock will be issued in connection with the exercise of a Warrant. In lieu of fractional shares, the holder will receive an amount in cash equal to the fractional amount multiplied by the fair market value of any such fractional shares. The Company has concluded that the Warrants are required to be equity classified. The Warrants were valued on the date of grant using Monte Carlo simulations. During the three months ended March 31, 2021, 1,165,575 Warrants were exercised for cash proceeds of $8.0 million. There were no Warrants exercised during the year ended December 31, 2022, or the six months ended June 30, 2023.

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

8. Stock Warrants – (continued)

On August 3, 2022, the Company announced the exercise price of Warrants issued by the Company in October 2018 was reduced from $6.90 per Warrant per full share of the Company's common stock, $0.001 par value per share to $1.22 per Warrant per full share of Common Stock. The reduction was the result of the issuance of shares of Preferred Stock by the Company in a private placement. The effect of the change in the exercise price of the Warrants as a result of the triggering of the down round protection clause in the Warrants was recorded as a deemed dividend of $340,000 during the year ended December 31, 2022, which reduces the income available to common stockholders.

A summary of all warrant activity for the Company for the six months ended June 30, 2023 and the year ended December 31, 2022 is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Balance at December 31, 2021	634,497	1.24	1.78 years
Granted	—	—	
Exercised	—	—	
Forfeited	(71)	182	
Balance at December 31, 2022	634,426	$ 1.22	0.78 years
Granted	—	—	
Exercised	—	—	
Forfeited	—	—	
Balance at June 30, 2023	634,426	$ 1.22	0.28 years

9. 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 six months ended June 30, 2023 was $5.1 million and 9.6, respectively. Net loss attributable to common stockholders for the three and six months ended June 30, 2022 was approximately $4.5 million and $8.8 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 and for the three and six months ended June 30, 2023 were 2,284,336 and 634,425, respectively and for the three and six months ended June 30, 2022 were 607,334 and 634,497, respectively, because their effect is anti-dilutive.

10. Related Party

On December 15, 2022, the Company approved the retention of MaryAnn Shallcross, the wife of Steven Shallcross, as director of Clinical Operations, for compensation of $145,000 and the grant of an option to purchase 50,000 shares of common stock having a value of $20,000. During the three and six months ended June 30, 2023, Ms. Shallcross had $36,000 and $72,000 in compensations expense, respectively. Ms. Shallcross had been performing services for us during 2022 for total compensation of less than $120,000.

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

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 $1.22 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 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 to 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 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 may be extended to December 31, 2022 if certain conditions are 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).

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.

In order to comply with Section 122 of the NYSE American Company Guide, on August 9, 2022 the Company and the holder of the Company's Series C preferred stock and Series D preferred stock amended the Securities Purchase Agreement entered into between them on July 28, 2022 to provide that the holder may only submit 1,549,295 of the votes relating to the Series C Preferred Stock that it would otherwise be entitled to vote.

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Notes to Condensed Consolidated Financial Statements

11. Common and Preferred Stock – (continued)

B. Riley Securities Sales Agreement

On August 5, 2016, the Company entered into the Sales Agreement (the "Original Sales Agreement") with FBR Capital Markets & Co. (now known as B. Riley Securities) to act as a sales agent, which agreement was amended and restated on February 9, 2021 to add Alliance Global Partners as a sale agent. The amended and restated Sales Agreement (the "Amended and Restated Sales Agreement") enables the Company to offer and sell shares of common stock from time to time through B. Riley Securities, Inc. and A.G.P./Alliance Global Partners as the Company's sales agent. Sales of common stock under the Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act. The sales agents are entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of the Common Stock sold on the Company's behalf. During the three and six months ended June 30, 2023, the Company sold through the At Market Issuance Sales Agreement and the Amended and Restated Sales Agreement approximately 1.9 million shares of the Company's common stock and received net proceeds of approximately $2.2 million. During the three and six months ended June 30, 2022, there were no sales of the Company's common stock through the At Market Issuance Sales Agreement and the Amended and Restated Sales Agreement.

12. Indebtedness

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 and ACC10 Generalitat de Catalunya (CDIT loans). 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 $100,000 relating to the RETOS loan, which is reflected as a non-current asset on the balance sheet.

	June 30, 2023 Current	June 30, 2023 Non-current	December 31, 2022 Current	December 31, 2022 Non-current
NEBT Loan	8	$ 24	13	31
RETOS 2015	59	129	44	190
	$ 67	$ 153	$ 57	$ 221

A maturity analysis of the debt as of June 30, 2023 is as follows *(amounts in thousands of dollars)*:

2024	62
2025	64
2026	52
2027	32
2028	10
Total	220

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13. Commitments and Contingencies

The Company's existing leases as of June 30, 2023 for its U.S. and Spanish facilities are classified as an 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 Amendment also gives the Company the right to expand its space by giving notice to the landlord before December 31, 2021. The Company did not give notice to expand the space during 2021. 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. There is an option in this Second Amendment to Lease for the Company to borrow funds for tenant improvements subject to an 8.5% interest rate.

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 Theriva S.L. 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 six months ended June 30, 2023 approximated $158,000 and $303,000, respectively and $138,000 and $245,000 the three and six months ended June 30, 2022, 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 our operating leases as of June 30, 2023 is as follows *(amounts in thousands of dollars)*:

Future undiscounted cash flow for the years ending June 30,	
2023	327
2024	664
2025	674
2026	589
2027	367
Total	2,621
Discount factor	(485)
Lease liability	2,136
Lease liability – current	(452)
Lease liability – long term	$ 1,684

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 our business in the future. We and our third-party contract manufacturers, contract research organizations, and clinical sites may also face disruptions in procuring items that are essential to our 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 because of ongoing efforts to address the outbreak. Further, although the Company has not experienced any material adverse effects on its 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 is conducting research and development, manufacturing, and clinical trials in Western European countries. The invasion of Ukraine by Russia 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 our supply chain, and despite the fact that we currently do not plan any clinical trials in Eastern Europe, may adversely impact the cost and conduct of R&D, manufacturing, and international clinical trials of our product candidates.

14. Subsequent events

On August 2, 2023, the Company announced that patient dosing has initiated in the U.S. and with four sites open in the U.S. and eight sites open in Spain and that the trial remains on track to be fully-enrolled in the first quarter of 2024. Dosing in Spain initiated in January 2023 and the first patients have now received their second doses of intravenous VCN-01. Initiating dosing in the U.S triggered the attainment of a milestone set forth in the Purchase Agreement which obligates requiring the Company to pay Grifols $3.25 million within 60 days.

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, 2022 included in our 2022 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 2022 Form 10-K.

Overview

We are a diversified clinical-stage company developing therapeutics in areas of high unmet need. As a result of the Acquisition of Theriva Biologics, S.L. ("VCN", formerly named VCN Biosciences, S.L.), described in more detail below, we began transitioning our 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, 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.

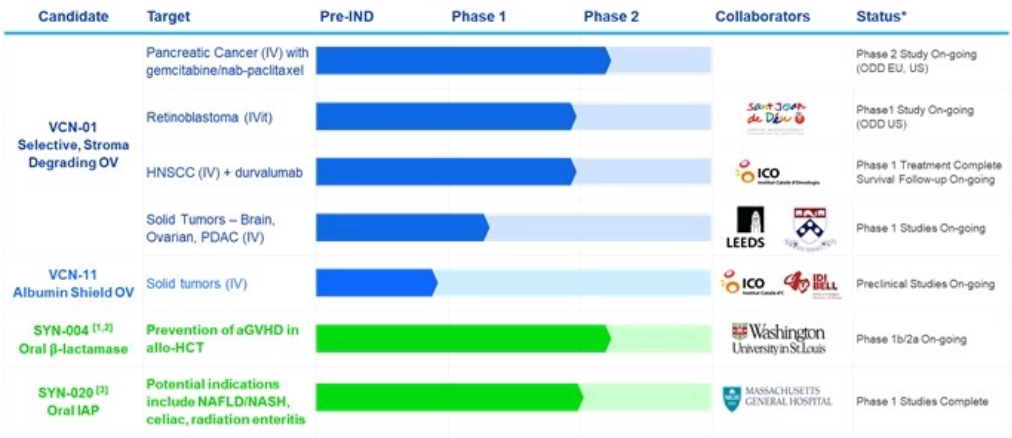
As part of our strategic transformation into an oncology focused company, we are exploring value creation options for our SYN-004 and SYN-020 assets. SYN-004 and SYN-020 both have significant potential opportunity in non-oncology related indications. Advancement of these products may be better achieved through out-licensing or partnering and we are exploring opportunities for both SYN-004 and SYN-020 moving forward.

Recent Financial Developments

B Riley and AGP Securities Sales Agreement

During the quarter ended June 30, 2023, we sold an aggregate of 1.9 million shares of our common stock and received net proceeds of approximately $2.2 million before deducting issuance expenses.

Our Current Product Pipeline



Based on management's current beliefs and expectations

allo-HCT allogeneic hematopoietic cell transplant. **CPI** immune checkpoint inhibitor. **HNSCC** head and neck squamous cell carcinoma. **IV** intravenous. **IVit** intravitreal. **ODD** Orphan Drug Designation. For other abbreviations see the text.

[1]Additional products with preclinical proof-of-concept include SYN-006 (carbapenemase) to prevent aGVHD and infection by carbapenem resistant enterococci and SYN-007 (ribaxamase) DR to prevent antibiotic associated diarrhea with oral β-lactam antibiotics.

[2]Depending on funding/partnership. SYN-004 may enter an FDA-agreed Phase 3 clinical trial for the treatment of CDI.

[3]We have an option-license agreement with Massachusetts General Hospital to develop SYN-020 in several potential indications related to inflammation and gut barrier dysfunction.

Recent Clinical Developments

On August 2, 2023, we announced that patient dosing has initiated in the U.S. and with four sites open in the U.S. and eight sites open in Spain and that the trial remains on track to be fully-enrolled in the first quarter of 2024. Dosing in Spain initiated in January 2023 and the first patients have now received their second doses of intravenous VCN-01. Initiating dosing in the U.S triggered the attainment of a milestone set forth in the Purchase Agreement which obligates requiring the Company to pay Grifols $3.25 million within 60 days,

On June 27, 2023 we announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to our lead clinical candidate VCN-01, our systemic, selective, stroma-degrading oncolytic adenovirus for the treatment of pancreatic cancer.

On February 16, 2023, we issued a press release announcing the presentation of blinded safety and pharmacokinetic (PK) data from the ongoing 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 (aGVHD). These data were featured in a poster presentation at 2023 Tandem Meetings: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR, being held in Orlando, Florida from February 15-19, 2023.

On January 9, 2023, we issued a press release announcing that the first patient has been dosed in the Phase 1 investigator sponsored clinical trial of intravenous VCN-01 in patients with high-grade brain tumors who are scheduled for surgical resection.

On January 17, 2023, we issued a press release announcing the first patient has been dosed 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 (PDAC) (NCT05673811).

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 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 are designed to 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 by OVs also alerts the immune system, which can then attack the virus infected cells and the tumor cells to help destroy the tumor in some instances.

Our OV candidates' products 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, 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, they will be further protected by data and/or market exclusivity in major markets.

VCN-01 has been administered to 93 patients across multiple Phase 1 clinical trials and Phase 2 VIRAGE trial, including patients with pancreatic cancer, head and neck squamous cell carcinoma, ovarian carcinoma, colorectal cancer, and retinoblastoma.

Current clinical update

We are currently conducting a Phase 2 trial of intravenous VCN-01 with or without nab-paclitaxel plus gemcitabine in patients with solid tumors and PDAC. Additional Phase 1 investigator sponsored studies are evaluating intravitreal VCN-01 in patients with retinoblastoma, a Phase 1 Trial of intravenous VCN-01 in combination with durvalumab in subjects with recurrent/ metastatic squamous cell carcinoma of the head and neck (SCCHN), 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.

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 solid tumors and PDAC (VIRAGE)

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 enroll 92 patients and be conducted at approximately 25 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.

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 doses of VCN-01 injected 14 days apart using a dose escalation regimen. At this time, the dose-escalation phase of the study has already been completed in 6 patients distributed in two cohorts (2×10^9 vp/eye and 2×10^{10} vp/eye). VCN-01 was well tolerated to date after intravitreal administration, although some degree of intravitreal inflammation and associated turbidity were observed. Inflammation has been managed and potential turbidity minimized with 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 and VCN-01 reduced the number of vitreous seeds in 4 out of 5 patients treated at 2×10^{10} vp/eye (n=5). The investigator has reported that one patient treated with VCN-01 has had a complete regression lasting more than 30 months.

Six (6) patients have been treated in this Phase 1 trial with VCN-01 to date. This study is ongoing and the enrollment period has been extended to include additional patients. We anticipate meeting with the FDA during the second half of 2023 to discuss the path forward for VCN-01 as an adjunct to chemotherapy in pediatric patients with advanced retinoblastoma.

On September 30, 2022, we issued a press release announcing an oral presentation entitled “Topotecan enhances oncolytic adenovirus infection, replication and antitumor activity in retinoblastoma,” featuring Dr. Angel Montero-Carcaboso, Researcher at Fundació Sant Joan de Déu at the SIOP 2022 Congress of the International Society of Pediatric Oncology, being held in Barcelona, Spain from September 28-October 1, 2022. The new data from the study for which Dr. Angel Montero-Carcaboso is the lead investigator further support evaluation of VCN-01, an oncolytic adenovirus expressing hyaluronidase, and topotecan for the treatment of refractory retinoblastoma.

Phase 1 Trial of intravenous VCN-01 in Combination with Durvalumab in Subjects with Recurrent/ Metastatic Squamous Cell Carcinoma of the Head and Neck (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) 2022 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. We expect to report additional results from this study in H2 2023 as data become available.

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. The study is on-going.

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 our programs are supported by our growing intellectual property portfolio. We are maintaining and building our patent portfolio through filing new patent applications; prosecuting existing applications; and licensing and acquiring new patents and patent applications.

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 randomized, double-blinded, placebo-controlled Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients for the prevention of acute graft-versus-host-disease (aGVHD, NCT04692181). 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.

To date, we have completed the first of 3 cohorts (Cohort 1) in this study, which enrolled 19 patients who received at least 1 dose of study drug (SYN-004 or Placebo randomized 2:1). Sixteen patients received at least one dose of intravenous (IV) meropenem and 12 of these patients completed sufficient doses of IV meropenem to be evaluable towards the study endpoints. 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 November 3, 2022 we announced the first patient had been dosed in Cohort 2. Patient dosing is on-going and if enrollment proceeds on the current schedule, we may be positioned to announce data readouts for the second cohort during the first half of 2024 and the third cohort during the first half of 2025

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," 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 for 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 which are supported by our collaboration with Massachusetts General Hospital ("MGH"). Across the six major markets, the total prevalent cases of celiac disease are expected to increase from 5.8 million cases in 2013 to an expected 8.1 million cases in 2023, representing an annual growth rate of approximately 4%. During the same period, prevalent cases in the U.S. are expected to increase from 2.8 million in 2013 to an expected 4.3 million in 2023, representing a significant market opportunity.

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 April 1, 2021, we announced that enrollment had commenced in the Phase 1 SAD clinical trial of SYN-020. 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). On October 21, 2021 we announced that patient enrollment, dosing, and observation commenced in the Phase 1 MAD of SYN-020. 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. During the second quarter of 2021, we announced an amendment to our option for an exclusive license agreement with MGH to include intellectual property and technology related to the use of SYN-020 to inhibit liver fibrosis in select diseases, including NAFLD. Research published by a team of investigators led by Richard Hodin, MD, Chief of the Massachusetts General Hospital Division of General and Gastrointestinal Surgery and Professor of Surgery, Harvard Medical School, evaluated long-term oral supplementation of IAP, including SYN-020, in mice. Dr. Hodin's research demonstrated that IAP administration, starting at 10 months of age, slowed the microbiome changes, gut-barrier dysfunction, and gastrointestinal and systemic inflammation that normally accompany aging. Additionally, the IAP administration resulted in improved metabolic profiles in the aged mice, diminished frailty, and extended lifespan. Under the terms of the agreement, we are granted exclusive rights to negotiate a worldwide license with MGH to commercially develop SYN-020 to treat and prevent metabolic and inflammatory diseases associated with aging. If executed, we plan to use this license in the advancement of an expanded clinical development program for SYN-020.

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 indications supported by our collaboration with Massachusetts General Hospital. With our transition to an oncology focused Company, we are exploring strategic opportunities to enable advancement of this potentially valuable asset.

Research Programs

VCN-11 Albumin Shield™ Technology

VCN-11 is a novel virus that we believe has the potential to extend our OV platform. VCN-11 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 albumin binding domain, 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 VCN-11 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 containing the albumin binding domain such as VCN-11 are not neutralized and retain their ability to infect and destroy tumor cells. We believe these results support the further development of VCN-11 for tumors in which rapid multi-dosing may be beneficial.

In the second quarter of 2020, VCN had several interactions with Spanish regulatory authorities (AEMPS) to agree on the design of the non-clinical GLP toxicology and biodistribution studies that are required to support a first-in-human clinical trial for VCN-11.

In March 2021, preclinical data obtained with VCN-11 was published (J Control Release. 2021 Apr 10;332:517-528), showing that VCN-11 induced 450 times more cytotoxicity in tumor cells than in normal cells. VCN confirmed VCN-11 hyaluronidase production 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. VCN-11 evaded NAbs from different sources and tumor levels of VCN-11 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). VCN-11 increased ALT levels on day 3 within an acceptable range that returned to normal levels by day 9. Fractionated intravenous administration of VCN-11 (splitting the dose into two portions administered 4 h apart) appeared to improve VCN-11 circulation kinetics and increase tumor levels. VCN-11 showed antitumor efficacy in the presence of NAbs against Ad5 and itself.

In May 2022, we presented on VCN-11 at the 25th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT). The presentation included preclinical results showcasing the potential of VCN-11 to balance safety, with no major toxicities observed, and effectively target tumors after intravenous re-administration, even in the presence of high level NAbs. Our internal discovery programs are currently evaluating new oncolytic viruses derived from VCN-11 that may expand the potential efficacy of Albumin Shield viruses.

SYN-006, SYN-007, other oncolytic virus

To date, our research programs have been primarily directed to the development of GI acting products that have generated preclinical proof-of-concept with two pipeline products (SYN-006 and SYN-007) that expand the potential utility of our beta-lactamase strategy. SYN-007 is a specially formulated version of SYN-004 (ribaxamase) designed to be used with orally administered beta-lactam antibiotics to protect the gut microbiome from antibiotic-mediated dysbiosis. SYN-006 is a carbapenemase designed to degrade intravenous (IV) carbapenem antibiotics within the GI tract to maintain the natural balance of the gut microbiome for the prevention of CDI, overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR). Our research programs may be expanded to include development of new oncolytic virus products and/or explore oncology applications of our existing products such as SYN-006 and SYN-007.

Intellectual Property

All of our programs are supported by growing patent estates. In total, Theriva Biologics has over 130 U.S. and foreign patents and over 65 U.S. and foreign patents pending. VCN, through assignment or exclusive licenses, controls over 40 U.S. and foreign patents and over 15 U.S. and foreign patents pending.

The SYN-004 (ribaxamase) program is supported by IP that is assigned to Theriva Biologics, namely U.S. and foreign patents and patent application (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 patent applications, which cover various formulations, medical uses and manufacture of SYN-020, are expected to expire in 2038-2040, if granted, and without taking potential patent term extensions or patent term adjustment into account.

The VCN-01 and VCN-11 programs are supported by U.S. and foreign patents and patent applications that are assigned to VCN or exclusively licensed from Fundacio 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 revenues and 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 research and development costs, business combinations, contingent consideration, and impairment of long-lived assets, goodwill and In-process research and development ("IPR&D").

Business Combination

The Company accounts for acquisitions using the acquisition method of accounting, which requires that all identifiable assets acquired, and liabilities assumed be recorded at their estimated fair values. The excess of the fair value of purchase consideration over the fair values of identifiable assets and liabilities is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions. Critical estimates in valuing certain intangible assets include but are not limited to future expected cash flows from acquired patented technology. Management's estimates of fair value are based upon assumptions believed to be reasonable, but are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates.

The Company classifies 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 its 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. The Company tests 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 the Company 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 the Company acquires, 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 the Company becomes 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, 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.

Goodwill represents the excess of the purchase price paid when the Company acquired VCN in March 2022, over the fair values of the acquired tangible or intangible assets and assumed liabilities. The Company will 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 the Company's fair value below its net equity value. During the quarters ended September 30 and December 31, 2022, 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. The Company performed an impairment analysis at both September 30 and December 31, 2022 and concluded that the Goodwill and IPR&D was not impaired at both dates.

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. The milestone payments will be made upon the achievement of clinical and commercialization milestones as well as single low digit royalty payments and payments upon receipt of sublicensing income. 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. 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.

Long-Lived Assets

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets.

Acquired In-Process Research & Development represents the fair value assigned to those research and development projects that were acquired in a business combination for which the related products have not received regulatory approval and have no alternative future use. IPR&D is capitalized at its fair value as an indefinite-lived intangible asset, and any development costs incurred after the acquisition are expensed as incurred. Upon achieving regulatory approval or commercial viability for the related product, the indefinite-lived intangible asset is accounted for as a finite-lived asset and is amortized on a straight-line basis over the estimated useful life. If the project is not completed or is terminated or abandoned, the Company may have an impairment related to the IPR&D which is charged to expense. Indefinite-lived intangible assets are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may be impaired. Impairment is calculated as the excess of the asset's carrying value over its fair value.

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. 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 June 30, 2023 and 2022, we have accrued CRO expenses of $1.0 million and $0.7 million, respectively, that are included in accrued expenses. As of June 30, 2023, and 2022, we have prepaid CRO costs of $2.1 million and $1.2 million, respectively, that are included in prepaid expenses.

Results of Operations

Three Months Ended June 30, 2023 and 2022

General and Administrative Expenses

General and administrative expenses increased to $2.7 million for the three months ended June 30, 2023, from $1.5 million for the three months ended June 30, 2022. This increase of 80% is primarily comprised of increased expense related to the fair value of the contingent consideration adjustment of $0.9 million, along with higher audit fees, consulting fees, travel, and VCN administrative expenses not included in the prior year, offset by a decrease in legal costs related to the VCN acquisition. The charge related to stock-based compensation expense was $106,000 for the three months ended June 30, 2023, compared to $86,000 for the three months ended June 30, 2022.

Research and Development Expenses

Research and development expenses decreased to $3.1 million for the three months ended June 30, 2023, from approximately $3.5 million for the three months ended June 30, 2022. This decrease of 11% is primarily the result of lower expenses related to our Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients Phase 1a clinical trial of SYN-020, and decreased manufacturing expenses related to our Phase 1a clinical trial of SYN-020, offset by increased clinical trial expenses related to VCN-01. We anticipate research and development expense to increase as we continue enrollment in our VIRAGE Phase 2 clinical trial of VCN-01 in PDAC, and our ongoing Phase 1 clinical trial in retinoblastoma, expand GMP manufacturing activities for VCN-01, and continue supporting our VCN-11 and other preclinical and discovery initiatives. The charge related to stock-based compensation expense was $40,000 for the three months ended June 30, 2023, compared to $27,000 related to stock-based compensation expense for the three months ended June 30, 2022.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the three months ended June 30, 2023 and 2022. 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	June 30, 2023	June 30, 2022
VCN-01	$ 1,659	$ 1,468
Ribaxamase	212	346
SYN-020	79	226
Other therapeutic areas	97	225
Total direct costs	2,047	2,265
Total indirect costs	1,086	1,220
Total Research and Development	$ 3,133	$ 3,485

Other Income/Expense

Other income was $377,000 for the three months ended June 30, 2023 compared to other expense of $17,000 for the three months ended June 30, 2022. Other income for the three months ended June 30, 2023 is primarily comprised of interest income of $381,000 and exchange loss of $4,000. Other income for the three months ended June 30, 2022 is primarily comprised of interest income of $26,000 offset by an exchange loss of $9,000.

Net Loss Attributable to Common Stockholders

Our net loss attributable to common stockholders was approximately $5.1 million, or $0.34 per basic and dilutive common share for the three months ended June 30, 2023, compared to a net loss of approximately $4.5 million, or $0.28 per basic common share and dilutive common share for the three months ended June 30, 2022.

Six Months Ended June 30, 2023 and 2022

General and Administrative Expenses

General and administrative expenses increased to $4.9 million for the six months ended June 30, 2023, from $3.2 million for the six months ended June 30, 2022. This increase of 53% primarily comprised of increased fair value of the contingent consideration adjustment of $0.9 million, along with higher audit fees, consulting fees, travel, and VCN administrative expenses not included in the prior year, offset by a decrease in legal costs related to the VCN acquisition and director and officer insurance. The charge related to stock-based compensation expense was $193,000 for the six months ended June 30, 2023, compared to $172,000 the six months ended June 30, 2022.

Research and Development Expenses

Research and development expenses increased to $6.1 million for the six months ended June 30, 2023, from approximately $6.1 million for the six months ended June 30, 2022. The movement between the two periods is primarily the result of higher increased clinical trial expenses related to VCN-01, offset by lower expenses related to our Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients, Phase 1a clinical trial of SYN-020, decreased manufacturing expenses related to our Phase 1a clinical trial of SYN-020 and lower other indirect costs. We anticipate research and development expense to increase as we continue enrollment in our VIRAGE Phase 2 clinical trial of VCN-01 in PDAC, and our ongoing Phase 1 clinical trial in retinoblastoma, expand GMP manufacturing activities for VCN-01, and continue supporting our VCN-11 and other preclinical and discovery initiatives. The charge related to stock-based compensation expense was $79,000 for the six months ended June 30, 2023, compared to $54,000 related to stock-based compensation expense for the six months ended June 30, 2022.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the six months ended June 30, 2023 and 2022. 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	June 30, 2023	June 30, 2022
VCN-01	$ 3,314	$ 1,528
Ribaxamase	407	723
SYN-020	144	885
Other therapeutic areas	157	277
Total direct costs	4,022	3,413
Total indirect costs	2,088	2,669
Total Research and Development	$ 6,110	$ 6,082

Other Income/Expense

Other income was $746,000 for the six months ended June 30, 2023 compared to other expense of $4,000 for the six months ended June 30, 2022. Other income for the six months ended June 30, 2023 is primarily comprised of interest income of $745,000 and exchange gain of $1,000. Other expense for the six months ended June 30, 2022 is primarily comprised of exchange loss of $31,000, offset by interest income of $27,000.

Net Loss Attributable to Common Stockholders

Our net loss attributable to common stockholders was approximately $9.6 million, or $0.63 per basic and dilutive common share for the six months ended June 30, 2023, compared to a net loss of approximately $8.8 million, or $0.59 per basic common share and dilutive common share for the six months ended June 30, 2022.

Liquidity and Capital Resources

As of June 30, 2023, the Company has 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. The Company expects to continue incurring losses for 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 $34.2 million as of June 30, 2023, a decrease of $7.5 million from December 31, 2022. During the three and six months ended June 30, 2023, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $5.1 million and $9.6 million for three and six months ended June 30, 2023, respectively. With our cash position of $32.8 million in early August 2023, we believe we will be able to fund our operations through the third quarter and into the fourth quarter of 2024. Management believes its plan, which includes the additional testing of SYN-004 (ribaxamase) and the advancement of VCN-01 will allow us to meet our financial obligations, further advance key products, and maintain our planned operations for at least one year from the issuance date of these consolidated financial statements. 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 ATM or seek to raise additional capital on the open market, 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, 2022, our only source of cash was from the sales of our Series C Preferred Stock and Series D Preferred Stock. During the three and six months ended June 30, 2023, our only source of cash was from sales of our common stock through the Amended and Restated ATM Sales Agreement in which we sold 1.9 million shares of our stock for net proceeds of $2.2 million.

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 Amended and Restated ATM Sales Agreement 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.

We have committed, and expect to continue to commit, substantial capital in order to implement our business strategy, including our planned product development efforts, preparation for our planned clinical trials, and performance of clinical trials and our research and discovery efforts. We believe our cash position of $32.8 million in early August 2023 is sufficient to fund our operations through at least the end of the third quarter of and into the fourth quarter 2024, including continuation of our ongoing Phase 1b/2a clinical study 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 of VCN-11 and related discovery initiatives, and to fund our committed obligations under the VCN Purchase Agreement for the VCN Acquisition.

Following the anticipated completion of our ongoing Phase 1b/2a clinical study of SYN-004 (ribaxamase) in allogeneic HCT recipients, our ongoing Phase 1 and Phase 2 clinical trials for VCN-01, and the preclinical studies of VCN-11, and related 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.

Cash Flows

Cash Used in Operating Activities

Net cash used in operating activities was $9.5 million and $9.3 million during the six months ended June 30, 2023 and 2022, 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 six months ended June 30, 2023 increased compared to the same period in 2022 due primarily to the ramp up in our Phase 2 trial.

Cash Used In Investing Activities

Cash used in investing activities during the six months ended June 30, 2023 was $17,000 for equipment purchase as compared to$ 4.3 million during the same period in the prior year, which were primarily related to the cash payment for the acquisition and a pre-acquisition loan to VCN.

Cash Provided by Financing Activities

Cash provided by financing activities during the six months ended June 30, 2023 included at the market offering proceeds of $2.2 million from sales of 1.9 shares of our common stock which was offset by $75,000 of payments of debt. Cash used in financing activities during the six months ended June 30, 2022 related solely to the payment of $1.4 million of debt payments related to loans extended by certain Spanish institutions.

Off-Balance Sheet Arrangements

During the three months ended June 30, 2023, 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. ROU assets are included in other noncurrent assets and lease liabilities are included in other current and non-current liabilities in our condensed consolidated balance sheets. As of June 30, 2023, 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 June 30, 2023, 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 June 30, 2023. 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 SEC’s rules and forms. 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 its Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were not effective.

Material Weakness over Non-Routine Transactions

During the course of the preparation of our interim and annual consolidated financial statements for the quarters ending March, 31, 2022 June 30, 2022, September 30, 2022 and year ended December 31, 2022, we identified material weaknesses in our controls relating to accounting and disclosure controls for non-routine transactions. Specifically, the controls related to the review of internally and externally prepared reports and analysis used in the financial reporting process and the related income tax implication of non-routine transactions.

Remediation Plan

In order to remediate these material weaknesses, we plan to implement the following steps to improve the overall processes of identifying and reviewing non-routine transactions and preparing interim financial statements:

- Perform additional internal review processes to ensure the appropriate accounting and disclosure of non-routine transactions.
- Engage a third-party tax specialist to assist us in the preparation and review of interim tax provisions.

Should additional changes to the remediation plan be warranted, management will modify the planned measures accordingly.

Material Weakness over Information Technology General Controls

During the preparation of our annual consolidated financial statements for the year ended December 31, 2022, we identified a material weakness in our controls relating to general information technology controls over logical access and program change management for certain of our key information systems used to support the financial reporting process.

Remediation Plan

Management will ensure proper segregation of duties over all IT functions ensuring IT personnel are properly trained as to the importance of and specifics over the internal controls for which they are responsible, including consistent, repeatable performance of such controls. Management will also evaluate the responsibilities of its control owners to ensure that proper segregation of duties exists within the process level controls that are dependent upon information produced by IT systems affected by segregation of duties conflicts. Further, management will ensure IT personnel do not have conflicting responsibilities with respect to program changes, administration and user access controls, or that additional controls are implemented to perform an effective review of program changes, administration and user access.

Material Weakness over Evidence of Control Performance

During the preparation of our annual consolidated financial statements for the year ended December 31, 2022, we identified a material weakness relating to the ineffective design and execution of management’s review of controls, particularly with regard to the precision of the review, evidence of review procedures performed, and the evaluation of the completeness and accuracy of information utilized in the performance of the control.

Remediation Plan

Management will ensure all personnel are properly trained as to the importance of properly documenting and evidencing the performance of controls.

When fully implemented, the Company believes that the measures described above will appropriately remediate the identified material weaknesses, although management may determine that taking additional measures to remediate the material weaknesses may be necessary.

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 fiscal 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 2022 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2022 Form 10-K.

RISKS RELATING TO OUR BUSINESS

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 six months ended June 30, 2023, our operating activities used net cash of approximately $9.5 million and our cash and cash equivalents were approximately $34.2 million as of June 30, 2023. 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 June 30, 2023, our accumulated deficit totaled approximately $300.5 million on a consolidated basis. Pursuant to the 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 the next 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 (our proposed clinical trials in PDAC and retinoblastoma), Phase 1a/2a clinical trial of SYN-004, but may not be sufficient for additional trials of SYN-020 or 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. 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 17,041,777 shares of common stock were issued and outstanding as of June 30, 2023. At June 30, 2023, we had reserved 5,377,777 shares of common stock for issuance upon exercise of our outstanding options, preferred shares and warrants. In addition, at such date, we had 4,917,845 shares of our common stock reserved for future issuance under our equity incentive plans. If all of these securities were to be exercised, the total number of shares of our common stock that we would be required to issue is 10,295,622, which in addition to the 17,041,777 shares issued and outstanding, would leave 322,622,601 authorized but unissued shares of common stock available to be issued.

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. In the event that we sell shares or other securities (other than pursuant to the ATM) at prices below the exercise price of the warrants that we issued in our October 2018 offering, the price protection anti-dilution provisions of the warrant provide that the exercise price of the warrants sold in our October 2018 offering is to be reduced which may result in additional warrant exercises and additional dilution to 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 this weakness 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. During the preparation of our annual tax provision for the year ended December 31, 2022, we identified a material weakness over non-routine transactions related to the review of internally and externally prepared reports and analysis used in the financial reporting process and the related income tax implication of the non-routine transactions, a material weakness over information technology general controls over logical access and program change management for certain of our key information systems used to support the financial reporting process and a material weakness relating to performance over certain controls not being adequately documented. In addition, during the course of the review for the Quarterly Report for the quarter ended March 31, 2022, we identified a material weakness in our controls relating to accounting and disclosure controls for non-routine transactions. While we plan to take remedial action to address the material weaknesses, we cannot provide any assurance that such remedial measures, or any other remedial measures we take, will be effective. If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, detect or prevent fraud, or file our periodic reports in a timely manner, which may, among other adverse consequences, cause investors to lose confidence in our reported financial information and lead to a decline in our stock price. In addition, a material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are designed and operating effectively. 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.

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

We did not sell any equity securities during the quarter ended June 30, 2023 in transactions that were not registered under the Securities Act other than as previously disclosed in our filings with the SEC.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

Not applicable

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, Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Date: August 8, 2023

EXHIBIT INDEX

Exhibit Number	Exhibit Title
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	Amended and Restated Bylaws Adopted and Effective October 31, 2011 (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed November 2, 2011, 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 February 16, 2012, 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 May 18, 2015, File No. 001-12584.)
3.8	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.)
3.9	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.)
3.10	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.)
3.11	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.)
3.12	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.)
3.13	Certificate of Amendment to Certificate of Designations 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.)
3.14	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.)
10.1	Separation Agreement dated as of May 8, 2023 between Theriva Biologics, Inc. and Frank Tufaro (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, File No. 001-12584)

10.2+††	Consulting Agreement dated as of May 8, 2023 between Theriva Biologics, Inc. and Frank Tufaro (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, 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.
+ Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.
†† Registrant has omitted certain portions of this exhibit in accordance with Item 601 (b)(10) of Regulation S-K. The Company agrees to furnish unredacted copies of these exhibits to the SEC upon request