Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2025

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 1-13602

Veru Inc.

(Exact Name of Registrant as Specified in its Charter)

Wisconsin (State of Incorporation)	**39-1144397** (I.R.S. Employer Identification No.)
2916 N. Miami Avenue, Suite 1000, Miami, FL (Address of Principal Executive Offices)	**33127** (Zip Code)

305-509-6897
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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, $0.01 par value per share	VERU	Nasdaq Capital Market

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 determined by Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 7, 2025, the registrant had 14,650,392 shares of $0.01 par value common stock outstanding.

VERU INC.
INDEX

FORWARD LOOKING STATEMENTS

Certain statements included in this quarterly report on Form 10-Q which are not statements of historical fact are intended to be, and are hereby identified as, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about our financial condition or business, our development and commercialization plans relating to our product candidates and products, including any potential development or commercialization of enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a glucagon-like peptide-1 receptor agonist ("GLP-1 RA") who are at-risk for developing muscle weakness and sabizabulin to treat cardiovascular atherosclerotic disease to reduce major cardiovascular events, future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, royalty payments, outcome of litigation and other contingencies, financial condition, results of operations, liquidity, cost savings, our ability to continue as a going concern, objectives of management, business strategies, clinical trial timing, plans and results, the achievement of clinical and commercial milestones, the advancement of our technologies and our products and drug candidates, our intellectual property strategy and whether any products may be patented, and other statements that are not historical facts. Forward-looking statements can be identified by the use of forward-looking words or phrases such as "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" or the negative of these terms or other words of similar meaning. These statements are based upon the Company's current plans and strategies and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this report. These statements are inherently subject to known and unknown risks and uncertainties. You should read these statements carefully because they discuss our future expectations or state other "forward-looking" information. There may be events in the future that we are not able to accurately predict or control and our actual results may differ materially from the expectations we describe in our forward-looking statements. Factors that could cause actual results to differ materially from those currently anticipated include the following:

- potential delays in the timing of and results from clinical trials and studies, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies, and the risk that such results will not support marketing approval or commercialization in the United States or in any foreign country;
- potential delays in the timing of any submission to the U.S. Food and Drug Administration (the "FDA") or any other regulatory authority around the world and potential delays in, or failure to obtain, from any such regulatory authority approval of products under development, including the risk of a delay or failure in reaching agreement with the FDA on the design of any clinical trial, including any post-approval or post-authorization study, or in obtaining authorization to commence a clinical trial or commercialize a product candidate in the U.S. or elsewhere;
- potential delays in the timing of approval by the FDA or any other regulatory authority of the release of manufactured lots of approved products;
- clinical trial results supporting any potential regulatory approval or authorization of any of our products, including enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle weakness and sabizabulin to treat cardiovascular atherosclerotic disease to reduce major cardiovascular events, may not be replicated in clinical practice;
- clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all;
- risks related to our ability to obtain sufficient financing on acceptable terms when needed to fund product development and our operations and to enable us to continue as a going concern;
- our ability to maintain compliance with the continued listing requirements of the Nasdaq Stock Market LLC ("Nasdaq"), including our ability to regain and subsequently maintain compliance with the Nasdaq minimum bid price requirement after our recently completed reverse stock split;
- we need to secure significant funding to advance our drug candidates, including government grants, pharmaceutical company partnerships, or similar external sources to advance the development of sabizabulin as a treatment for slowing progression of or promoting regression of atherosclerosis disease;
- we may not receive any additional payments from Onconetix, Inc. formerly known as Blue Water Vaccines Inc. ("ONCO") in connection with the sale of our ENTADFI assets;
- risks related to the development of our product portfolio, including clinical trials, regulatory approvals and time and cost to bring any of our product candidates to market, and risks related to efforts of our collaborators;
- product demand and market acceptance of our products in development, if approved;

- risks related to our ability to obtain insurance reimbursement from private payors or government payors, including Medicare and Medicaid, and similar risks relating to market or political acceptance of any potential or actual pricing for any of our product candidates that, if approved, we attempt to commercialize;
- all of our products are in development and we may fail to successfully commercialize such products;
- risks related to intellectual property, including the uncertainty of obtaining intellectual property protections and in enforcing them, the possibility of infringing a third party's intellectual property, and licensing risks;
- competition from existing and new competitors with respect to our products in development, if approved, including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- risks related to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation as well as potential healthcare reform measures;
- the risk that we will be affected by regulatory and legal developments, including a repeal or modification of part or all of the Patient Protection and Affordable Care Act;
- risks inherent in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers;
- risks related to our growth strategy;
- our continued ability to attract and retain highly skilled and qualified personnel;
- risks relating to the restatement of our unaudited condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023 and the restatement of our audited consolidated financial statements as of and for the years ended September 30, 2023 and 2022;
- risks relating to our history of losses and the fact we currently have no commercial revenue and may never generate revenue or become profitable;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations, and other claims against us;
- the risk that we may identify material weaknesses or other deficiencies in our internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal controls;
- our ability to identify, successfully negotiate and complete suitable acquisitions, out-licensing transactions, in-licensing transactions or other strategic initiatives and to realize any potential benefits of such transactions or initiatives; and
- our ability to successfully integrate acquired businesses, technologies or products.

All forward-looking statements in this report should be considered in the context of the risks and other factors described above and in "Risk Factors" in Item 1A. of this report. These factors are not exhaustive. All forward-looking statements in this report should be considered in the context of the risks and other factors described above, and in Part II, Item 1A, "Risk Factors" below in this report. Additional factors that we do not yet know of or that we currently think are immaterial may also impair our business operations, and new risk factors may emerge from time to time. It is not possible to predict all such risk factors, nor can the Company assess the impact of all such risk factors on its business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements, which speak only as of the date hereof. All forward-looking statements attributable to the Company or persons acting on its behalf are expressly qualified in their entirety by the foregoing cautionary statements. The Company undertakes no obligation to make any revisions to the forward-looking statements contained in this report or to update them to reflect events or circumstances occurring after the date of this report except as required by applicable law.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2025	September 30, 2024
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	$ 15,010,154	$ 24,916,285
Prepaid expenses and other current assets	1,183,023	1,547,928
Current assets of discontinued operations	—	8,759,011
Total current assets	16,193,177	35,223,224
Property and equipment, net	393,381	481,372
Operating lease right-of-use assets	2,875,672	3,250,623
Goodwill	6,878,932	6,878,932
Other assets	989,596	989,596
Long-term assets of discontinued operations	—	13,595,025
Total assets	$ 27,330,758	$ 60,418,772
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,538,724	$ 2,259,668
Accrued research and development costs	230,634	120,448
Accrued compensation	2,780,570	4,494,278
Accrued expenses and other current liabilities	378,687	549,237
Residual royalty agreement liability, short-term portion	—	1,025,837
Operating lease liability, short-term portion	753,400	736,970
Current liabilities of discontinued operations	—	2,681,530
Total current liabilities	6,682,015	11,867,968
Residual royalty agreement liability, long-term portion	—	8,850,792
Operating lease liability, long-term portion	2,500,736	2,905,309
Other liabilities	2,803,374	4,461,920
Long-term liabilities of discontinued operations	—	16,071
Total liabilities	11,986,125	28,102,060
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock; no shares issued and outstanding at June 30, 2025 and September 30, 2024	—	—
Common stock, par value $0.01 per share; 308,000,000 shares authorized, 14,868,762 and 14,856,762 shares issued and 14,650,392 and 14,638,392 shares outstanding at June 30, 2025 and September 30, 2024, respectively	148,688	148,568
Additional paid-in-capital	341,751,971	335,125,903
Accumulated other comprehensive loss	—	(581,519)
Accumulated deficit	(318,749,421)	(294,569,635)
Treasury stock, 218,370 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	15,344,633	32,316,712
Total liabilities and stockholders' equity	$ 27,330,758	$ 60,418,772

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 3,020,563	$ 4,846,156	$ 12,669,495	$ 9,489,848
Selling, general and administrative	5,010,528	5,809,325	15,402,074	18,364,622
Total operating expenses	8,031,091	10,655,481	28,071,569	27,854,470
Gain on sale of ENTADFI® assets	484,615	110,000	2,154,134	1,028,372
Operating loss from continuing operations	(7,546,476)	(10,545,481)	(25,917,435)	(26,826,098)
Non-operating income (expenses):				
Gain on extinguishment of debt	—	—	8,624,778	—
Change in fair value of equity securities	—	(117,620)	(349,078)	(689,548)
Other income, net	223,375	323,045	656,338	805,109
Total non-operating income	223,375	205,425	8,932,038	115,561
Net loss from continuing operations	(7,323,101)	(10,340,056)	(16,985,397)	(26,710,537)
Net loss from discontinued operations, net of taxes	(9,719)	(628,818)	(7,194,389)	(2,560,266)
Net loss	$ (7,332,820)	$ (10,968,874)	$ (24,179,786)	$ (29,270,803)
Net loss from continuing operations per basic and diluted common shares outstanding	$ (0.50)	$ (0.71)	$ (1.16)	$ (2.04)
Net loss from discontinued operations per basic and diluted common shares outstanding	$ (0.00)	$ (0.04)	$ (0.49)	$ (0.20)
Net loss per basic and diluted common shares outstanding	$ (0.50)	$ (0.75)	$ (1.65)	$ (2.23)
Basic and diluted weighted average common shares outstanding	14,657,777	14,638,317	14,644,927	13,101,071

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock, at Cost	Total
	Shares	Amount					
Balance at September 30, 2024	14,856,762	$ 148,568	$ 335,125,903	$ (581,519)	$ (294,569,635)	$ (7,806,605)	$ 32,316,712
Share-based compensation	—	—	2,674,105	—	—	—	2,674,105
Release of cumulative foreign currency translation adjustment to discontinued operations	—	—	—	581,519	—	—	581,519
Net loss	—	—	—	—	(8,945,347)	—	(8,945,347)
Balance at December 31, 2024	14,856,762	148,568	337,800,008	—	(303,514,982)	(7,806,605)	26,626,989
Share-based compensation	—	—	2,223,843	—	—	—	2,223,843
Shares issued for consulting services	20,000	200	97,820	—	—	—	98,020
Net loss	—	—	—	—	(7,901,619)	—	(7,901,619)
Balance at March 31, 2025	14,876,762	148,768	340,121,671	—	(311,416,601)	(7,806,605)	21,047,233
Share-based compensation	—	—	1,669,428	—	—	—	1,669,428
Shares issued for consulting services	(8,000)	(80)	(39,128)	—	—	—	(39,208)
Net loss	—	—	—	—	(7,332,820)	—	(7,332,820)
Balance at June 30, 2025	14,868,762	$ 148,688	$ 341,751,971	$ —	$ (318,749,421)	$ (7,806,605)	$ 15,344,633

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock, at Cost	Total
	Shares	Amount					
Balance at September 30, 2023	9,396,640	$ 93,967	$ 284,740,527	$ (581,519)	$ (256,768,209)	$ (7,806,605)	$ 19,678,161
Share-based compensation	—	—	3,406,949	—	—	—	3,406,949
Issuance of shares pursuant to Jefferies Sales Agreement, net of commissions and costs	9,016	90	66,461	—	—	—	66,551
Shares issued in connection with common stock purchase agreement	180,000	1,800	1,659,690	—	—	—	1,661,490
Amortization of deferred costs	—	—	(164,313)	—	—	—	(164,313)
Shares issued in connection with public offering of common stock, net of fees and costs	5,270,833	52,708	35,176,707	—	—	—	35,229,415
Net loss	—	—	—	—	(8,275,981)	—	(8,275,981)
Balance at December 31, 2023	14,856,489	148,565	324,886,021	(581,519)	(265,044,190)	(7,806,605)	51,602,272
Share-based compensation	—	—	3,634,171	—	—	—	3,634,171
Costs of shares issued in connection with public offering of common stock	—	—	(851)	—	—	—	(851)
Net loss	—	—	—	—	(10,025,948)	—	(10,025,948)
Balance at March 31, 2024	14,856,489	148,565	328,519,341	(581,519)	(275,070,138)	(7,806,605)	45,209,644
Share-based compensation	—	—	3,376,406	—	—	—	3,376,406
Issuance of shares pursuant to share-based awards	273	3	3,277	—	—	—	3,280
Net loss	—	—	—	—	(10,968,874)	—	(10,968,874)
Balance at June 30, 2024	14,856,762	$ 148,568	$ 331,899,024	$ (581,519)	$ (286,039,012)	$ (7,806,605)	$ 37,620,456

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended June 30,	
	2025	2024
OPERATING ACTIVITIES		
Net loss	$ (24,179,786)	$ (29,270,803)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	123,532	203,033
Noncash change in right-of-use assets	451,795	575,661
Noncash interest expense, net of interest paid	(168,556)	(69,304)
Gain on extinguishment of debt	(8,624,778)	—
Loss on sale of FC2 business	4,253,405	—
Gain on sale of ENTADFI® assets	(2,154,134)	(1,028,372)
Share-based compensation	6,567,376	10,417,526
Deferred income taxes	(1,915)	227,931
Change in fair value of derivative liabilities	3,138,316	(102,000)
Change in fair value of equity securities	349,078	689,548
Provision for obsolete inventory	—	1,266,167
Other	(14,019)	(2,592)
Changes in current assets and liabilities:		
(Increase) decrease in accounts receivable	(657,253)	2,864,445
Decrease in inventories	863,928	488,704
Increase in prepaid expenses and other assets	(248,677)	(609,130)
Decrease in accounts payable	(1,899,508)	(5,173,463)
(Decrease) increase in accrued expenses and other liabilities	(1,862,377)	2,763,598
Decrease in operating lease liabilities	(488,179)	(557,188)
Net cash used in operating activities	(24,551,752)	(17,316,239)
INVESTING ACTIVITIES		
Proceeds from sale of FC2 business, net of costs	16,320,964	—
Cash proceeds from sale of ENTADFI® assets	2,154,134	110,000
Proceeds from sale of equity securities	393,217	—
Capital expenditures	(1,083)	(95,286)
Net cash provided by investing activities	18,867,232	14,714
FINANCING ACTIVITIES		
Payment on extinguishment of residual royalty agreement liabilities	(4,221,611)	—
Proceeds from sale of shares under common stock purchase agreement	—	1,661,490
Proceeds from sale of shares in public offering, net of commissions and costs	—	35,228,564
Proceeds from sale of shares pursuant to Jefferies Sales Agreement, net of commissions	—	66,551
Proceeds from stock option exercises	—	3,280
Installment payments on premium finance agreement	—	(132,975)
Net cash (used in) provided by financing activities	(4,221,611)	36,826,910
Net (decrease) increase in cash, cash equivalents, and restricted cash	(9,906,131)	19,525,385
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF PERIOD	24,916,285	9,625,494
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF PERIOD	$ 15,010,154	$ 29,150,879
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 332,826	$ 506,907
Schedule of non-cash investing and financing activities:		
Equity securities received for sale of ENTADFI® assets	$ —	$ 918,372
Amortization of deferred costs related to common stock purchase agreement	$ —	$ 164,313

See notes to unaudited condensed consolidated financial statements.

Note 1 – Basis of Presentation and Significant Accounting Policies

The accompanying unaudited interim condensed consolidated financial statements for Veru Inc. ("we," "our," "us," "Veru" or the "Company") have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for reporting of interim financial information. Pursuant to these rules and regulations, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) have been condensed or omitted, although the Company believes that the disclosures made are adequate to make the information not misleading. Accordingly, these statements do not include all the disclosures normally required by U.S. GAAP for annual financial statements and should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations contained in this report and the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2024. The accompanying condensed consolidated balance sheet as of September 30, 2024 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three and nine months ended June 30, 2025 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2025.

The preparation of our unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments (consisting of only normally recurring adjustments) necessary to present fairly the financial position and results of operations as of the dates and for the periods presented.

Principles of consolidation and nature of operations: Veru Inc. is referred to in these notes collectively with its subsidiaries as "we," "our," "us," "Veru" or the "Company." The consolidated financial statements include the accounts of Veru and its wholly owned subsidiaries, Veru International Holdco Inc., Aspen Park Pharmaceuticals, Inc. (APP) and PCHC Limited (formerly known as The Female Health Company Limited); and Veru International Holdco Inc.'s wholly owned subsidiaries, Veru Biopharma UK Limited and Veru Biopharma Europe Limited. The Female Health Company Limited sold the stock of its wholly owned subsidiary, The Female Health Company (UK) plc effective December 30, 2024, as part of the FC2 Business Sale (see Note 3 for additional information). The Female Health Company (UK) plc and The Female Health Company (UK) plc's wholly owned subsidiary, The Female Health Company (M) SDN.BHD (the "Malaysia subsidiary") are included in the consolidated financial statements through December 30, 2024. Veru International Holdco Inc.'s wholly owned subsidiary, Veru Biopharma Netherlands B.V. was dissolved during the quarter ended December 31, 2024 and is included in the consolidated financial statements through the date of dissolution. Veru Biopharma Netherlands B.V. did not have a material impact on the consolidated financial statements. All significant intercompany transactions and accounts have been eliminated in consolidation. The Company is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of cardiometabolic and inflammatory diseases. Our drug development program includes enobosarm, a selective androgen receptor modulator, to improve body composition by augmenting fat loss and preventing muscle loss and physical function decline, in older patients receiving weight reduction drugs, and sabizabulin, a microtubule disruptor, which is being developed as a broad anti-inflammatory agent to reduce inflammation to slow the progression or promote the regression of atherosclerotic cardiovascular disease. The Company had the FC2 Female Condom/FC2 Internal Condom® (FC2), an FDA-approved commercial product for the dual protection against unplanned pregnancy and sexually transmitted infections. The Company sold the FC2 business on December 30, 2024. See Note 3 for additional information. The Company also had ENTADFI® (finasteride and tadalafil) capsules for oral use (ENTADFI), a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021. We sold substantially all of the assets related to ENTADFI on April 19, 2023. See Note 15 for additional information. Most of the Company's net revenues during the nine months ended June 30, 2025 and the three and nine months ended June 30, 2024 were derived from sales of FC2 and are included within discontinued operations. The Company had no net revenues during the three months ended June 30, 2025.

Reclassifications: Certain prior period amounts in the accompanying consolidated financial statements have been reclassified to conform with the current period presentation. The reclassifications had no effect on the results of operations or financial position for any period presented.

Reverse stock split: As described more fully in Note 16, effective August 8, 2025, the Company effected a 1-for-10 reverse stock split for all of its issued and outstanding shares of common stock. All share and per share amounts presented in these condensed consolidated financial statements and accompanying notes and elsewhere in this Quarterly Report on Form 10-Q, including but not limited to shares issued and outstanding, loss per share, and stock options and stock appreciation rights, as well as the dollar amounts of common stock and paid-in-capital, have been retroactively adjusted for all periods presented. There was no change to the total number of shares authorized or par value per share as a result of this reverse stock split.

Other comprehensive loss: Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net loss. Although certain changes in assets and liabilities, such as foreign currency translation adjustments, are reported as a separate component of the equity section of the accompanying unaudited condensed consolidated balance sheets, these items, along with net loss, are components of other comprehensive loss. For the three and nine months ended June 30, 2025 and 2024, comprehensive loss is equivalent to the reported net loss.

Recent accounting pronouncements not yet adopted: In November 2023, the FASB issued Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The ASU expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly reviewed by the chief operating decision maker (CODM) and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. The ASU also allows, in addition to the measure that is most consistent with U.S. GAAP, the disclosure of additional measures of segment profit or loss that are used by the CODM in assessing segment performance and deciding how to allocate resources. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. The ASU is effective for the Company's annual periods for the fiscal year ending September 30, 2025, and subsequent interim periods, with early adoption permitted. The Company is currently evaluating the impact of adopting this ASU on its disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which includes amendments that further enhance income tax disclosures, primarily through standardization and disaggregation of rate reconciliation categories and income taxes paid by jurisdiction. ASU 2023-09 is effective for the Company's annual periods beginning with the fiscal year ending September 30, 2026, with early adoption permitted, and should be applied either prospectively or retrospectively. The Company is currently evaluating the impact of adopting this ASU on its disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires more detailed disclosures about specified categories of expenses (including employee compensation, deprecation, and selling expenses) included in certain expense captions presented on the face of the statement of operations. In January 2025, the FASB issued ASU 2025-01 to clarify the effective date of ASU 2024-03. ASU 2024-03 is effective for the Company's annual reporting periods beginning with the fiscal year ending September 30, 2028, and subsequent interim periods, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2024-03 on its consolidated financial statements and disclosures.

We have reviewed all other recently issued accounting pronouncements and have determined that such standards that are not yet effective will not have a material impact on our financial statements or do not otherwise apply to our operations.

Note 2 – Going Concern

The Company is not profitable and has had negative cash flow from operations. We will need substantial capital to support our drug development and any related commercialization efforts for our drug candidates. Based upon the Company's current operating plan, it estimates that its cash and cash equivalents as of the issuance date of these financial statements are insufficient for the Company to fund operating, investing and financing cash flow needs for the twelve months subsequent to the issuance date of these financial statements. To obtain the capital necessary to fund our operations, we expect to finance our cash needs through public or private equity offerings, debt financing transactions and/or other capital sources. Additional capital may not be available at such times and in such amounts as needed by us to fund our activities on a timely basis.

These uncertainties raise substantial doubt regarding our ability to continue as a going concern for a period of twelve months subsequent to the issuance date of these financial statements. Certain elements of our operating plan to alleviate the conditions that raise substantial doubt, including but not limited to our ability to secure equity financing or other financing alternatives, are outside of our control and cannot be included in management's evaluation under the requirement of ASC 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least twelve months subsequent to the issuance date of these financial statements.

Note 3 – Discontinued Operations

On December 30, 2024, the Company and The Female Health Company Limited (collectively, the "Sellers") entered into a Stock and Asset Purchase Agreement (the "Purchase Agreement") with Clear Future, Inc. (the "Purchaser"). Pursuant to, and subject to the terms and conditions of, the Purchase Agreement, the Purchaser purchased substantially all of the assets (the "FC2 Business Sale") related to the Company's FC2 business, including the stock of The Female Health Company (UK) plc and the Malaysia subsidiary. The Purchaser assumed certain liabilities relating to the FC2 business that are specified in the Purchase Agreement. The transaction closed on December 30, 2024. The Sellers and the Purchaser made customary representations and warranties, and agreed to certain customary covenants, in the Purchase Agreement. Subject to certain exceptions and limitations, each party agreed to indemnify the other for breaches of representations, warranties and covenants and for certain other matters. The Purchase Agreement also specifies that, subject to a $54,000 retention amount, a representations and warranties insurance policy issued to the Purchaser would be the sole and exclusive remedy for breach of representations and warranties (other than certain specified representations and warranties) by the Sellers except in the case of fraud.

The purchase price for the FC2 Business Sale was $18.0 million in cash, subject to adjustment as set forth in the Purchase Agreement. The adjustments to the purchase price in the Purchase Agreement include a customary working capital adjustment in 90 days from closing based on the amount by which certain working capital items at closing are greater or less than a target set forth in the Purchase Agreement. Net proceeds from the FC2 Business Sale are expected to be $16.3 million, which is the $18.0 million purchase price per the Purchase Agreement, net of costs incurred of $1.4 million, estimated purchase price adjustments of $0.1 million, and amounts allocated to the related transition services agreement of $0.2 million but excluding the change of control payment pursuant to the Residual Royalty Agreement of $4.2 million (see Note 8 for additional information). These net proceeds are subject to adjustment as set forth in the Purchase Agreement. The loss on sale of the FC2 business is $4.3 million, which is the difference between estimated net proceeds of $16.3 million and the total carrying value of the FC2 business of $20.6 million. The carrying value of the FC2 business at December 30, 2024 primarily included deferred income tax assets of $12.3 million, accounts receivable of $4.6 million, and inventory of $3.4 million, partially offset by accrued expenses and other current liabilities of $1.5 million.

The Purchase Agreement contains a provision for an adjustment to the purchase price, including an adjustment based on the working capital of the FC2 business as of the closing date. The Purchaser was required to deliver its purchase price adjustment calculation within 90 days after the closing date. The Purchaser delivered its calculation in April 2025 and we have disputed its calculation. This dispute has been submitted to an accounting firm for binding resolution pursuant to the terms of the Purchase Agreement. Resolution of that dispute may result in an adjustment to the net proceeds from the FC2 Business Sale and the loss on sale of the FC2 business.

In connection with the FC2 Business Sale, the Company and the Purchaser entered into a transition services agreement (the "TSA"). Under the terms of the TSA, the Company will provide to the Purchaser, on a transitional basis, certain services or functions, including information technology services, facilitating the transition of assignable and non-assignable contracts, and other corporate and administrative matters. Generally, these services will be provided within six months, with certain services related to the transition of IT and technology systems extending up to 12 months and certain services related to the transition of contracts extending up to 32 months. The transition services will be provided at no fees but the TSA provides for the reimbursement of certain out-of-pocket costs. The Company allocated $0.2 million of the purchase price per the Purchase Agreement to the transition services per the TSA, based on an estimate of the fair value of the services to be provided, which was recognized by the Company over a six month period. The Company estimates that any transition services extending beyond six months have a de minimis value.

Pursuant to the terms of the Purchase Agreement, the Company, the Purchaser, and an escrow agent entered into an Escrow Agreement at closing, pursuant to which the Purchaser deposited $0.4 million of the aggregate purchase price of the FC2 Business Sale into an escrow account established with the escrow agent for the following purposes: (1) $0.3 million, from which any adjustment amount requiring payment from the Company to the Purchaser may be recovered upon final determination of such adjustments pursuant to the Purchase Agreement and (2) $0.1 million for certain indemnity obligations, if any, that arise under the Purchase Agreement, to be held for 18 months from the closing date to the extent not subject to a pending indemnity claim. The amounts held in escrow of $0.4 million as of June 30, 2025 are classified as restricted cash and included within cash, cash equivalents, and restricted cash on the accompanying condensed consolidated balance sheet.

The FC2 Business Sale represented a strategic shift, which had a major effect on our operations and financial results. We have classified all direct revenues, costs and expenses related to the FC2 business within loss from discontinued operations, net of tax, in the condensed consolidated statements of operations for all periods presented. We have not allocated any amounts for shared general and administrative operating support expense to discontinued operations. Additionally, the related assets and liabilities have been reported as assets and liabilities of discontinued operations in our condensed consolidated balance sheet as of September 30, 2024. The assets and liabilities sold as part of the FC2 Business Sale were written off upon the closing of the FC2 Business Sale, and therefore there are no assets and liabilities of discontinued operations in our condensed consolidated balance sheet as of June 30, 2025.

The following table presents results of discontinued operations for the three and nine months ended June 30, 2025 and 2024. Amounts included in discontinued operations during the three months ended June 30, 2025 represent changes in estimates.

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2025	2024	2025	2024
Net revenues	$ —	$ 3,953,870	$ 4,484,591	$ 10,229,897
Cost of sales	—	2,615,855	2,900,514	7,063,131
Gross profit	—	1,338,015	1,584,077	3,166,766
Operating expenses	565	1,731,152	1,111,962	5,050,775
Loss on sale of FC2 business	(9,154)	—	(4,253,405)	—
Operating loss	(9,719)	(393,137)	(3,781,290)	(1,884,009)
Non-operating expenses:				
Interest expense	—	(127,336)	(164,270)	(437,603)
Change in fair value of derivative liabilities	—	83,000	(3,138,316)	102,000
Other expense, net	—	(28,923)	(31,960)	(68,669)
Total non-operating expenses	—	(73,259)	(3,334,546)	(404,272)
Loss before income taxes	(9,719)	(466,396)	(7,115,836)	(2,288,281)
Income tax expense	—	162,422	78,553	271,985
Net loss from discontinued operations, net of taxes	$ (9,719)	$ (628,818)	$ (7,194,389)	$ (2,560,266)

The following table presents the carrying amounts of assets and liabilities of discontinued operations as of September 30, 2024:

	September 30, 2024
Current assets:	
Accounts receivable, net	$ 3,960,305
Inventories, net	4,144,179
Prepaid expenses and other current assets	654,527
Total current assets of discontinued operations	$ 8,759,011
Long-term assets:	
Plant and equipment, net	$ 803,282
Operating lease right-of-use asset	311,150
Deferred income taxes	12,340,237
Other assets	140,356
Total long-term assets of discontinued operations	$ 13,595,025
Current liabilities:	
Accounts payable	$ 777,173
Accrued compensation	185,418
Accrued expenses and other current liabilities	1,390,412
Operating lease liability, short-term portion	328,527
Total current liabilities of discontinued operations	$ 2,681,530
Long-term liabilities:	
Operating lease liability, long-term portion	$ 16,071
Long-term liabilities of discontinued operations	$ 16,071

The cash flows related to discontinued operations have not been segregated and are included in the consolidated statements of cash flows. Total operating and investing cash flows, which includes net proceeds from the sale of FC2, from discontinued operations for the nine months ended June 30, 2025 and 2024 are comprised of the following:

	Nine Months Ended June 30,	
	2025	2024
Total net cash (used in) provided by operating activities from discontinued operations	$ (335,429)	$ 4,108,879
Total net cash provided by investing activities from discontinued operations	$ 16,319,881	$ (95,901)

Note 4 – Fair Value Measurements

ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

Level 1 – Quoted prices for identical instruments in active markets.

Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 – Instruments with primarily unobservable value drivers.

As September 30, 2024, the Company's financial liability measured at fair value on a recurring basis, which consisted of an embedded derivative, was classified within Level 3 of the fair value hierarchy. The liability associated with embedded derivatives represented the fair value of the change of control provision in the Residual Royalty Agreement. During the nine months ended June 30, 2025, the Residual Royalty Agreement was terminated and the embedded derivative was extinguished together with the debt. See Note 8 for additional information.

The following table provides a reconciliation of the beginning and ending liability balance associated with embedded derivatives measured at fair value using significant unobservable inputs (Level 3) as of June 30, 2025 and 2024:

	Nine Months Ended June 30,	
	2025	**2024**
Beginning balance	$ 1,570,000	$ 1,331,000
Change in fair value of derivative liabilities	3,138,316	(102,000)
Extinguishments	(4,708,316)	—
Ending balance	$ —	$ 1,229,000

The gain or loss associated with the change in fair value of the embedded derivatives is included within net loss from discontinued operations on the accompanying unaudited condensed consolidated statements of operations. It is included in discontinued operations because the related debt was required to be repaid as a result of the FC2 Business Sale.

There is no current observable market for these types of derivatives. The Company estimated the fair value of the embedded derivative within the Residual Royalty Agreement by using a scenario-based method, whereby different scenarios were valued and probability weighted. The scenario-based valuation model incorporated transaction details such as the contractual terms of the instrument and assumptions including projected FC2 revenues, expected cash outflows, probability and estimated dates of a change of control, risk-free interest rates and applicable credit risk. A significant increase in projected FC2 revenues or a significant increase in the probability or acceleration of the timing of a change of control event, in isolation, would have resulted in a significantly higher fair value measurement of the liability associated with the embedded derivative. On December 30, 2024, upon the FC2 Business Sale, the Company adjusted the fair value of the embedded derivative to the estimated fair value on that date and included the fair value of the embedded derivative in the carrying amount of debt, used to determine the gain on extinguishment of debt.

The following tables present quantitative information about the inputs and valuation methodologies used to determine the fair value of the embedded derivatives classified in Level 3 of the fair value hierarchy as of December 30, 2024, the date the Residual Royalty Agreement was terminated, and September 30, 2024:

Valuation Methodology	**Significant Unobservable Input**	**December 30, 2024**	**September 30, 2024**
Scenario-Based	Estimated change of control dates	December 2024	March 2025 to March 2027
	Discount rate	N/A	12.1% to 12.3%
	Probability of change of control	100%	60% to 90%

The Company also had an investment in equity securities consisting of 142,749 shares of common stock of ONCO (the "ONCO Common Stock"), which were sold during the quarter ended December 31, 2024 for net proceeds of $0.4 million. The value of the ONCO Common Stock was $0.7 million as of September 30, 2024, which was included in prepaid expenses and other current assets on the accompanying unaudited condensed consolidated balance sheet. The Company recognized a loss from the change in fair value of equity securities of $0.3 million during the nine months ended June 30, 2025 and recognized losses from the change in fair value of equity securities of $0.1 million and $0.7 million during the three and nine months ended June 30, 2024, respectively.

The Company received 3,000 shares of Series A Convertible Preferred Stock (the "ONCO Preferred Stock") of ONCO on October 3, 2023 as part of a settlement of the receivable due on September 30, 2023 related to the sale of ENTADFI. See Note 15 for additional information. The Company elected to measure the ONCO Preferred Stock at fair value in accordance with ASC 825. The investment in the ONCO Preferred Stock was classified within Level 3 of the fair value hierarchy because there is no market for the ONCO Preferred Stock and the fair value was determined using significant unobservable inputs. The fair value of the ONCO Preferred Stock was determined on the date received using a probability-weighted bond plus call option model, which incorporated the stock price of ONCO on the valuation date, expected volatility of 79%, expected term of 3 years, and a discount rate of 35%. The Company also applied a 15% discount for lack of marketability due to the fact that there is no market for the preferred stock and a 60% probability of dissolution. The valuation was determined to be $0.9 million at October 3, 2023. On September 24, 2024, the Company converted all of the shares of ONCO Preferred Stock it held into 142,749 shares of ONCO Common Stock. As of September 30, 2024, the ONCO Common Stock was classified within Level 1 of the fair value hierarchy and the valuation was determined based on the closing price of the ONCO Common Stock.

Note 5 – Accounts Receivable

All of the Company's accounts receivables were included in the assets sold as part of the FC2 Business Sale, except for the Company's accounts receivables due from The Pill Club. The Company has an allowance for credit losses of $3.9 million related to the total amount of receivables due from The Pill Club due to The Pill Club's Chapter 11 bankruptcy, filed on April 18, 2023. The Company has an open claim with The Pill Club bankruptcy estate for these receivables but the timing and amount of recovery, if any, are unknown at this time.

Note 6 – Fixed Assets

We record equipment, furniture and fixtures, and leasehold improvements at historical cost. Expenditures for maintenance and repairs are recorded to expense. Depreciation and amortization are primarily computed using the straight-line method. Depreciation and amortization are computed over the estimated useful lives of the respective assets. Leasehold improvements are depreciated on a straight-line basis over the lesser of the remaining lease term or the estimated useful lives of the improvements.

Property and equipment consisted of the following at June 30, 2025 and September 30, 2024:

	Estimated Useful Life (in years)	June 30, 2025	September 30, 2024
Property and equipment:			
Office equipment, furniture and fixtures	3 - 7	765,911	765,911
Leasehold improvements	8	199,532	199,532
Total property and equipment		965,443	965,443
Less: accumulated depreciation and amortization		(572,062)	(484,071)
Property and equipment, net		$ 393,381	$ 481,372

Depreciation expense was approximately $29,000 and $32,000 for the three months ended June 30, 2025 and 2024, respectively, and approximately $88,000 and $95,000 for the nine months ended June 30, 2025 and 2024, respectively.

Note 7 – Goodwill

The carrying amount of goodwill at June 30, 2025 and September 30, 2024 was $6.9 million. There was no change in the balance during the nine months ended June 30, 2025 and 2024.

Note 8 – Debt

SWK Residual Royalty Agreement

On March 5, 2018, the Company entered into a Credit Agreement (as amended, the "Credit Agreement") with the financial institutions party thereto from time to time (the "Lenders") and SWK Funding LLC, as agent for the Lenders (the "Agent"), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders provided the Company with a term loan of $10.0 million, which was advanced to the Company on the date of the Credit Agreement. The Company repaid the loan and return premium specified in the Credit Agreement in August 2021, and as a result has no further obligations under the Credit Agreement. The Agent has released its security interest in Company collateral previously pledged to secure its obligations under the Credit Agreement.

In connection with the Credit Agreement, the Company and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (as amended, the "Residual Royalty Agreement"), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2. The Residual Royalty Agreement will terminate upon (i) a change of control or sale of the FC2 business and the payment by the Company of the amount due in connection therewith pursuant to the Residual Royalty Agreement, or (ii) mutual agreement of the parties. If a change of control or sale of the FC2 business occurs, the Agent will receive a payment that is the greater of (A) $2.0 million or (B) the product of (x) 5% of the product revenue from net sales of FC2 for the most recently completed 12-month period multiplied by (y) five.

In connection with the closing of the FC2 Business Sale, on December 30, 2024, the Company made a change of control payment of $4.2 million to SWK pursuant to the Residual Royalty Agreement, and upon such payment, the Residual Royalty Agreement terminated in accordance with its terms. The Company recognized a gain on extinguishment of debt of $8.6 million for the difference between the change of control payment of $4.2 million and the net carrying amount of the extinguished debt, which included an embedded derivative for the change of control provision at fair value. See Note 4 for additional information.

For accounting purposes, the $10.0 million advance under the Credit Agreement was allocated between the Credit Agreement and the Residual Royalty Agreement on a relative fair value basis. A portion of the amount allocated to the Residual Royalty Agreement, equal to the fair value of the respective change of control provisions, was allocated to the embedded derivative liability. The derivative liability was adjusted to fair market value at each reporting period.

At June 30, 2025 and September 30, 2024, the Residual Royalty Agreement liability consisted of the following:

	June 30, 2025	September 30, 2024
Residual royalty agreement liability, fair value at inception	$ 346,000	$ 346,000
Add: accretion of liability using effective interest rate	13,149,689	12,985,419
Less: cumulative payments	(5,357,616)	(5,024,790)
Less: extinguishments	(8,138,073)	—
Residual royalty agreement liability, excluding embedded derivative liability	—	8,306,629
Add: embedded derivative liability at fair value (see Note 4)	—	1,570,000
Total residual royalty agreement liability	—	9,876,629
Residual royalty agreement liability, short-term portion	—	(1,025,837)
Residual royalty agreement liability, long-term portion	$ —	$ 8,850,792

Premium Finance Agreement

On November 1, 2022, the Company entered into a Premium Finance Agreement to finance $1.4 million of its directors and officers liability insurance premium at an annual percentage rate of 6.3%. The financing is payable in eleven monthly installments of principal and interest, beginning on December 1, 2022. The balance of the insurance premium liability was $0.1 million as of September 30, 2023. The last payment was made in October 2023 and there is no balance outstanding as of June 30, 2025 or September 30, 2024.

Note 9 – Stockholders' Equity

Preferred Stock

The Company has 5,000,000 authorized shares designated as Class A Preferred Stock with a par value of $0.01 per share. There are 1,040,000 shares of Class A Preferred Stock – Series 1 authorized; 1,500,000 shares of Class A Preferred Stock – Series 2 authorized; 700,000 shares of Class A Preferred Stock – Series 3 authorized; and 548,000 shares of Class A Preferred Stock – Series 4 (the "Series 4 Preferred Stock") authorized. There were no shares of Class A Preferred Stock of any series issued and outstanding at June 30, 2025 and September 30, 2024. The Company has 15,000 authorized shares designated as Class B Preferred Stock with a par value of $0.50 per share. There were no shares of Class B Preferred Stock issued and outstanding at June 30, 2025 and September 30, 2024, and there was no activity during the three and nine months ended June 30, 2025 and 2024.

Shelf Registration Statement

In March 2023, the Company filed a shelf registration statement on Form S-3 (File No. 333-270606) with a capacity of $200 million, which was declared effective by the SEC on April 14, 2023. As of June 30, 2025, $109.0 million remains available under that shelf registration statement.

Common Stock

In March 2025, the Company issued 20,000 shares of common stock to a third party consultant for services to be provided over a six month period totaling $98,000. In June 2025, the consulting agreement was terminated and 8,000 shares of common stock were returned to the Company.

On December 18, 2023, we completed an underwritten public offering of 5,270,833 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of $7.20 per share. Net proceeds to the Company from this offering were approximately $35.2 million after deducting underwriting discounts and commissions and costs incurred by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-270606).

Lincoln Park Capital Fund LLC Purchase Agreement

On May 2, 2023, the Company entered into a purchase agreement (as amended, the "Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park up to $100.0 million of shares (the "Purchase Shares") of the Company's common stock over the 36 month term of the Lincoln Park Purchase Agreement. The Lincoln Park Purchase Agreement may be terminated by the Company at any time, at its sole discretion, without any cost or penalty, by giving one business day notice to Lincoln Park. Lincoln Park has covenanted not to in any manner whatsoever enter into or effect, directly or indirectly, any short selling or hedging of the Company's common stock. On December 13, 2023, the Company entered into an amendment (the "Lincoln Park Amendment") with Lincoln Park to reduce the amount of shares of common stock subject to the registration from $100.0 million to $50.0 million until the Company has sold at least $50.0 million of shares of common stock under the Lincoln Park Purchase Agreement. The issuance of shares of common stock pursuant to the Lincoln Park Purchase Agreement up to $50.0 million have been registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 3, 2023, as further supplemented on December 13, 2023 to reflect the Lincoln Park Amendment.

Under the Lincoln Park Purchase Agreement, the Company has the right, but not the obligation, on any business day selected by the Company (the "Purchase Date"), provided that on such day the closing sale price per share of the Company's common stock is not below $2.50 per share, to require Lincoln Park to purchase up to 22,500 shares of the Company's common stock (the "Regular Purchase Amount") at the Purchase Price (as defined below) per purchase notice (each such purchase, a "Regular Purchase") provided, however, that (1) the limit on the Regular Purchase Amount will be increased to 25,000 shares, if the closing sale price of the Company's common stock on the applicable Purchase Date is not below $60.00 and to 27,500 shares, if the closing sale price of the Company's common stock on the applicable Purchase Date is not below $80.00. Lincoln Park's committed obligation under each Regular Purchase shall not exceed $2,500,000 or 200,000 Purchase Shares per each Regular Purchase. The share and per share amounts in the Lincoln Park Purchase Agreement are subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Lincoln Park Purchase Agreement. The purchase price for Regular Purchases (the "Purchase Price") shall be equal to the lesser of: (i) the lowest sale price of the Company's common stock during the Purchase Date, or (ii) the average of the three lowest closing sale prices of the Company's common stock on the 10 consecutive business days ending on the business day immediately preceding such Purchase Date. The Company shall have the right to submit a Regular Purchase notice to Lincoln Park as often as every business day. A Regular Purchase notice is delivered to Lincoln Park after the market has closed (i.e., after 4:00 P.M. Eastern Time) so that the Purchase Price is always fixed and known at the time the Company elects to sell shares to Lincoln Park.

In addition to Regular Purchases and provided that the Company has directed a Regular Purchase in full, the Company in its sole discretion may require Lincoln Park on each Purchase Date to purchase on the following business day ("Accelerated Purchase Date") up to the lesser of (i) three times the number of shares purchased pursuant to such Regular Purchase or (ii) 30% of the trading volume on the Accelerated Purchase Date (the "Accelerated Purchase") at a purchase price equal to the lesser of 97% of (i) the closing sale price on the Accelerated Purchase Date, or (ii) the Accelerated Purchase Date's volume weighted average price (the "Accelerated Purchase Price"). The Company may also direct Lincoln Park, on any business day on which an Accelerated Purchase has been completed and all of the shares to be purchased thereunder have been properly delivered to Lincoln Park in accordance with the Lincoln Park Purchase Agreement, to make additional purchases upon the same terms as an Accelerated Purchase (an "Additional Accelerated Purchase").

The purchase price of Regular Purchases, Accelerated Purchases and Additional Accelerated Purchases and the minimum closing sale price for a Regular Purchase will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction occurring during the business days used to compute the purchase price. The aggregate number of shares that the Company can sell to Lincoln Park under the Lincoln Park Purchase Agreement may in no case exceed 1,767,850 shares of the Company's common stock (which is equal to approximately 19.99% of the shares of the Company's common stock outstanding immediately prior to the execution of the Lincoln Park Purchase Agreement) (the "Exchange Cap"), unless (i) shareholder approval is obtained to issue Purchase Shares above the Exchange Cap, in which case the Exchange Cap will no longer apply, or (ii) the average price of all applicable sales of the Company's common stock to Lincoln Park under the Lincoln Park Purchase Agreement equals or exceeds $12.60 per share (which represents the Minimum Price, as defined under Nasdaq Listing Rule 5635(d), on the Nasdaq Capital Market immediately preceding the signing of the Lincoln Park Purchase Agreement, such that the transactions contemplated by the Lincoln Park Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules).

During the nine months ended June 30, 2025, we did not sell any shares under the Lincoln Park Purchase Agreement. During the nine months ended June 30, 2024, we sold 180,000 shares of common stock to Lincoln Park resulting in proceeds to the Company of $1.7 million. As a result of these sales, we recorded approximately $164,000 of deferred costs to additional paid-in capital. Since inception of the Lincoln Park Purchase Agreement through June 30, 2025, we have sold 302,500 shares of common stock to Lincoln Park resulting in proceeds to the Company of $3.1 million.

In consideration for entering into the Lincoln Park Purchase Agreement, concurrently with the execution of the Lincoln Park Purchase Agreement, the Company issued 80,000 shares of the Company's common stock to Lincoln Park. The shares of common stock issued as consideration were valued at $1.0 million, based on the closing price per share of the Company's common stock on the date the shares were issued. This amount and related expenses of $57,000, which total approximately $1.1 million, were recorded as deferred costs. The unamortized deferred costs related to the Lincoln Park Purchase Agreement of $870,000 as of June 30, 2025 and September 30, 2024 are included in other assets on the accompanying unaudited condensed consolidated balance sheets.

At-the-Market Sale Agreement

On May 12, 2023, the Company entered into an Open Market Sale Agreement℠ (the "Jefferies Sales Agreement") with Jefferies LLC ("Jefferies"), as sales agent, pursuant to which the Company could issue and sell, from time to time, through Jefferies, shares of the Company's common stock, with an aggregate value of up to $75 million (not to exceed the lesser of 3,960,907 shares of common stock or the number of authorized, unissued and available shares of common stock at any time). Shares of common stock offered and sold pursuant to the Jefferies Sale Agreement have been registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 12, 2023. On August 19, 2024, the Company delivered notice to Jefferies to terminate the Jefferies Sales Agreement, which was effective on September 3, 2024. As a result of the termination of the Jefferies Sales Agreement, the Company will not issue or sell any additional shares of common stock under the Jefferies Sales Agreement.

During the nine months ended June 30, 2024, we sold 9,016 shares of common stock under the Jefferies Sales Agreement resulting in net proceeds to the Company of $67,000.

Note 10 – Share-based Compensation

We allocate share-based compensation expense to selling, general and administrative expense and research and development expense based on the award holder's employment function. For the three and nine months ended June 30, 2025 and 2024, we recorded share-based compensation expenses as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2025	2024	2025	2024
Selling, general and administrative	$ 1,290,912	$ 2,310,153	$ 4,914,586	$ 7,005,004
Research and development	378,516	758,532	1,662,839	2,077,235
Discontinued operations	—	307,721	(10,049)	1,335,287
Share-based compensation	$ 1,669,428	$ 3,376,406	$ 6,567,376	$ 10,417,526

We have issued share-based awards to employees and non-executive directors under the Company's approved equity plans. Upon the exercise of share-based awards, new shares are issued from authorized common stock.

Equity Plans

In June 2022, the Company's board of directors adopted the Company's 2022 Employment Inducement Equity Incentive Plan (the "Inducement Plan"). The Inducement Plan is a non-shareholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The Inducement Plan is used exclusively for the issuance of equity awards to certain new hires who satisfied the requirements to be granted inducement grants under Nasdaq rules as an inducement material to the individual's entry into employment with the Company. The Company reserved 400,000 shares of common stock under the Inducement Plan and as of June 30, 2025, 400,000 shares are available for issuance under the Inducement Plan.

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (as amended, the "2018 Plan"). On March 13, 2025, the Company's stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 2.6 million. As of June 30, 2025, 813,539 shares remain available for issuance under the 2018 Plan.

In July 2017, the Company's stockholders approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). A total of 470,000 shares are authorized for issuance under the 2017 Plan. As of June 30, 2025, 10,168 shares remain available for issuance under the 2017 Plan. The 2017 Plan replaced the Company's 2008 Stock Incentive Plan (the "2008 Plan"), and no further awards will be made under the 2008 Plan.

Stock Options

Each option grants the holder the right to purchase from us one share of our common stock at a specified price, which is generally the closing price per share of our common stock on the date the option is issued. Options generally vest on a pro-rata basis on each anniversary of the issuance date within three years of the date the option is issued. Options may be exercised after they have vested and prior to the specified expiry date provided applicable exercise conditions are met, if any. The expiry date can be for periods of up to ten years from the date the option is issued. The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions established at that time. The Company accounts for forfeitures as they occur and does not estimate forfeitures as of the option grant date. The Company recognized a reduction in share-based compensation expense for stock options forfeited during the period of $36,000 and $0.2 million during the three months ended June 30, 2025 and 2024, respectively, and a reduction of $0.5 million and $1.5 million during the nine months ended June 30, 2025 and 2024, respectively.

The following table outlines the weighted average assumptions for options granted during the three and nine months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2025	2024	2025	2024
Weighted Average Assumptions:				
Expected volatility	115.3%	109.6%	114.6%	108.9%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Risk-free interest rate	4.0%	4.5%	4.0%	4.5%
Expected term (in years)	6.0	6.0	6.0	6.0
Fair value of options granted	$ 4.32	$ 13.74	$ 4.59	$ 12.16

During the three and nine months ended June 30, 2025 and 2024, the Company used historical volatility of our common stock over a period equal to the expected life of the options to estimate their fair value. The dividend yield assumption is based on the Company's recent history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining term.

The following table summarizes the stock options outstanding and exercisable at June 30, 2025:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2024	1,846,243	$ 45.92		
Granted	184,000	$ 5.36		
Exercised	—	$ —		
Forfeited and expired	(78,175)	$ 48.70		
Outstanding at June 30, 2025	1,952,068	$ 41.98	5.49	$ 136,465
Exercisable at June 30, 2025	1,553,904	$ 46.88	4.61	$ 8,180

The aggregate intrinsic values in the table above are before income taxes and represent the number of in-the-money options outstanding or exercisable multiplied by the closing price per share of the Company's common stock on the last trading day of the quarter ended June 30, 2025 of $5.82, less the respective weighted average exercise price per share at period end.

As of June 30, 2025, the Company had unrecognized compensation expense of approximately $4.1 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 2.0 years.

Stock Appreciation Rights

In connection with the closing of our acquisition of Aspen Park Pharmaceuticals, Inc. on October 31, 2016 (the "APP Acquisition"), the Company issued stock appreciation rights based on 5,000 and 14,000 shares of the Company's common stock to an employee and an outside director, respectively, that vested on October 31, 2018. The stock appreciation rights have a ten-year term and an exercise price per share of $9.50, which was the closing price per share of the Company's common stock as quoted on Nasdaq on the trading day immediately preceding the date of the completion of the APP Acquisition. Upon exercise, the stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of June 30, 2025, vested stock appreciation rights based on 5,000 shares of common stock remain outstanding.

Note 11 – Leases

The Company has operating leases for its office and office equipment. The Company's leases have remaining lease terms of less than three years to less than six years. Certain of our lease agreements include variable lease payments for common area maintenance, real estate taxes, and insurance or based on usage for certain equipment leases. For one of our office space leases, the Company entered into a sublease, for which it received sublease income. Sublease income was recognized as a reduction to operating lease costs as the sublease is outside of the Company's normal business operations. This lease, and the related sublease, terminated on October 31, 2023. The Company does not have any leases that have not yet commenced as of June 30, 2025.

The components of the Company's lease costs were as follows for the three and nine months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2025	2024	2025	2024
Operating lease cost	$ 186,233	$ 186,233	$ 558,699	$ 560,689
Short-term lease cost	2,541	2,541	7,623	7,623
Variable lease cost	5,440	1,318	54,009	18,263
Sublease income	—	—	—	(15,148)
Total lease cost	$ 194,214	$ 190,092	$ 620,331	$ 571,427

The Company paid cash of $572,000 and $565,000 for amounts included in the measurement of operating lease liabilities during the nine months ended June 30, 2025 and 2024, respectively.

The Company's operating lease right-of-use assets and the related lease liabilities are presented as separate line items on the accompanying unaudited condensed consolidated balance sheets as of June 30, 2025 and September 30, 2024.

Other information related to the Company's leases as of June 30, 2025 and September 30, 2024 was as follows:

	June 30, 2025	September 30, 2024
Operating Leases		
Weighted-average remaining lease term (years)	4.7	5.4
Weighted-average discount rate	7.1%	7.1%

The Company's lease agreements do not provide a readily determinable implicit rate. Therefore, the Company estimates its incremental borrowing rate based on information available at lease commencement in order to discount lease payments to present value.

Note 12 – Contingent Liabilities

The testing, manufacturing and marketing of consumer products by the Company and the clinical testing of our product candidates entail an inherent risk that product liability claims will be asserted against the Company. The Company maintains product liability insurance coverage for claims arising from the use of its products. The coverage amount is currently $10.0 million.

Legal Proceedings

On December 5, 2022, a putative class action complaint was filed in federal district court for the Southern District of Florida (Ewing v. Veru Inc., et al., Case No. 1:22-cv-23960) against the Company and Mitchell Steiner, its Chairman, CEO and President, and Michele Greco, its CFO (the "Ewing Lawsuit"). The First Amended Class Action Complaint, filed on September 15, 2023 by purported stockholders Dr. Myo Thant and Karen Brounstein, alleges that certain public statements about sabizabulin as a treatment for COVID-19 between March 1, 2021 and March 2, 2023 violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and seeks monetary damages.

On July 7, 2023, Anthony Maglia, a purported stockholder, filed a derivative action in the Circuit Court for the Eleventh Judicial Circuit, Miami-Dade County, Florida (Maglia v. Steiner et al., Case No. 2023-019406-CA-01), against the Company as a nominal defendant, and Company officers and directors Mitchell S. Steiner, Michele Greco, Harry Fisch, Mario Eisenberger, Grace S. Hyun, Lucy Lu and Michael L. Rankowitz (the "Maglia Lawsuit"). The Maglia lawsuit asserts claims for breach of fiduciary duty, waste of corporate assets, and unjust enrichment primarily in connection with the issues and claims asserted in the Ewing Lawsuit. The Maglia Lawsuit seeks to direct the Company to improve its corporate governance and internal procedures, and also seeks monetary damages, injunctive relief, restitution, and an award of reasonable fees and expenses.

On September 1, 2023, Anthony Franchi, a purported stockholder, filed a derivative action in the United States District Court for the Eastern District of Wisconsin (Franchi v. Steiner et al., Case No. 2:23-CV-01164), against the Company as a nominal defendant, and Company officers and directors Mitchell S. Steiner, Mario Eisenberger, Harry Fisch, Michael L. Rankowitz, Grace Hyun, Lucy Lu, and Michele Greco (the "Franchi Lawsuit"). The Franchi lawsuit asserts claims for breach of fiduciary duty and unjust enrichment primarily in connection with the issues and claims asserted in the Ewing Lawsuit. The Franchi Lawsuit seeks to direct the Company to improve its corporate governance and internal procedures, and also seeks monetary damages, restitution, and an award of reasonable fees and expenses. On November 8, 2023, this action was consolidated with the Renbarger action, discussed below.

On September 28, 2023, Philip Renbarger, a purported stockholder, filed a derivative action in the United States District Court for the Eastern District of Wisconsin (Renbarger v. Steiner et al., Case No. 2:23-CV-01291), against the Company as a nominal defendant, and Company officers and directors Mitchell Steiner, Mario Eisenberger, Harry Fisch, Michael L. Rankowitz, Grace S. Hyun, Lucy Lu, and Michele Greco (the "Renbarger Lawsuit"). The Renbarger lawsuit asserts claims for breach of fiduciary duty, aiding and abetting, gross mismanagement, waste of corporate assets, and unjust enrichment primarily in connection with the issues and claims asserted in the Ewing Lawsuit. The Renbarger Lawsuit seeks to direct the Company to improve its corporate governance and internal procedures, and also seeks monetary damages and an award of reasonable fees and expenses. On November 8, 2023, the Renbarger Lawsuit was consolidated with the Franchi Lawsuit, discussed above.

On October 9, 2023, Mohamed Alshourbagy, a purported stockholder, filed a derivative action in the United States District Court for the Southern District of Florida (Alshourbagy v. Steiner et al., Case No. 1:23-cv-23846), against the Company as a nominal defendant, and Company officers and directors Mitchell S. Steiner, Mario A. Eisenberger, Harry D. Fisch, Michael L. Rankowitz, Grace S. Hyun, Lucy Lu, and Michele Greco (the "Alshourbagy Lawsuit"). The Alshourbagy lawsuit asserts claims for breach of fiduciary duty and contribution primarily in connection with the issues and claims asserted in the Ewing Lawsuit. The Alshourbagy Lawsuit seeks to direct the Company to improve its corporate governance and internal procedures, and also seeks monetary damages, injunctive relief, restitution, and an award of reasonable fees and expenses.

On September 30, 2024, June Ovadias, a purported stockholder, filed a derivative action in the United States District Court for the Western District of Wisconsin (Ovadias v. Steiner et al., Case *No.* 3:24-cv-00676), against the Company as a nominal defendant, and Company officers and directors Mitchell S. Steiner, Michele Greco, Mario A. Eisenberger, Harry D. Fisch, Grace S. Hyun, Lucy Lu, and Michael L. Rankowitz (the "Ovadias Lawsuit"). The Ovadias lawsuit asserts claims for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and contribution primarily in connection with the issues and claims asserted in the Ewing Lawsuit. The Ovadias Lawsuit seeks to direct the Company to improve its corporate governance and internal procedures, and also seeks monetary damages, restitution, and an award of reasonable fees and expenses

The Ewing Lawsuit, Maglia Lawsuit, Franchi Lawsuit, Renbarger Lawsuit, Alshourbagy Lawsuit and the Ovadias Lawsuit are collectively referred to as the "Shareholder Litigation." At this time, the Company is unable to estimate potential losses, if any, related to the Shareholder Litigation.

On August 5, 2025, the Purchaser filed a complaint in the Superior Court of the State of Delaware (Clear Future, Inc. v. Veru Inc., Case No. N25C-08-066 EMD) against the Company (the "Clear Future Lawsuit"). The complaint alleges that the Company breached certain representations and warranties in the Purchase Agreement for the FC2 Business Sale and otherwise made false representations relating to a customer relationship. The complaint makes claims for fraud, breach of representations and warranties, indemnification and breach of contract. At this time, the Company is unable to estimate potential losses, if any, related to the Clear Future Lawsuit.

License and Purchase Agreements

From time to time, we license or purchase rights to technology or intellectual property from third parties. These licenses and purchase agreements require us to pay upfront payments as well as development or other payments upon successful completion of preclinical, clinical, regulatory or revenue milestones. In addition, these agreements may require us to pay royalties on sales of products arising from the licensed or acquired technology or intellectual property. Because the achievement of future milestones is not reasonably estimable, we have not recorded a liability on the accompanying unaudited condensed consolidated financial statements for any of these contingencies.

Resolution of Commercial Dispute

A supplier claimed that we owed approximately $10 million for products and services relating to our efforts to commercialize sabizabulin under an emergency use authorization. We disputed the amount owed and on February 29, 2024, we entered into an agreement with the supplier, which resolves the dispute by modifying the payment terms under the original agreement. The Company agreed to pay $8.3 million, with $2.3 million payable upon execution of the agreement, $3.5 million payable in equal monthly installments over 48 months, and $2.5 million payable (the "Balance") on or prior to December 31, 2025 out of the proceeds of certain payments that may be received by the Company from ONCO on promissory notes due in April 2024 and September 2024. If all or any portion of the Balance remains unpaid as of December 31, 2025, the Company shall pay the amount of the unpaid Balance in equal monthly installments over 24 months, commencing in January 2026. $1.4 million is included in accounts payable and $2.8 million is included in other liabilities related to this agreement as of June 30, 2025 on the accompanying condensed consolidated balance sheet.

Note 13 – Income Taxes

The Company accounts for income taxes using the liability method, which requires the recognition of deferred tax assets or liabilities for the tax-effected temporary differences between the financial reporting and tax bases of its assets and liabilities, and for net operating loss (NOL) and tax credit carryforwards.

A reconciliation of income tax expense, which is zero as a result of the Company's full valuation allowance for deferred tax assets, and the amount computed by applying the U.S. statutory rate of 21% to loss from continuing operations is as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2025	2024	2025	2024
Income tax benefit at U.S. federal statutory rates	$ (1,537,851)	$ (2,171,412)	$ (3,566,933)	$ (5,609,213)
State income tax benefit, net of federal benefit	(403,409)	(168,129)	(560,518)	(434,313)
Non-deductible expenses	58,150	2,000	78,763	2,708
U.S. research and development tax credit	6,722	1,109,784	(421,986)	692,784
Effect of change in effective tax rate	554,430	—	554,430	—
Change in valuation allowance	1,321,958	1,227,757	3,916,244	5,348,034
Income tax expense	$ —	$ —	$ —	$ —

Note 14 – Net Loss Per Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period after giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of the incremental common shares issuable upon the exercise of stock options and stock appreciation rights. Due to our net loss for the periods presented, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. See Note 10 for a discussion of our potentially dilutive common shares.

Note 15 – Sale of ENTADFI Assets

On April 19, 2023, the Company entered into an asset purchase agreement (the "Asset Purchase Agreement") to sell substantially all of the assets related to ENTADFI® (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021, with ONCO. The transaction closed on April 19, 2023. The purchase price for the transaction was $20.0 million, consisting of $6.0 million paid at closing, $4.0 million payable pursuant to a promissory note due on September 30, 2023, $5.0 million payable pursuant to a promissory note due on April 19, 2024 (the "April 2024 Promissory Note"), and $5.0 million payable pursuant to a promissory note due on September 30, 2024 (the "September 2024 Promissory Note" and, together with the April 2024 Promissory Note, the "ONCO Promissory Notes"), plus up to $80.0 million based on ONCO's net revenues from ENTADFI after closing (the "Milestone Payments"). The Company believes the probability of receiving any Milestone Payments is remote.

On September 29, 2023, the Company entered into an Amendment to the Asset Purchase Agreement (the "Amendment") providing that the promissory note for the $4.0 million installment of the purchase price due September 30, 2023 would be deemed paid and fully satisfied upon (1) the payment to the Company of the sum of $1.0 million in immediately available funds on September 29, 2023 and (2) the issuance to the Company by October 3, 2023 of 3,000 shares of ONCO Preferred Stock. The Company received payment of $1.0 million on September 29, 2023 and the ONCO Preferred Stock on October 3, 2023, which the Company determined had a fair value as of October 3, 2023 of $0.9 million. The ONCO Preferred Stock was convertible by the Company at any time and from time to time from and after one year from the date of issuance of the ONCO Preferred Stock into that number of shares of the Purchaser's common stock determined by dividing the stated value of $1,000 per share by the Conversion Price of $0.5254 per share. The ONCO Preferred Stock issued to the Company was initially convertible into an aggregate of approximately 5,709,935 shares of ONCO Common Stock, subject to certain shareholder approval limitations. Shareholder approval was obtained on September 5, 2024. Effective September 24, 2024, ONCO effected a reverse stock split of all the outstanding shares of ONCO Common Stock at a ratio of one-for-forty (1:40). Proportional adjustments were made to the number of shares of ONCO Common Stock issuable upon conversion of the ONCO Preferred Stock, such that the ONCO Preferred Stock was convertible into 142,749 shares of ONCO Common Stock. On September 24, 2024, the Company converted all of its ONCO Preferred Stock into 142,749 shares of ONCO Common Stock and during the nine months ended June 30, 2025, the Company sold all 142,749 shares of ONCO Common Stock for net proceeds of $0.4 million.

On April 24, 2024, the Company entered into a Forbearance Agreement (the "Forbearance Agreement") with ONCO, relating to certain defaults under the ONCO Promissory Notes. Pursuant to the Forbearance Agreement, (a) ONCO agreed to make a payment of $50,000 of the principal payable under the April 2024 Promissory Note not later than April 29, 2024, which was paid on April 25, 2024, and (b) the Company agreed, subject to the terms and conditions set forth in the Forbearance Agreement, to forbear from exercising its rights and remedies on account of the failure by ONCO to pay the amounts due under the April 2024 Promissory Note on the due date of April 19, 2024, and on account of any failure by ONCO to make any mandatory repayment under the ONCO Promissory Notes that may have become due or may become due in connection with certain transactions relating to ONCO's acquisition of Proteomedix AG, in each case for a period (the "April 2024 Forbearance Period") commencing on April 24, 2024 and ending on the earlier of (a) March 31, 2025 and (b) the occurrence of an Event of Default (as defined in the Forbearance Agreement). The Company also agreed that during the April 2024 Forbearance Period the default provision in the ONCO Promissory Notes relating to insolvency of ONCO will not apply.

ONCO agreed in the Forbearance Agreement to make the following required payments during the April 2024 Forbearance Period towards the remaining principal balance of the April 2024 Promissory Note: (1) monthly payments equal to 15% of cash receipts of ONCO or its subsidiaries from certain sale or licensing revenues or payments; and (2) payment of 10% of the net proceeds from certain financing or other transactions outside the ordinary course of business completed by ONCO or any of its subsidiaries during the April 2024 Forbearance Period.

On September 19, 2024, the Company entered into an Amended and Restated Forbearance Agreement and Amendment to September 2024 Note (the "Amended Forbearance Agreement") with ONCO. The Amended Forbearance Agreement amends and restates the entirety of the Forbearance Agreement.

Pursuant to the Amended Forbearance Agreement, the April 2024 Forbearance Period continued to end on the earlier of (a) March 31, 2025 and (b) the occurrence of an Event of Default (as defined in the Amended Forbearance Agreement). The Amended Forbearance Agreement extends the due date for the September Promissory Note until the earlier to occur of: (i) June 30, 2025 or (ii) the occurrence of any Event of Default under the Amended Forbearance Agreement. The Amended Forbearance Agreement also effected certain modifications to the payment terms in the Forbearance Agreement and amended certain terms of the September 2024 Promissory Note as summarized below.

The Borrower agreed in the Amended Forbearance Agreement to make the following required payments (the "Required Payments") during the April 2024 Forbearance Period first to accrued and unpaid interest under the April 2024 Promissory Note and then any remainder to the outstanding principal amount of the April 2024 Promissory Note:

- monthly payments equal to 25% (increased from 15% in the Original Forbearance Agreement) of cash receipts of the Borrower or its subsidiaries from certain sale or licensing revenues or payments, which increased amount shall begin on October 20, 2024 for cash receipts in September 2024; and
- payment of 20% (increased from 10% in the Original Forbearance Agreement) of the net proceeds from certain financing or other transactions outside the ordinary course of business completed by the Borrower or any of its subsidiaries during the April 2024 Forbearance Period, which increased amount will begin for any net proceeds received after September 19, 2024.

The remaining balance of the April 2024 Promissory Note will be due at the end of the April 2024 Forbearance Period.

The Borrower and the Company also agreed to the following amendments to the September 2024 Promissory Note in the Amended Forbearance Agreement:

- As noted above, an extension of the maturity date to June 30, 2025.
- The accrual of interest at the rate of 10% per annum on any unpaid principal balance of the September 2024 Promissory Note commencing on October 1, 2024 through the date that the outstanding principal balance under the September 2024 Promissory Note is paid in full.
- Any amounts owed on the September 2024 Promissory Note, including but not limited to unpaid principal and accrued interest, will be paid in cash or, upon the mutual written consent of the Borrower and the Company, in shares of the Borrower's common stock or a combination of cash and the Borrower's common stock.
- Following full repayment of all principal and interest under the April 2024 Promissory Note, the Borrower will make the Required Payments first towards accrued and unpaid interest under the September 2024 Promissory Note and then towards the remaining principal balance payable under the September 2024 Promissory Note.
- If the aggregate unpaid principal outstanding under the April 2024 Promissory Note and the September 2024 Promissory Note and all accrued and unpaid interest thereon is repaid in cash on or before December 31, 2024, then the total principal balance under the September 2024 Promissory Note that will be payable by the Borrower in satisfaction of its obligations under the September 2024 Promissory Note will be reduced from $5,000,000 to $3,500,000.

The Company and ONCO entered into a Waiver and Amendment No. 1 to the Forbearance Agreement, dated November 26, 2024, that (x) extended the time for the payment by ONCO of the monthly payment of a percentage of its cash receipts referenced above and conditioned the payment of those amounts upon ONCO being able to raise capital of at least $97,000 and (y) increased the percentage of the net proceeds from certain financings payable to the Company from 20% to 25%. The Company and ONCO entered into a Limited Waiver, dated March 31, 2025, to extend the maturity date of the April 2024 Promissory Note to April 14, 2025; the Company and ONCO entered into a Limited Waiver, dated April 23, 2025, to extend the maturity date of the April 2024 Promissory Note to June 30, 2025; the Company and ONCO entered into a Limited Waiver, dated June 30, 2025, to extend the maturity dates of the April 2024 Promissory Note and the September 2024 Promissory Note to July 31, 2025; and the Company and ONCO entered into a Limited Waiver, dated July 31, 2025, to extend the maturity dates of the April 2024 Promissory Note and the September 2024 Promissory Note to August 14, 2025. On August 7, 2025, the Company and ONCO entered into an Amended and Restated Promissory Note increasing the principal amount due under the September 2024 Promissory Note to $5.1 million from $5.0 million, after the Company loaned an additional $0.1 million to ONCO.

The Company determined that it was not probable, at the time of the transaction and at June 30, 2025, that substantially all of the consideration promised under the Asset Purchase Agreement would be collected. Therefore, the Company recognized the difference between the nonrefundable consideration received and the carrying amount of the assets as a gain. The Company recorded a gain on sale of ENTADFI assets of $0.5 million during the three months ended June 30, 2025 and $2.2 million and $1.0 million during the nine months ended June 30, 2025 and 2024, respectively, for the nonrefundable consideration received during each period. Additional gain could be recognized in future periods if additional consideration is received or when it is deemed probable that substantially all of the consideration promised will be collected. The Company will continue to evaluate the collectability of the ONCO Promissory Notes for future installments of the purchase price.

Note 16 – Subsequent Events

Reverse Stock Split

On August 8, 2025, the Company effected a 1-for-10 reverse stock split of its issued and outstanding common stock. As a result of the reverse split, each 10 shares of issued and outstanding common stock were automatically converted into one share of common stock. The reverse stock split did not change the total number of shares authorized or par value per share. The reverse stock split was approved by the Company's shareholders on July 25, 2025.

All share and per share amounts presented in these condensed consolidated financial statements and accompanying notes and elsewhere in this Quarterly Report on Form 10-Q, including but not limited to shares issued and outstanding, loss per share, and stock options and stock appreciation rights, as well as the dollar amounts of common stock and paid-in-capital, have been retroactively adjusted for all periods presented. No fractional shares were issued in connection with the reverse stock split. Shareholders who would have otherwise been entitled to receive fractional shares as a result of the reverse stock split received a cash payment in lieu thereof, based on the closing price of the Company's common stock on August 7, 2025.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

We are a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of cardiometabolic and inflammatory diseases. Our drug development program consists of two late-stage new chemical entities, enobosarm and sabizabulin. Enobosarm, an oral selective androgen receptor modulator ("SARM"), is initially being developed as a treatment to augment fat loss and to prevent lean mass (muscle) loss in sarcopenic obese or overweight older patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness. Sabizabulin, an oral microtubule disruptor, is being developed as a broad anti-inflammatory agent to reduce inflammation to slow the progression or promote the regression of atherosclerotic cardiovascular disease. On December 30, 2024, the Company sold its FDA-approved commercial product, the FC2 Female Condom® (Internal Condom), for the dual protection against unplanned pregnancy and sexually transmitted infections.

Obesity Program

In reported third-party clinical trials evaluating currently approved GLP-1 RA in obese patients, trial participants exhibited significant weight loss composed of reductions in both fat and lean (muscle) mass. Of the total weight loss reported in certain of these third-party clinical trials, 20-50% of the total weight loss reported by patients was attributable to lean mass (muscle) loss. According to the Centers for Disease Control and Prevention, 41.5% of older adults are obese and could benefit from weight loss medication. Up to 34.4% of people over the age of 60 with obesity in the United States have sarcopenic obesity. Sarcopenic obese patients are patients who have obesity and low muscle mass at the same time and are potentially at the greatest risk for developing critically low muscle mass when taking a currently approved GLP-1 RA. We therefore believe there is an urgent unmet need for a drug that can ameliorate the muscle wasting effects of currently approved GLP-1 RA therapies and also allow for greater loss of fat mass in at-risk sarcopenic obese and overweight older patients.

We are developing enobosarm which is an oral, novel SARM that has demonstrated in previous clinical studies improvements in body composition with tissue selective increases in lean mass and decreases in fat mass, improvements in both muscle strength and physical function, no masculinizing effects in women, and neutral prostate effects in men.

Enobosarm has been evaluated in five separate third-party clinical trials in which lean mass measurement was a primary or co-primary endpoint. These third-party clinical trials include two Phase 2 clinical trials in healthy older or sarcopenic subjects (168 subjects) and one Phase 2b clinical trial and two Phase 3 clinical trials in subjects with muscle wasting because of cancer (800 subjects), generating lean mass and safety data from a total of 968 patients. Based on a large safety database which includes 1,581 men and women with treatment duration for up to 3 years, enobosarm has been generally well tolerated in clinical trials completed to date. All the nonclinical and clinical efficacy and safety data on enobosarm including those generated by these five third-party clinical trials are owned by Veru pursuant to an assignment from the University of Tennessee Research Foundation.

We believe the clinical data we own that was generated from third-party clinical trials of enobosarm in both older patients and in patients with initial and ongoing muscle wasting, provide strong clinical rationale for the co-administration of enobosarm and a GLP-1 RA in at-risk sarcopenic obese or overweight older patients as the combination has the potential to ameliorate the muscle wasting effects of currently approved GLP-1 RA therapies and also allow for preferential and selective loss of fat mass.

We submitted an Investigational New Drug Application (IND) for enobosarm for a Phase 2b clinical study in January 2024. In February 2024, the Company received FDA clearance to initiate the Phase 2b, multicenter, double-blind, placebo-controlled, randomized, dose-finding QUALITY clinical trial designed to evaluate the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight older (≥60 years of age) patients receiving semaglutide (Wegovy®) for chronic weight management. The primary endpoint is percent change from baseline in total lean body mass, and the key secondary endpoints are percent change from baseline in total body fat mass, total body weight, and physical function as measured by stair climb test at 16 weeks. In April 2024 the Company announced that it had enrolled its first patients in the Phase 2b QUALITY clinical study and in August 2024 the Company completed enrollment of 168 subjects in 14 clinical sites in the U.S. The purpose of the Phase 2b QUALITY clinical trial is to select the dose of enobosarm in combination with semaglutide (Wegovy) that best preserves lean mass (muscle) and physical function after 16 weeks of treatment to advance into a Phase 3 obesity clinical trial.

After completing the efficacy dose-assessment portion of the Phase 2b QUALITY clinical trial, the participants continued into a Phase 2b extension maintenance trial where all patients have stopped treatment with semaglutide (Wegovy), but continue taking placebo, enobosarm 3mg, or enobosarm 6mg in a blinded fashion for 12 additional weeks. The Phase 2b extension clinical trial evaluated whether enobosarm can maintain muscle and prevent the fat regain that generally occurs after discontinuing a GLP-1 RA.

The Phase 2b QUALITY study is the first human study to report the effects of a muscle preservation drug candidate on body composition in older patients who have obesity or are overweight and receiving a GLP-1 receptor agonist. The trial met its prespecified primary endpoint with a statistically significant and a clinically meaningful benefit in the preservation of total lean body mass in all patients receiving enobosarm 3mg + semaglutide versus placebo + semaglutide at 16 weeks (100% relative reduction in lean mass loss, $p<0.001$).

As for secondary clinical endpoints, enobosarm + semaglutide treatment resulted in dose dependent greater loss of fat mass compared to placebo + semaglutide with the enobosarm 6mg dose having a 42% greater relative loss of fat mass compared to placebo + semaglutide group at 16 weeks ($p=0.017$) and the enobosarm 3mg having a 12% greater fat loss. Although enobosarm + semaglutide significantly preserved lean mass, the additional loss of fat mass caused by enobosarm treatment was able to replace the lean mass preserved to allow a similar net mean weight loss measured by DEXA with semaglutide at 16 weeks. Accordingly, the tissue composition of the total weight loss shifted to greater and selective loss of fat with enobosarm treatment. The mean percentage of total body mass loss in the placebo + semaglutide group that was due to lean mass was 34% and estimated fat loss was 66%. In contrast, in the enobosarm 3mg + semaglutide group, the total weight loss due to lean mass was 0% and estimated fat loss was 100%, and for the enobosarm 6mg + semaglutide group, it was 16.7% lean mass and 83.3% estimated fat loss. Therefore, enobosarm + semaglutide improved changes in body composition resulting in more selective and greater loss of adiposity than in subjects receiving placebo + semaglutide.

Physical function was measured by the Stair Climb Test. Climbing stairs is an activity of daily living, and the Stair Climb Test measures functional muscle strength, balance and agility. Declines in performance measured by Stair Climb Test predicts in older patients a higher risk for mobility disabilities, gait difficulties, falls and bone fractures, hospitalizations, and mortality. As a point of reference, stair climb power declines by -1.38% annually with aging according to Van Roie E. PLOS ONE 14:e0210653, 2019.

- **Phase 2b QUALITY clinical trial is the first human study to demonstrate that older patients who are overweight or have obesity receiving semaglutide GLP-1 RA are at higher risk for accelerated loss of lean mass with physical function decline.** A responder analysis was conducted using a greater than 10% decline in stair climb power as the cut off at 16 weeks which represents an approximate 7 to 8 year loss of stair climb power that naturally occurs with aging. In our study, the loss of lean mass mattered as 43.8% of patients on placebo + semaglutide group had at least a 10% decline in stair climb power physical function at 16 weeks.

- **Enobosarm treatment preserved lean mass (muscle) which translated into a reduction in the proportion of patients that had a clinically significant stair climb physical function decline versus subjects receiving semaglutide alone.** The all enobosarm 3mg + semaglutide group had a statistically significant and clinically meaningfully 59.8% relative reduction in the proportion of subjects that lost at least 10% stair climb power compared to placebo + semaglutide group ($p=0.0006$). In enobosarm 6mg + semaglutide, there was a 44.1% relative reduction in the proportion of patients with at least a 10% decline in stair climb power from baseline vs. placebo + semaglutide group ($p=0.051$).

Enobosarm represents a novel drug that improves GLP-1 RA therapy resulting in tissue selective quality weight reduction, that is, enobosarm + semaglutide improved changes in body composition which resulted in more selective and greater loss of adiposity (fat mass) than in subjects receiving placebo + semaglutide alone.

On May 28, 2025, we announced positive topline safety results for the Phase 2b QUALITY clinical study that showed the enobosarm + semaglutide combination had a positive safety profile compared to semaglutide alone. There were no increases in gastrointestinal side effects, no evidence of drug induced liver injury (as defined by Hy's law), and no increases in obstructive sleep apnea at any dose of enobosarm compared to placebo (semaglutide alone). There were no adverse events of increases in prostate specific antigen in men. There were no adverse events related to masculinization in women. There were no reports of suicidal ideation observed (Columbia-Suicide Severity Rating Scale). Enobosarm 3mg + semaglutide combination had the added benefit of fewer gastrointestinal side effects (diarrhea, nausea, and gastroesophageal reflux disease) compared to semaglutide alone. There were five non-treatment related serious adverse events equally distributed between the treatment groups. At the proposed Phase 3 clinical program dose of enobosarm 3mg, one subject experienced an adverse event of transient, mild increase in alanine aminotransferase, which returned to baseline while remaining on enobosarm. There were no accompanying increases in aspartate aminotransferase, alkaline phosphatase, or total bilirubin.

Phase 2b Extension Maintenance Study

After completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial, participants continued into a Phase 2b maintenance extension study where all patients discontinued semaglutide treatment, but continued receiving placebo, enobosarm 3mg, or enobosarm 6mg as monotherapy in a double-blind fashion for 12 weeks. On June 24, 2025, we announced positive results from the Phase 2b QUALITY and Maintenance Extension clinical study.

At the end of the Phase 2b QUALITY study active weight loss period of 16 weeks, body weight loss was similar across treatment groups with the semaglutide + placebo group losing an average of 11.88 lbs. After the 12-week Maintenance and Extension study period (Day 112 to Day 196) where all treatment groups discontinued semaglutide, the placebo monotherapy group regained 43% of body weight that was previously lost during the Phase 2b QUALITY for a mean percent change of 2.57% (5.06 lbs) in body weight, compared to 1.41% (2.73 lbs) for the 3mg enobosarm group ($p=0.038$) and 2.87% (5.29lbs) for the 6mg enobosarm group. The 3mg enobosarm monotherapy significantly reduced the body weight regained by 46%. On average, the placebo monotherapy group regained 2.27% in fat mass, while the enobosarm monotherapy cohorts had a loss of fat mass of -0.27% for the 3mg and -0.50% for the 6mg doses. The mean tissue composition of body weight regained was 28% fat and 72% lean mass in the placebo group, versus 0% fat and 100% lean mass in both the 3mg and the 6mg enobosarm groups. By the end of the study at 28 weeks (Day 1 to Day 196), the placebo + semaglutide followed by placebo monotherapy group experienced a loss of lean mass, while both enobosarm + semaglutide followed by enobosarm monotherapy groups (3 mg and 6 mg doses) significantly preserved more than 100% of lean mass (enobosarm 3mg $p<0.001$ and enobosarm 6mg $p=0.004$). The enobosarm + semaglutide followed by enobosarm monotherapy patients had a 58% greater loss of fat with enobosarm 3mg ($p=0.085$) and a 93% greater loss of fat with enobosarm 6mg ($p=0.008$) compared to placebo + semaglutide followed by placebo monotherapy.

In the double-blind Phase 2b QUALITY Maintenance Extension clinical trial (Day 112-196), enobosarm monotherapy had a positive safety profile. After discontinuation of semaglutide, there were essentially no gastrointestinal side effects, no evidence of drug induced liver injury (by Hy's law), and no increases in obstructive sleep apnea observed at any dose of enobosarm compared to placebo monotherapy. There were no adverse events of increases in prostate specific antigen in men. There were no adverse events related to masculinization in women. There were no reports of suicidal ideation observed (Columbia-Suicide Severity Rating Scale). The proposed Phase 3 clinical program dose of enobosarm 3mg continued to have a positive safety profile in the Phase 2b maintenance extension clinical trial.

The Phase 2b QUALITY and Maintenance Extension clinical trial confirmed that preserving lean mass with enobosarm plus semaglutide led to greater fat loss during the active weight loss period, and after semaglutide was discontinued, enobosarm monotherapy significantly prevented the regain of both weight and fat mass during the maintenance period such that by end of study there was greater loss of fat mass while preserving lean mass for a higher quality weight reduction compared to the placebo group.

Regulatory Next Steps

We have been granted a meeting with the FDA to discuss our planned Phase 3 clinical program for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA for chronic weight management. During the preIND FDA meeting, the FDA provided general comments about a regulatory path forward for enobosarm as a drug that improves body composition during weight loss including input on Phase 3 clinical program design.

As a path forward, we plan to propose a Phase 3 clinical program that is similar to the positive Phase 2b QUALITY clinical trial. The proposed Phase 3 clinical trial design is a double-blind, placebo-controlled study in patients 60 years of age and older who have obesity or who are overweight and who are eligible for treatment with GLP-1 RA. The GLP-1 RA may be either WEGOVY (semaglutide) and/or Zepbound® (tirzepatide). Patients will be randomized to oral daily enobosarm or matching placebo. All subjects will start and receive GLP-1 RA during the study. The proposed primary objective will be the effect of enobosarm on physical function measured by the Stair Climb Test at 24 weeks. Proposed key secondary objectives will be to assess the effect of enobosarm on total lean mass, total fat mass, HOMA-IR, and hemoglobin A1c at 24 weeks.

After the Phase 3 clinical trial ends at 24 weeks of treatment, the plan is to continue to measure total lean mass, total body weight, stair climb, total fat mass, bone mineral density, HOMA-IR, and hemoglobin A1c up to 68 weeks to capture the longer-term benefits of enobosarm improvements on body composition for greater loss of adiposity or fat, weight reduction, and preservation of both lean mass and bone.

Novel Modified Release Oral Enobosarm Formulation is on Track to be Available for Phase 3 Clinical Studies and Commercialization

Veru is currently developing a novel, patentable, modified release oral formulation for enobosarm. The actual formulation, pharmacokinetic release profile(s), and method of manufacturing will be the subjects of future patent applications. If issued, the expiry for the new modified release oral enobosarm formulation patent is expected to be 2045. The new enobosarm formulation has completed the initial Phase 1 bioavailability clinical trial in July 2025. The expectation is that this novel modified release oral enobosarm formulation will be available for the Phase 3 clinical studies and for commercialization.

In a pilot pharmacokinetic study, the new modified release formulation resulted in a significant reduction in maximum plasma concentration (Cmax), a delayed time to maximum plasma concentration (Tmax), a distinct secondary peak, and similar extent of absorption (AUC) compared to historical values for enobosarm immediate release capsules.

Atherosclerosis Inflammation Program

Atherosclerotic coronary artery disease (CAD) remains the leading cause of mortality worldwide. Inflammation and high cholesterol jointly contribute to atherosclerotic cardiovascular disease. It appears that the pathogenesis and progression of coronary artery disease, however, is largely driven by inflammation in response to atheromatous plaques containing cholesterol in the arterial wall. In fact, inflammation mediates all stages of atherosclerotic coronary vascular disease: plaque initiation, plaque progression, and plaque rupture and the resulting thrombotic complications. Even with cholesterol reduction therapies, there remains a major and largely untreated residual inflammatory risk. Using high sensitivity C-reactive protein (CRP) blood levels to assess the contribution of inflammation, a recent analysis of 31,245 patients receiving statin lipid lowering therapy showed that inflammation was a stronger predictor for risk of future major cardiovascular events and death than cholesterol by LDL-C. The realization that the combined use of aggressive lipid-lowering and inflammation-inhibiting therapies might be needed to further reduce atherosclerotic risk has sparked the search for anti-inflammatory medications that could lower the risk of atherosclerotic events in patients with CAD.

An old drug, colchicine, inhibits tubulin polymerization to disrupt microtubules resulting in broad anti-inflammatory activity. Recent randomized controlled trials assessing the role of low-dose colchicine to treat inflammation to reduce major adverse cardiovascular events (MACE), including COLCOT (Efficacy and Safety of Low-Dose colchicine after Myocardial Infarction), LoDoCo (Low-dose colchicine for secondary prevention of cardiovascular disease) and LoDoCo-2 (Colchicine in Patients with Chronic Coronary Disease) trials, had promising results demonstrating significant cardiovascular risk reduction. Colchicine lowered major adverse cardiovascular events by 31% among those with stable CAD and by 23% in patients following a recent myocardial infarction. This magnitude of benefit is greater than what has been observed in contemporary trials of lipid lowering medications including those with proprotein convertase subtilisin/kexin type 9 (PCSK-9) inhibitors.

To gain mechanistic insight, Vaidya et al. (2018) conducted a prospective open label single center clinical study to evaluate the effects of colchicine on modifying the atheromatous coronary artery plaques by coronary CT angiography (CCTA) imaging. Eighty patients who had recent acute coronary syndrome received either low dose colchicine plus optimal medical therapy or optimal medical therapy alone for 12 months. The primary endpoint was low attenuation plaque volume (LAPV), a marker of plaque instability on CCTA and a strong predictor of major adverse cardiovascular events. High sensitivity CRP blood levels, a biomarker of inflammation, was also measured.

The study results showed that colchicine + optimal medical therapy versus optimal medical therapy alone significantly reduced the primary endpoint of LAPV by -40.9% and high sensitivity CRP by -37.3%. (Vaidya 2018). This was an important milestone for the treatment of CAD as colchicine therapy was able to directly modify coronary arterial plaque independent of high dose statins that lower LDL. Further, because of the reduction of high sensitivity CRP, the improvements in plaque morphology were most likely driven by colchicine's anti-inflammatory effects.

Data from these trials led the FDA in June 2023 to approve colchicine for reducing cardiovascular events in adults with established atherosclerotic cardiovascular disease (ASCVD), making colchicine the first anti-inflammatory drug with such an indication. Furthermore, the American College of Cardiology/American Heart Association, European Society of Cardiology as well as national guidelines in Canada and South America have endorsed the use of low-dose colchicine (0.5 mg/d orally) in patients with coronary artery disease, especially among those with uncontrolled risk factors or recurrent events despite optimal medical therapy.

Unfortunately, colchicine has well known serious safety concerns. Colchicine has high potential for drug-drug interactions as it is a substrate for CYP3A4 and P-glycoprotein. Consequently, commonly used cardiovascular drugs including almost all statins (HMG-CoA reductase inhibitors) may interact with colchicine resulting in erratic or higher blood levels of colchicine. Colchicine has a narrow therapeutic index and extreme care must be taken to avoid accidental overdoses, which may be fatal. Accordingly, patients receiving regular colchicine therapy require close clinical supervision. Common side effects are gastrointestinal symptoms (diarrhea, vomiting, and abdominal cramping) and myalgia. Blood dyscrasias which may be fatal, neurotoxicity, and rhabdomyolysis may also rarely occur (LODOCO FDA PI 2023).

Given the recent positive topline results from the Phase 2b QUALITY study evaluating enobosarm as a cardiometabolic agent that has the potential to preserve muscle and augment fat loss in overweight and obese patients receiving GLP-1 RA therapy for weight reduction, Veru has evolved its drug development strategy for sabizabulin and is exploring the possibility of the clinical development of sabizabulin, a novel oral broad anti-inflammatory agent, for the treatment of inflammation in atherosclerotic cardiovascular disease. The Company's decision to explore this major cardiometabolic indication was based on the significant unmet medical need to treat inflammation in atherosclerotic cardiovascular disease, the large global market opportunity, current clinical and safety sabizabulin database of 266 patients, high probability of success of the drug's mechanism of action which is similar to colchicine, and strong intellectual property position. Furthermore, we believe sabizabulin may be evaluated in a small Phase 2 dose finding proof of concept study to assess whether sabizabulin reduces blood levels of high sensitivity C-reactive protein, a measurement of inflammation, in patients with stable CAD.

We believe there is compelling scientific evidence and rationale to evaluate sabizabulin as a treatment for the inflammation associated with atherosclerotic cardiovascular disease. Sabizabulin is an oral novel microtubule disruptor that targets the colchicine binding site of beta tubulin, and binds and crosslinks both the α and β tubulin subunits to inhibit tubulin polymerization and to induce depolymerization of microtubules at low nanomolar concentrations. Sabizabulin is more effective than colchicine in inhibiting tubulin polymerization. Sabizabulin is orally bioavailable with a 5-hour half-life. Sabizabulin is not a substrate for P-glycoprotein or CYP3A4. Overall preclinical data from *in vitro* and *in vivo* inflammation studies show that sabizabulin treatment suppressed all cytokines and chemokines tested which includes IL-1α, IL-1β, IL-6, IL-8, TNF-α, Interferon-γ, and IP-10 (CXCL-10). In Phase 2 and 3 pulmonary inflammation COVID-19 clinical studies, sabizabulin has demonstrated broad anti-inflammatory activity. The safety database consists of 266 dosed patients from the sabizabulin clinical development program comprised of the Phase 2 and Phase 3 studies in hospitalized COVID-19 patients for acute use (149 patients at 9 mg daily for ≤ 21 days), as well as data from the Phase 1b/2 and Phase 3 studies in prostate cancer for chronic use (117 patients treated at up to 32 mg daily for up to 3 years).

In summary, inflammation plays a significant role in the pathogenesis of atherosclerosis as evidenced by the data of preclinical studies and large epidemiological trials. The pathophysiological association between inflammation and atherosclerosis is very complex and many inflammatory mediators are involved. The most important inflammatory mediators of this association are the cytokines IL-1β and IL-6, Interferon-γ, and TNF-α. Randomized clinical studies and meta-analyses have shown that anti-inflammatory therapies can reduce the hazard of cardiovascular events. With the FDA's 2023 approval of colchicine for reducing cardiovascular events in subjects with atherosclerotic cardiovascular disease, we believe a novel clinical pathway is now open to develop anti-inflammatory drugs as a secondary treatment in combination with lipid lowering statin drugs to prevent and treat atherosclerotic CAD.

Colchicine may be first-in-class and the first FDA approved treatment for this significant indication to treat atherosclerotic inflammation, but unfortunately colchicine has significant safety concerns that may limit its expected widespread use and therefore does not address the current unmet medical need of atherosclerotic inflammation. Sabizabulin is a new molecular entity, small molecule that targets the colchicine binding site on β-tubulin. Like colchicine, sabizabulin inhibits microtubule polymerization and has demonstrated the ability to reduce the most important inflammatory mediators that play a role in the initiation and progression of atherosclerotic CAD. However, because sabizabulin has a different chemical structure than colchicine, it is not a substrate for CYP3A4 and P-glycoprotein potentially eliminating drug-drug interactions concerns associated with colchicine. In contrast to colchicine, sabizabulin has stable pharmacokinetics and low potential for drug-drug interactions; thus, sabizabulin may be administered potentially more safely as a secondary therapy in combination with statin therapy for the reduction of inflammation to slow the progression or promote regression of atherosclerotic cardiovascular disease.

Veru had a pre-IND meeting with the FDA Division of Cardiology and Nephrology Center for Drug Evaluation and Research on December 26, 2024. The indication for discussion was the use of sabizabulin to slow progression or promote regression of atherosclerotic disease in patients with a history of coronary artery disease. The FDA agreed that there remains an unmet medical need based on disease pathophysiology. Veru currently has sufficient drug substance to supply the proposed Phase 2 clinical study in patients with stable CAD to measure levels of high sensitivity C-reactive protein.

FC2 Business Sale and Discontinued Operations

On December 30, 2024, the Company and The Female Health Company Limited (collectively, the "Sellers") entered into a Stock and Asset Purchase Agreement (the "Purchase Agreement") with Clear Future, Inc. (the "Purchaser"). Pursuant to, and subject to the terms and conditions of, the Purchase Agreement, the Purchaser purchased substantially all of the assets (the "FC2 Business Sale") related to the Company's FC2 female condom business ® (internal condom), including the stock of the Company's U.K. and Malaysian operating subsidiaries. The Purchaser assumed certain liabilities relating to the FC2 business that are specified in the Purchase Agreement. The transaction closed on December 30, 2024. The Sellers and the Purchaser made customary representations and warranties, and agreed to certain customary covenants, in the Purchase Agreement. Subject to certain exceptions and limitations, each party agreed to indemnify the other for breaches of representations, warranties and covenants and for certain other matters. The Purchase Agreement also specifies that, subject to a $54,000 retention amount, a representations and warranties insurance policy (the "R&W Policy") issued to the Purchaser would be the sole and exclusive remedy for breach of representations and warranties (other than certain specified representations and warranties) by the Sellers except in the case of fraud.

The purchase price for the FC2 Business Sale was $18.0 million in cash, subject to adjustment as set forth in the Purchase Agreement. The adjustments to the purchase price in the Purchase Agreement include a customary working capital adjustment in 90 days from closing based on the amount by which certain working capital items at closing are greater or less than a target set forth in the Purchase Agreement. Net proceeds from the FC2 Business Sale are expected to be $16.3 million, which is the purchase price per the Purchase Agreement, net of costs incurred of $1.4 million, estimated purchase price adjustments of $0.1 million, and amounts allocated to the related Transition Services Agreement of $0.2 million, but excluding the change of control payment pursuant to the Residual Royalty Agreement of $4.2 million. These net proceeds are subject to adjustment as set forth in the Purchase Agreement. The loss on sale of the FC2 business is $4.3 million, which is the difference between estimated net proceeds of $16.3 million and the total carrying value of the FC2 business of $20.6 million. The carrying value of the FC2 business at December 30, 2024 primarily included deferred income tax assets of $12.3 million, accounts receivable of $4.6 million, and inventory of $3.4 million, partially offset by accrued expenses and other current liabilities of $1.5 million. In addition, due to the FC2 Business Sale, liabilities associated with the Residual Royalty Agreement, which totaled $9.9 million at September 30, 2024, were extinguished.

The FC2 Business Sale represented a strategic shift, which had a major effect on our operations and financial results. We have classified all direct revenues, costs and expenses related to the FC2 business within loss from discontinued operations, net of tax, in the condensed consolidated statements of operations for all periods presented. We have not allocated any amounts for shared general and administrative operating support expense to discontinued operations. Additionally, the related assets and liabilities have been reported as assets and liabilities of discontinued operations in our condensed consolidated balance sheet as of September 30, 2024. The assets and liabilities sold as part of the FC2 Business Sale were written off upon the closing of the FC2 Business Sale, and therefore there are no assets and liabilities of discontinued operations in our condensed consolidated balance sheet as of June 30, 2025.

Sale of ENTADFI

On April 19, 2023, the Company entered into an asset purchase agreement (the "Asset Purchase Agreement") to sell substantially all of the assets related to ENTADFI® (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021, with Onconetix, Inc. formerly known as Blue Water Vaccines Inc. ("ONCO"). The transaction closed on April 19, 2023. The purchase price for the transaction was $20.0 million, consisting of $6.0 million paid at closing, $4.0 million payable pursuant to a promissory note due on September 30, 2023, $5.0 million payable pursuant to a Promissory Note due on April 19, 2024 (the "April 2024 Promissory Note"), and $5.0 million payable pursuant to a Promissory Note due on September 30, 2024 (the "September 2024 Promissory Note" and, together with the April 2024 Promissory Note, the "ONCO Promissory Notes"), plus up to $80.0 million based on ONCO's net revenues from ENTADFI after closing (the "Milestone Payments"). The Company believes the probability of receiving any Milestone Payments is remote.

On September 29, 2023, the Company entered into an Amendment to the Asset Purchase Agreement providing that the promissory note for the $4.0 million installment of the purchase price due September 30, 2023 would be deemed paid and fully satisfied upon (1) the payment to the Company of the sum of $1.0 million in immediately available funds on September 29, 2023 and (2) the issuance to the Company by October 3, 2023 of 3,000 shares of Series A Convertible Preferred Stock of ONCO (the "ONCO Preferred Stock"). The Company received payment of $1.0 million on September 29, 2023 and the ONCO Preferred Stock on October 3, 2023. The shares of ONCO Preferred Stock held by the Company were converted into 142,749 shares of common stock of ONCO (the "ONCO Common Stock") on September 24, 2024, and the Company sold all 142,749 shares of ONCO Common Stock during the three months ended December 31, 2024 for net proceeds of $0.4 million.

On April 24, 2024, the Company entered into a Forbearance Agreement with ONCO, which was amended and restated as of September 19, 2024 (as amended and restated, the "Forbearance Agreement"), relating to certain defaults under the ONCO Promissory Notes. Pursuant to the Forbearance Agreement, (a) ONCO agreed to make a payment of $50,000 of the principal payable under the April 2024 Promissory Note not later than April 29, 2024, which was paid on April 25, 2024, and (b) the Company agreed, subject to the terms and conditions set forth in the Forbearance Agreement, to forbear from exercising its rights and remedies on account of the failure by ONCO to pay the amounts due under the April 2024 Promissory Note on the due date of April 19, 2024, and on account of any failure by ONCO to make any mandatory repayment under the ONCO Promissory Notes that may have become due or may become due in connection with certain transactions relating to ONCO's acquisition of Proteomedix AG, in each case for a period (the "April 2024 Forbearance Period") commencing on April 24, 2024 and ending on the earlier of (a) March 31, 2025 and (b) the occurrence of an Event of Default (as defined in the Forbearance Agreement). The Company also agreed that during the Forbearance Period the default provision in the ONCO Promissory Notes relating to insolvency of ONCO will not apply. The Forbearance Agreement also amended certain terms of the September 2024 Promissory Note as described below.

ONCO agreed in the Forbearance Agreement to make the following required payments (the "Required Payments") to Veru during the April 2024 Forbearance Period first to accrued and unpaid interest under the April 2024 Promissory Note and then any remainder to the outstanding principal balance of the April 2024 Promissory Note: (1) monthly payments equal to 25% (increased from 15% in the original April 24, 2024 Forbearance Agreement) of cash receipts of ONCO or its subsidiaries from certain sale or licensing revenues or payments, which increased amount began on October 20, 2024 for cash receipts in September 2024; and (2) payment of 20% (increased from 10% in the original April 24, 2024 Forbearance Agreement) of the net proceeds from certain financing or other transactions outside the ordinary course of business completed by ONCO or any of its subsidiaries during the April 24 Forbearance Period, which increased amount began for any net proceeds received after September 19, 2024. The remaining balance of the April 2024 Promissory Note will be due at the end of the April 2024 Forbearance Period. The remaining balance of the April 2024 Promissory Note will be due at the end of the Forbearance Period. The Company and ONCO entered into a Waiver and Amendment No. 1 to Forbearance Agreement, dated November 26, 2024, that (x) extended the time for the payment by ONCO of the monthly payment of a percentage of its cash receipts referenced in clause (1) above in this paragraph and conditioned the payment of those amounts upon ONCO being able to raise capital of at least $97,000 and (y) increased the percentage of the net proceeds from certain financings payable to the Company from 20% to 25%. The Company and ONCO entered into a Limited Waiver, dated March 31, 2025, to extend the maturity date of the April 2024 Promissory Note to April 14, 2025; the Company and ONCO entered into a Limited Waiver, dated April 23, 2025, to extend the maturity date of the April 2024 Promissory Note to June 30, 2025; the Company and ONCO entered into a Limited Waiver, dated June 30, 2025, to extend the maturity date of the April 2024 Promissory Note to July 31, 2025; and the Company and ONCO entered into a Limited Waiver, dated July 31, 2025, to extend the maturity date of the April 2024 Promissory Note to August 14, 2025.

ONCO and the Company also agreed to the following amendments to the September 2024 Promissory Note in the Forbearance Agreement: (1) the maturity date of the September 2024 Promissory Note was extended to June 30, 2025; (2) the accrual of interest at the rate of 10% per annum on any unpaid principal balance of the September 2024 Promissory Note commencing on October 1, 2024 through the date that the outstanding principal balance under the September 2024 Promissory Note is paid in full; (3) any amounts owed on the September 2024 Promissory Note, including but not limited to unpaid principal and accrued interest, will be paid in cash or, upon the mutual written consent of ONCO and the Company, in shares of the ONCO common stock or a combination of cash and ONCO common stock; (4) following full repayment of all principal and interest under the April 2024 Promissory Note, ONCO will make the Required Payments first towards accrued and unpaid interest under the September 2024 Promissory Note and then towards the remaining principal balance payable under the September 2024 Promissory Note; and (5) if the aggregate unpaid principal outstanding under the April 2024 Promissory Note and the September 2024 Promissory Note and all accrued and unpaid interest thereon is repaid in cash on or before December 31, 2024, then the total principal balance under the September 2024 Promissory Note that will be payable by ONCO in satisfaction of its obligations under the September 2024 Promissory Note will be reduced from $5,000,000 to $3,500,000. The Company and ONCO entered into a Limited Waiver, dated June 30, 2025, to extend the maturity date of the September 2024 Promissory Note to July 31, 2025 and the Company and ONCO entered into a Limited Waiver, dated July 31, 2025, to extend the maturity of the September 2024 Promissory Note to August 14, 2025. On August 7, 2025, the Company and ONCO entered into an Amended and Restated Promissory Note increasing the principal amount due under the September 2024 Promissory Note to $5.1 million from $5.0 million, after the Company loaned an additional $0.1 million to ONCO.

Consolidated Operations:

Operating Expenses. Conducting research and development is central to our drug development programs. The Company has several products under development and management routinely evaluates each product in its portfolio of products. Advancement is limited to available working capital and management's understanding of the prospects for each product. If future prospects do not meet management's strategic goals, advancement may be discontinued. We have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were $3.0 million and $4.8 million for the three months ended June 30, 2025 and 2024, respectively, and $12.7 million and $9.5 million for the nine months ended June 30, 2025 and 2024, respectively. The expenses incurred in the three and nine months ended June 30, 2025 are primarily due to the Phase 2b QUALITY clinical trial. We expect to continue investing significant resources in research and development in the future due to advancement of our drug candidates.

Results of Operations

THREE MONTHS ENDED JUNE 30, 2025 COMPARED TO THREE MONTHS ENDED JUNE 30, 2024

Research and development expenses decreased to $3.0 million in the three months ended June 30, 2025 from $4.8 million in the same period in fiscal 2024. The decrease in research and development expenses is due primarily to the wind down of the Company's Phase 2b QUALITY clinical study for enobosarm as a treatment to augment fat loss and to prevent muscle loss, which was completed during the quarter ended June 30, 2025. The Company initiated the Phase 2b QUALITY clinical study during the quarter ended June 30, 2024.

Selling, general and administrative expenses were $5.0 million in the three months ended June 30, 2025, which is a decrease from $5.8 million in the three months ended June 30, 2024. The decrease is due primarily to a decrease in corporate personnel costs, due to a decrease in share-based compensation expense of $1.0 million.

The Company recorded a gain on sale of ENTADFI assets of $0.5 million in the three months ended June 30, 2025, compared to $0.1 million in the three months ended June 30, 2024. The Company recognizes a gain on sale of ENTADFI assets as nonrefundable consideration is received. Refer to Note 15 to the financial statements included in this report for additional information.

The Company recorded a net loss from discontinued operations, net of taxes, related to the FC2 business of $10,000 for the three months ended June 30, 2025, compared with $0.6 million for the three months ended June 30, 2024. The net loss from discontinued operations during the three months ended June 30, 2025 is due to changes in estimates made at the time the FC2 business was sold. The net loss from discontinued operations in the three months ended June 30, 2024 is attributable to the operations of the FC2 business during that period.

NINE MONTHS ENDED JUNE 30, 2025 COMPARED TO NINE MONTHS ENDED JUNE 30, 2024

Research and development expenses increased to $12.7 million in the nine months ended June 30, 2025 from $9.5 million in the same period in fiscal 2024. The increase is due to an increase of $4.5 million incurred related to the Company's Phase 2b QUALITY clinical study for enobosarm as a treatment to augment fat loss and to prevent muscle loss, partially offset by a decrease in expenditures related to the Company's other drug development programs that were terminated in previous years.

Selling, general and administrative expenses were $15.4 million in the nine months ended June 30, 2025, which is a decrease from $18.4 million in the nine months ended June 30, 2024. The decrease is due primarily to a decrease in corporate personnel costs, due to a decrease in share-based compensation expense of $2.6 million.

The Company recorded a gain on sale of ENTADFI assets of $2.2 million in the nine months ended June 30, 2025, an increase from the gain of $1.0 million in the nine months ended June 30, 2024. The Company recognizes a gain on sale of ENTADFI assets as nonrefundable consideration is received. Refer to Note 15 to the financial statements included in this report for additional information.

The Company recorded a gain on extinguishment of debt of $8.6 million in the nine months ended June 30, 2025, related to the termination of the Residual Royalty Agreement, in connection with the FC2 Business Sale. The gain is the difference between the change of control payment of $4.2 million and the net carrying amount of the extinguished debt of $12.8 million, which included an embedded derivative for the change of control provision at fair value of $4.7 million.

The loss associated with the change in fair value of equity securities for the nine months ended June 30, 2025 was $0.3 million compared with the $0.7 million loss for the nine months ended June 30, 2024. This is due to the change in fair value of the shares of ONCO Preferred Stock or ONCO Common Stock, which were sold during the nine months ended June 30, 2025. Refer to Note 4 to the financial statements included in this report for additional information.

The Company recorded a net loss from discontinued operations, net of taxes, related to the FC2 business of $7.2 million for the nine months ended June 30, 2025, which includes a loss on the sale of the FC2 business of $4.3 million, compared with $2.6 million for the nine months ended June 30, 2024. The increase in the net loss from discontinued operations of $4.6 million is due primarily to the loss on the sale of the FC2 business of $4.3 million as well as an increase in the loss from the change in fair value of derivative liabilities of $3.2 million, partially offset by a decrease in operating expenses of $3.9 million.

Liquidity and Sources of Capital

Liquidity

Our cash, cash equivalents, and restricted cash on hand at June 30, 2025 was $15.0 million, compared to $24.9 million at September 30, 2024. Restricted cash included in this balance is $0.4 million at June 30, 2025, for amounts held in escrow related to the FC2 Business Sale, compared to zero at September 30, 2024. At June 30, 2025, the Company had working capital of $9.5 million and stockholders' equity of $15.3 million compared to working capital of $23.4 million and stockholders' equity of $32.3 million as of September 30, 2024. The decrease in working capital is due to the decrease in cash, cash equivalents, and restricted cash of $9.9 million and a decrease in working capital of discontinued operations, related to the FC2 Business, of $6.1 million at September 30, 2024, which was partially offset by a decrease in accrued compensation of $1.7 million and the extinguishment of the residual royalty agreement liability, which had a current balance of $1.0 million at September 30, 2024.

The Company is not profitable and has had negative cash flow from operations. We will need substantial capital to support our drug development and any related commercialization efforts for our drug candidates. Based upon the Company's current operating plan, it estimates that its cash and cash equivalents as of the issuance date of the financial statements included in this report are insufficient for the Company to fund operating, investing and financing cash flow needs for the twelve months subsequent to the issuance date of the financial statements included in this report. To obtain the capital necessary to fund our operations, we expect to finance our cash needs through public or private equity offerings, debt financing transactions and/or other capital sources. Additional capital may not be available at such times and in such amounts as needed by us to fund our activities on a timely basis. The Company's future capital requirements will depend on many factors. See Part II, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" for a description of certain risks that will affect our future capital requirements.

These uncertainties raise substantial doubt regarding our ability to continue as a going concern for a period of twelve months subsequent to the issuance date of the financial statements included in this report. Certain elements of our operating plan to alleviate the conditions that raise substantial doubt, including but not limited to our ability to secure equity financing or other financing alternatives, are outside of our control and cannot be included in management's evaluation under the requirements of ASC 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least twelve months subsequent to the issuance date of the financial statements included in this report.

Operating activities

Operating activities used cash of $24.6 million in the nine months ended June 30, 2025. Cash used in operating activities included net loss of $24.2 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $3.9 million and changes in operating assets and liabilities resulting in a decrease of $4.3 million. Adjustments to net loss primarily consisted of $6.6 million for share-based compensation, $4.3 million for the loss on sale of the FC2 business, $3.1 million for the change in fair value of derivative liabilities, partially offset by the gain on extinguishment of debt of $8.6 million and the gain on sale of ENTADFI assets of $2.2 million. The decrease in cash from changes in operating assets and liabilities primarily included a decrease in accrued expenses and other current liabilities of $1.9 million and a decrease in accounts payable of $1.9 million.

Operating activities used cash of $17.3 million in the nine months ended June 30, 2024. Cash used in operating activities included net loss of $29.3 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $12.2 million and changes in operating assets and liabilities resulting in a decrease of $0.2 million. Adjustments to net loss primarily consisted of $10.4 million of share-based compensation, $1.3 million for a provision for obsolete inventory, and $0.7 million for the change in fair value of equity securities, partially offset by the gain on sale of ENTADFI assets of $1.0 million. The decrease in cash from changes in operating assets and liabilities included a decrease in accounts payable of $5.2 million and a decrease in operating lease liabilities of $0.6 million, partially offset by a decrease in accounts receivable of $2.9 million and an increase in accrued expenses and other current liabilities of $2.8 million.

The cash flows related to discontinued operations have not been segregated and are included in the consolidated statements of cash flows. Total operating cash flows of discontinued operations for the nine months ended June 30, 2025 and 2024 are outflows of $0.3 million and inflows of $4.1 million, respectively.

Investing activities

Net cash provided by investing activities was $18.9 million in the nine months ended June 30, 2025, and primarily consisted of net proceeds of $16.3 million from the sale of the FC2 business, proceeds of $2.2 million from the sale of ENTADFI assets, and proceeds of $0.4 million from the sale of equity securities.

Net cash used in investing activities was $15,000 during the nine months ended June 30, 2024, and consisted of proceeds of $110,000 from the sale of ENTADFI assets, partially offset by $95,000 of capital expenditures primarily at our Malaysia location, related to the FC2 business.

The cash flows related to discontinued operations have not been segregated and are included in the consolidated statements of cash flows. Total investing cash flows of discontinued operations for the nine months ended June 30, 2025 and 2024 are inflows of $16.3 million, which includes net proceeds from the sale of the FC2 business, and outflows of $96,000, respectively.

Financing activities

Net cash used in financing activities in the nine months ended June 30, 2025 was $4.2 million, and consisted of a change of control payment of $4.2 million to SWK pursuant to the Residual Royalty Agreement, which terminated the Residual Royalty Agreement and extinguished the related debt.

Net cash provided by financing activities in the nine months ended June 30, 2024 was $36.8 million, and primarily consisted of proceeds from the sale of shares in a public offering, net of commissions and costs, of $35.2 million and proceeds from sale of shares under the common stock purchase agreement with Lincoln Park Capital (see discussion below) of $1.7 million.

Sources of Capital

SWK Credit Agreement

On March 5, 2018, the Company entered into a Credit Agreement (as amended, the "Credit Agreement") with the financial institutions party thereto from time to time (the "Lenders") and SWK Funding LLC, as agent for the Lenders (the "Agent"), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders provided the Company with a term loan of $10.0 million, which was advanced to the Company on the date of the Credit Agreement. The Company repaid the loan and return premium specified in the Credit Agreement in August 2021, and as a result has no further obligations under the Credit Agreement. The Agent has released its security interest in Company collateral previously pledged to secure its obligations under the Credit Agreement.

In connection with the Credit Agreement, Veru and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (as amended, the "Residual Royalty Agreement"), which provided for an ongoing royalty payment of 5% of product revenue from net sales of FC2, which continued after the repayment of the loan and return premium under the Credit Agreement.

In connection with the closing of the FC2 Business Sale, on December 30, 2024, the Company made a change of control payment of $4.2 million to SWK pursuant to the Residual Royalty Agreement, and upon such payment, the Residual Royalty Agreement terminated in accordance with its terms. The Company recognized a gain on extinguishment of debt of $8.6 million for the difference between the change of control payment of $4.2 million and the net carrying amount of the extinguished debt, which included an embedded derivative for the change of control provision at fair value.

Excluding the change of control payment, the Company made total payments under the Residual Royalty Agreement of $0.3 million and $0.5 million during the nine months ended June 30, 2025 and 2024, respectively. The Company is not required to make any additional payments under the Residual Royalty Agreement.

Common Stock Offering

On December 18, 2023, we completed an underwritten public offering of 5,270,833 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of $7.20 per share. Net proceeds to the Company from this offering were approximately $35.2 million after deducting underwriting discounts and commissions and costs paid by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-270606).

Lincoln Park Capital Fund, LLC Purchase Agreement

On May 2, 2023, the Company entered into a common stock purchase agreement (as amended, the "Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, but not the obligation, to sell to Lincoln Park up to $100.0 million of shares (the "Purchase Shares") of the Company's common stock over the 36-month term of the Lincoln Park Purchase Agreement. On the date the Company executed the Lincoln Park Purchase Agreement, we also issued 80,000 shares of the Company's common stock to Lincoln Park as an initial fee for Lincoln Park's commitment to purchase shares of the Company's common stock under the Lincoln Park Purchase Agreement, and we are obligated to issue $1.0 million of shares of the Company's common stock at the time Lincoln Park's purchases cumulatively reach an aggregate amount of $50.0 million (such shares, collectively, the "Commitment Shares"). On December 13, 2023, the Company entered into an amendment (the "Lincoln Park Amendment") with Lincoln Park to reduce the amount of shares of common stock subject to the registration from $100.0 million to $50.0 million until the Company has sold at least $50.0 million of shares of common stock under the Lincoln Park Purchase Agreement. The Purchase Shares up to $50.0 million and Commitment Shares under the Lincoln Park Purchase Agreement have been registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 3, 2023, as further supplemented on December 13, 2023 to reflect the Lincoln Park Amendment.

During the nine months ended June 30, 2025, we did not sell any shares under the Lincoln Park Purchase Agreement. During the nine months ended June 30, 2024, we sold 180,000 shares of common stock to Lincoln Park resulting in proceeds to the Company of $1.7 million. As a result of these sales, we recorded approximately $164,000 of deferred costs to additional paid-in capital. Since inception of the Lincoln Park Purchase Agreement through June 30, 2025, we have sold 302,500 shares of common stock to Lincoln Park resulting in proceeds to the Company of $3.1 million.

Open Market Sale Agreement with Jefferies LLC

On May 12, 2023, the Company entered into an Open Market Sale Agreement℠ (the "Jefferies Sales Agreement") with Jefferies LLC ("Jefferies"), as sales agent, pursuant to which we could issue and sell, from time to time, through Jefferies, shares of the Company's common stock, with an aggregate value of up to $75 million (not to exceed the lesser of 3,960,907 shares of common stock or the number of authorized, unissued and available shares of common stock at any time). On August 19, 2024, the Company delivered notice to Jefferies to terminate the Jefferies Sales Agreement, which was effective on September 3, 2024. As a result of the termination of the Jefferies Sales Agreement, the Company will not issue or sell any additional shares of common stock under the Jefferies Sales Agreement

During the nine months ended June 30, 2024, we sold 9,016 shares of common stock under the Jefferies Sales Agreement resulting in net proceeds to the Company of $67,000. Since inception of the Jefferies Sales Agreement through the date the Jefferies Sales Agreement was terminated, we sold 136,742 shares of common stock resulting in net proceeds to the Company of $1.1 million.

Fair Value Measurements

As of September 30, 2024, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, represented the fair value of the change of control provision in the Residual Royalty Agreement. During the nine months ended June 30, 2025, the Residual Royalty Agreement was terminated and the embedded derivative was extinguished together with the debt. See Note 8 to the financial statements included in this report for additional information.

The fair values of these liabilities were estimated based on unobservable inputs (Level 3 measurement), which required highly subjective judgment and assumptions. The Company estimated the fair value of the embedded derivative within the Residual Royalty Agreement using a scenario-based method, whereby different scenarios are valued and probability weighted. The scenario-based valuation model incorporated transaction details such as the contractual terms of the instrument and assumptions including projected FC2 revenues, expected cash outflows, probability and estimated dates of a change of control, risk-free interest rates and applicable credit risk. As a result, the use of different estimates or assumptions would have resulted in a higher or lower fair value and different amounts being recorded in the Company's financial statements. Material changes in any of these inputs could result in a significantly higher or lower fair value measurement at future reporting dates, which could have a material effect on our results of operations. See Note 4 to the financial statements included in this report for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company's exposure to market risk was discussed in the "Quantitative and Qualitative Disclosures About Market Risk" section contained in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2024. Following the FC2 Business Sale on December 30, 2024, the Company is no longer subject to significant exposure to market risk relating to fluctuations in raw material commodity prices or to foreign currency exchange rate risk.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective. It should be noted that in designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has designed its disclosure controls and procedures to reach a level of reasonable assurance of achieving desired control objectives and, based on the evaluation described above, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at reaching that level of reasonable assurance.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the Company's most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For a description of our material pending legal proceedings, see Legal Proceedings in Note 12, Contingent Liabilities, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and incorporated herein by reference.

Item 1A. Risk Factors

Our business is subject to a number of risks of which you should be aware before making an investment decision. The following summary highlights some of the risks you should consider with respect to our business and prospects. This summary is not complete and the risks summarized below are not the only risks we face. For a more complete understanding of the risks related to our business and an investment in our common stock, we encourage you to read and consider the more detailed discussion of these highlighted risks, which discussion immediately follows this summary. A summary of the material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

Risks Related to the Regulation and Commercialization of Our Products and Drug Candidates

- We currently have no commercial revenue and may never generate revenue or become profitable.
- We have limited experience in obtaining regulatory approval for a drug.
- We could experience delays in our planned clinical trials.
- Our clinical trials may be suspended or discontinued.
- We could experience delays or unanticipated costs in connection with our planned clinical development program of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA.
- We could experience delays or unanticipated costs in connection with our planned clinical development program of sabizabulin as a treatment to slow the progression of or promote regression of cardiovascular atherosclerotic disease if the FDA does not accept our trial design.
- Interim, preliminary and topline data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We may be subject to risks relating to collaboration with third parties.
- We rely on contract research organizations (CROs) to conduct our research and development activities.
- We rely on third party manufacturers for our drug candidates.
- Changes in law could have a negative impact on the approval of our drug candidates.
- We may fail or elect not to commercialize our drug candidates or our approved or authorized products.
- We are subject to extensive and costly governmental regulation.
- Our business could be negatively impacted by disruptions at the FDA or other government agencies.
- We could experience misconduct by our employees.
- Coverage and reimbursement may not be available for our products.
- We may not be able to gain and retain market acceptance for our drug candidates.
- Our drug products may be subject to governmental pricing controls.
- Third parties may obtain FDA regulatory exclusivity to our detriment.

Risks Related to Our Financial Position and Need for Capital

- We have incurred net losses in recent fiscal years and expect to continue to incur losses for the foreseeable future.
- Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2024.
- We will need to raise additional capital to fund our operations in the future. If we are unsuccessful in attracting new capital, we may not be able to continue operations or may be forced to sell assets to do so. Alternatively, capital may not be available to us on favorable terms, or if at all. If available, financing terms may lead to significant dilution of our stockholders' equity.
- The amount of additional financing that we will need to support our development and commercialization activities is uncertain.
- Unstable market and economic conditions may have serious adverse consequences on our ability to raise funds, which may cause us to delay, restructure or cease our operations.
- We may not receive any additional payments from ONCO in connection with the sale of our ENTADFI assets and may not receive any value for the shares of ONCO common stock that we might hold from time to time.

Risks Related to Our Business

- We may experience competition, especially for enobosarm as a treatment for metabolic diseases, if approved.
- An inability to identify or complete future acquisitions could adversely affect our future growth.
- We may experience difficulties in integrating strategic acquisitions.
- We may be subject to claims or investigations relating to The Pill Club's business practices with respect to sales of FC2.
- It is unlikely that we will collect any amount of our accounts receivable with The Pill Club.
- We are subject to significant payment obligations pursuant to the resolution of a dispute with a supplier.
- Uncertainty and adverse changes in the general economic conditions may negatively affect our business.
- Material adverse or unforeseen legal judgments, fines, penalties, or settlements could have an adverse impact on our profits and cash flows.
- We have been named a defendant in stockholder class actions. These, and potential similar or related lawsuits or investigations, could result in substantial legal fees, fines, penalties or damages and may divert management's time and attention from our business.
- Our business and operations would suffer if we sustain cyber-attacks or other privacy or data security incidents that result in security breaches.
- Any failure to comply with the FCPA and similar anti-bribery laws in non-U.S. jurisdiction could materially adversely affect our business and result in civil and/or criminal sanctions.
- We will need to increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.
- Uncertainties in the interpretation and application of tax rules in the various jurisdictions in which we operate could materially affect our deferred tax assets, tax obligations and effective tax rate.
- Our effective tax rate may be negatively impacted if we are unable to realize deferred tax assets or by future changes to tax laws in jurisdictions in which we operate.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- There are risks and uncertainties associated with the sale of the FC2 business, including those related to outstanding litigation or other claims by or disputes with the Purchaser of the FC2 business, which could result in substantial legal fees or damages and may divert management's time and attention from our business.

Risks Relating to Our Intellectual Property

- We may be unable to protect the proprietary nature of the intellectual property covering our products.
- Our or our licensors' patents may expire or be invalidated, found to be unenforceable, narrowed or otherwise limited or our or our licensors' patent applications may not result in issued patents or may result in patents with narrow, overbroad, or unenforceable claims.
- We may not have sufficient intellectual property protection for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness.
- We are dependent in part on some license relationships.
- We may face claims that our intellectual property infringes on the intellectual property rights of third parties. If we infringe intellectual property rights of third parties, it may increase our costs or prevent us from being able to commercialize our product candidates.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of our competitors.
- We may need to file lawsuits or take other actions to protect or enforce our intellectual property rights.
- We may fail to protect the confidentiality of commercially sensitive information.

Risks Related to Ownership of Our Common Stock

- Ownership in our common stock is highly concentrated and your ability to influence corporate matters may be limited as a result.
- If our stock price declines, we may be subject to delisting from the Nasdaq Capital Market.
- We incurred charges to earnings in fiscal 2020 and in fiscal 2023 resulting from the APP Acquisition, and additional charges to earnings resulting from the APP Acquisition in the future may cause our operating results to suffer.

- The restatements of our prior financial statements may affect stockholder and investor confidence in us or harm our reputation, and may subject us to additional risks and uncertainties, including increased costs and the increased possibility of legal proceedings and regulatory inquiries, sanctions or investigations.
- We previously had identified two material weaknesses in our internal control over financial reporting, and determined that they resulted in our internal control over financial reporting and disclosure controls and procedures not being effective, as of September 30, 2023. Although we have remediated these material weaknesses, we may identify additional material weaknesses or other deficiencies in the future or otherwise fail to maintain an effective system of internal controls, including disclosure controls and procedures, and this could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations.
- We are a "smaller reporting company" and will be able to avail ourselves of reduced disclosure requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors.
- There are provisions in our charter documents and Wisconsin law that might prevent or delay a change in control of our company.
- The trading price of our common stock has been volatile, and investors in our common stock may experience substantial losses.
- A substantial number of shares may be sold in the market, which may depress the market price for our common stock.
- Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our shareholders' sole source of gain.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this report and our other SEC filings, in considering our business and prospects. The risks described below are not the only risks we face. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks occurs, our business, financial condition, results of operations or prospects could be materially adversely affected. In such cases, the trading price of our common stock could decline.

Risks Related to the Regulation and Commercialization of Our Products and Drug Candidates

We currently have no commercial revenue and may never generate revenue or become profitable.

After the completion of the FC2 Business Sale on December 30, 2024, we do not currently have any source of revenue. Our ability to generate revenue and become profitable depends upon our ability to obtain regulatory approval for, and successfully commercialize, our product candidates that we may develop, in-license or acquire in the future.

Even if we are able to successfully achieve regulatory approval for any of our product candidates, we do not know what the reimbursement status of our product candidates will be or when any of these products will generate revenue for us, if at all. We do not expect to generate any revenue from our product candidates for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies and clinical trials and the regulatory approval process for our product candidates. The amount of future losses is uncertain and will depend, in part, on the rate of growth of our expenses.

Our ability to generate revenue from our product candidates also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including any remaining preclinical studies and ongoing and planned clinical trials for our product candidates;
- complete and submit NDAs to the FDA and any applicable applications to foreign regulatory authorities, and obtain regulatory approval for indications for which there is a commercial market;
- manufacture any approved products in commercial quantities and on commercially reasonable terms;
- develop a commercial organization, or find suitable partners, to market, sell and distribute approved products in the markets in which we have retained commercialization rights;
- achieve acceptance among patients, clinicians, and advocacy groups for any products we develop;
- obtain coverage and adequate reimbursement from third parties, including government payors; and
- set a commercially viable price and obtain reasonable price increases over time for any products for which we may receive approval.

We are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the processes described above, we anticipate incurring significant costs associated with commercializing our product candidates.

We have limited experience in obtaining regulatory approval for a drug.

We have only obtained regulatory approval for one drug, ENTADFI (tadalafil and finasteride) capsules, for oral use, which we sold to ONCO in April 2023. It is possible that the FDA or other regulatory authorities may refuse to accept any or all of our planned NDAs for substantive review or may conclude, after review of our data, that our applications are insufficient to obtain regulatory authorization or approval of any of our drug candidates. The FDA may also require that we conduct additional clinical or manufacturing validation studies, which may be costly and time-consuming, and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA required studies, approval of any NDA that we submit may be significantly delayed, possibly for years, or may require us to expend more resources than we have available or can secure. Any delay or inability in obtaining regulatory approvals would delay or prevent us from commercializing our drug candidates, generating revenue from these proposed products and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA we submit. If any of these outcomes occur, we may be forced to abandon our planned NDAs for one or more of our drug candidates, which would materially adversely affect our business.

Clinical trials involve a lengthy and expensive process with an uncertain outcome and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols or other factors. New drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our future clinical trials may not be successful or may be more expensive or time-consuming than we currently expect. If clinical trials for any of our drug candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA will not approve that drug and we would not be able to commercialize it, which will have a material adverse effect on our business, financial condition, results of operations and prospects.

We could experience delays in our planned clinical trials.

We may experience delays in any of the clinical trials that will be required to be conducted for our drug candidates. Our planned clinical trials might not begin on time; may be interrupted, delayed, suspended, or terminated once commenced; might need to be redesigned; might not enroll a sufficient number of patients; or might not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following:

- delays in obtaining regulatory approval to commence a trial;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- imposition of a clinical hold because of safety or efficacy concerns by the FDA, a data safety monitoring board (DSMB) or independent data monitoring committee (IDMC), a clinical trial site's independent institutional review board (IRB) or us;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new sites;
- delays in obtaining sufficient supplies of clinical trial materials, including suitable active pharmaceutical ingredients;
- delays resulting from negative or equivocal findings of a DSMB or IDMC for a trial; or
- delays resulting from shutdowns or quarantines or staffing shortages relating to a pandemic or other reasons.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, a pandemic, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Any of these delays in completing our clinical trials could increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue as to the affected drug candidate.

Our clinical trials may be suspended or discontinued.

Before we can obtain regulatory approval for the commercial sale of our drug candidates, we may be required to complete preclinical development with respect to such drug candidates and/or extensive clinical trials in humans to demonstrate the safety and efficacy of the drug candidates.

Unfavorable results from preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data. Such top-line data may be subject to change following a more comprehensive review of the data related to the applicable clinical trial. If we delay or abandon our development efforts related to any of our drug candidates, we would experience potentially significant delays in, or be required to abandon, development of that drug candidate. If we delay or abandon our development efforts related to any of our drug candidates, our business, financial condition, results of operations and prospects may be materially adversely affected.

Our clinical trials may be suspended or terminated at any time for a number of reasons. A clinical trial may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities because of a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or negative or equivocal findings of the DSMB, IDMC or the IRB for a clinical trial. An IRB may also suspend or terminate our clinical trials for failure to protect patient safety or patient rights. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe the clinical trials are not being conducted in accordance with applicable regulatory requirements or present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any drug candidate we are developing, the commercial prospects of such drug candidate will be harmed and our ability to generate revenue from such drug candidate will be delayed or eliminated. Any of these occurrences may materially harm our business, financial condition, results of operations and prospects.

We could experience delays or unanticipated costs in connection with our planned clinical development program of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight older patients receiving a GLP-1 RA.

Our future prospects are substantially dependent on our ability to successfully advance the development of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA. We have conducted a Phase 2b multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial designed to evaluate the safety and efficacy of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, and have announced topline results from the Phase 2b clinical study as well as complete unblinded safety data and topline data from a Phase 2b extension study. We have been granted a meeting with the FDA to discuss our planned Phase 3 clinical program for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA for chronic weight management. We will need to raise additional capital to conduct this Phase 3 clinical program, which may not be available when needed or on terms acceptable to us, and if the FDA does not accept our planned Phase 3 trial design, the costs of the Phase 3 trial may exceed our expectations. As a result, we may be forced to abandon our development of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness. There can be no assurances that the FDA will accept our proposed Phase 3 trial design, that we will be able to cost-effectively continue development of enobosarm, or that enobosarm will receive FDA approval or be commercialized, for any application.

We could experience delays or unanticipated costs in connection with our planned clinical development program of sabizabulin as a treatment to slow the progression of or promote regression of cardiovascular atherosclerotic disease if the FDA does not accept our trial design.

We intend to submit an IND for sabizabulin as a treatment to slow the progression of or promote regression of cardiovascular atherosclerotic disease in the first quarter of calendar 2026. Subject to receiving clearance of our IND, we plan to conduct a Phase 2, double-blind, placebo-controlled, efficacy and safety study of oral sabizabulin to treat inflammation to slow the progression or promote the regression of atherosclerosis in patients with stable coronary artery disease. Upon the review of our IND and clinical trial design, the FDA may require that we conduct preclinical studies or additional or earlier clinical trials or that we conduct larger and more expensive clinical trials than the planned Phase 2 clinical trial we have described in this report. The FDA may also disagree with the indication we have proposed and require us to more clearly define or otherwise alter the condition we are seeking to treat. Any delays of or unanticipated changes to the planned Phase 2 clinical trial may increase our costs, slow down our product development and approval process and jeopardize our ability to develop sabizabulin as a treatment to slow the progression of or promote regression of cardiovascular atherosclerotic disease. As we have prioritized our clinical programs to focus on enobosarm for obesity, the clinical development of sabizabulin to treat inflammation associated with atherosclerotic disease is subject to the availability of sufficient funding in excess of any funds we use for enobosarm for obesity or other uses. As a result, we may be forced to abandon our development of sabizabulin as a treatment to slow the progression of or promote regression of cardiovascular atherosclerotic disease. There can be no assurances that the FDA will accept our proposed trial design, that we will be able to cost-effectively continue development of sabizabulin, or that sabizabulin will receive FDA approval or be commercialized, for any application.

Interim, preliminary and topline data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

We may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, including our announcement on January 27, 2025, of topline results from our Phase 2b clinical study topline data from our clinical trial of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA. These interim updates are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, preliminary or topline results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, preliminary and topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, preliminary or topline data we previously published. As a result, interim, preliminary and topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim, preliminary and topline data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim, preliminary or topline data and final data could significantly harm our business and prospects. Further, additional disclosure of interim, preliminary or topline data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or trial is typically selected from a more extensive amount of available information. Investors may not agree with what we determine is the material or otherwise appropriate information to include in our public disclosures, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

We may be subject to risks relating to collaboration with third parties.

As part of our business strategy, we may enter into collaboration arrangements with strategic partners to develop and commercialize our drug candidates or to develop companion diagnostics for our drug candidates. For our collaboration efforts to be successful, we must identify partners whose competencies complement our competencies. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements. Also, we may be unsuccessful in integrating the resources and capabilities of these collaborators with our own. In addition, we may face a disadvantage in seeking to enter into or negotiating collaborations with potential partners because other potential collaborators may have greater management and financial resources than we do. Our collaborators may prove difficult to work with or less skilled than originally expected or may require more time to achieve the planned goals of any such collaboration, if they are achieved at all. For companion diagnostics, any such collaborator may be unsuccessful in obtaining regulatory approval for the planned diagnostic and, even if approved, may not be successful in commercializing the diagnostic or achieving widespread adoption of the diagnostic by physicians. If we are unsuccessful in our collaborative efforts, our ability to develop and market drug candidates could be severely limited.

We rely on CROs to conduct our research and development activities.

We do not have the resources to independently conduct research and development activities. Therefore, we intend to and do rely on CROs to conduct research and development activities for our drug candidates and for the execution of our clinical studies. Although we will control only certain aspects of our CROs' activities, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We cannot be sure that the CROs will conduct the research properly in a timely manner or on a cost-effective basis, or that the results will be reproducible. We and our CROs are required to comply with the FDA's current Good Clinical Practices (cGCPs), which are regulations and guidelines enforced by the FDA for all of our drug products in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable or invalid and the FDA may require us to perform additional clinical trials before approving our drug candidates. In addition, to evaluate the safety and effectiveness compared to placebo of our drug candidates to a statistically significant degree, our clinical trials will require an adequately large number of test subjects. Any clinical trial that a CRO conducts abroad on our behalf is subject to similar regulation. Accordingly, if our CROs fail to comply with these regulations or recruit a sufficient number of patients, we may be required to repeat clinical trials, which would delay the regulatory approval process.

In addition, we will not employ the personnel of our CROs, and, except for remedies available to us under our agreements with such organizations, we cannot control whether or not they will devote sufficient time and resources to our research and development and our clinical studies. Our CROs may also have relationships with other commercial entities, including one or more of our competitors, for which they may also be conducting clinical studies or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised because of the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates that we seeks to develop. As a result, our financial results and the commercial prospects for our drug candidates that we seek to develop would be harmed, our costs could increase and our ability to generate revenue from such drug candidates could be delayed or ended.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or entering into new relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially affect our ability to meet our desired clinical development timelines and can increase our costs significantly. We may encounter challenges or delays in entering into or maintaining these relationships, and any such delays or challenges may have a material adverse impact on our business, financial condition, results of operations and prospects.

We rely on third party manufacturers for our drug candidates.

For the foreseeable future, we expect to and do rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of drug candidates for use in our clinical trials. These drug candidates and products are complicated and expensive to manufacture. If our third-party manufacturers fail to deliver our drug candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our drug candidates. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for these drug candidates or products, this process would likely cause a delay in the availability of our drug candidates or products and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which our drug candidates or products can be produced, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available drug candidates or products.

In addition, regulatory requirements could pose barriers to the manufacture of our drug candidates. Third-party manufacturers are required to comply with the FDA's current Good Manufacturing Practices (cGMPs). As a result, the facilities used by any manufacturers of our drug candidates must maintain a compliance status acceptable to the FDA. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are responsible for manufacturing even though that manufacturing is conducted by a third-party contract manufacturing organization (CMO). Our third-party manufacturers will be required to produce our drug candidates under FDA cGMPs in order to meet acceptable standards. Our third-party manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to gain approval for or commercialize our drug candidates. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts and criminal prosecutions, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Finally, we also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over our products or otherwise do not satisfactorily perform according to the terms of their agreements with us.

If any supplier for our drug candidates experiences any significant difficulties in its manufacturing processes, does not comply with the terms of the agreement between us or does not devote sufficient time, energy and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our drug candidates, which could impair our ability to supply our drug candidates at the levels required for our clinical trials or commercialization and prevent or delay their successful development and commercialization.

Changes in law could have a negative impact on the approval of our drug candidates.

The FDA has established regulations, guidelines and policies to govern the drug development and approval process, as have foreign regulatory authorities. Any change in regulatory requirements resulting from the adoption of new legislation, regulations or policies may require us to amend existing clinical trial protocols or add new clinical trials to comply with these changes. Such amendments to existing protocols or clinical trial applications or the need for new ones, may significantly and adversely affect the cost, timing and completion of the clinical trials for our drug candidates. In addition, the FDA's policies may change and additional government regulations may be issued that could prevent, limit or delay regulatory approval of our drug candidates, or impose more stringent product labeling and post-marketing testing and other requirements. The political environment in the U.S. could result in significant changes in, and uncertainty with respect to, legislation, regulation and government policy that could significantly impact our business and the health care industry. While it is not possible to predict whether and when any such changes will occur, specific proposals that have been discussed or implemented which could have a material impact on us include, but are not limited to, potential changes to the Affordable Care Act (ACA), recently issued regulations offering employers religious and moral exemptions from the ACA's requirement to provide insurance covering birth control, and the enactment of the 21st Century Cures Act. If we are slow or unable to adapt to any such changes, our business, prospects and ability to achieve or sustain profitability would be adversely affected.

We may fail or elect not to commercialize our drug candidates or our approved or authorized products.

We cannot be sure that, if our clinical trials for any of our drug candidates are successfully completed, we will be able to submit an NDA to the FDA or that any NDA we submit will be approved by the FDA in a timely manner, if at all, or that the submission of any NDA is commercially feasible. After completing clinical trials for a drug candidate in humans, a drug dossier is prepared and submitted to the FDA as an NDA, and includes all preclinical studies and clinical trial data relevant to the safety and effectiveness of the product at the suggested dose and duration of use for the proposed indication as well as manufacturing information, in order to allow the FDA to review such drug dossier and to consider a drug candidate for approval for commercialization in the United States. If we are unable to submit an NDA with respect to any of our current drug candidates, if any NDA we submit is not approved by the FDA, or we elect not to file an NDA, or if we are unable to obtain any required state and local distribution licenses or similar authorizations, we will be unable to commercialize that product. The FDA can and does reject NDAs and require additional clinical trials, even when drug candidates achieve favorable results in Phase 3 clinical trials.

If we fail to commercialize any of these drug candidates, or approved or authorized products, our business, financial condition, results of operations and prospects may be materially adversely affected and our reputation in the industry and in the investment community would likely be damaged.

We are subject to extensive and costly governmental regulation.

Our drug candidates are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Federal Trade Commission, the Centers for Medicare & Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services, including its Office of Inspector General, the U.S. Department of Justice, the Departments of Defense and Veterans Affairs, to the extent our products are paid for directly or indirectly by those departments, state and local governments and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical products and medical devices under various regulatory provisions. The Office of Prescription Drug Promotion (OPDP) division of the FDA also regulates the advertising, marketing, and promotion of the Company's products. Many states and local governments require distribution licenses or similar authorizations to sell products in their jurisdictions. Any of our products that are tested or marketed outside the U.S. are also subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

We are subject to additional health care regulation and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under government health care programs such as the Medicare and Medicaid programs;
- the federal False Claims Act that prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, there has been a recent trend of increased federal and state regulation of payments made by drug manufacturers to health care practitioners. Some states, such as California, Connecticut, Massachusetts and Nevada, mandate implementation of corporate compliance programs, while other state laws prohibit, or require tracking and reporting of, certain gifts, compensation and other remuneration to physicians and other health care practitioners.

In recent years, a number of states, including California, Minnesota, Oregon, Texas and Washington, have enacted laws requiring manufacturers to submit reports on drugs whose list price has increased by more than a certain percentage during a specified period and/or new drugs that are being launched at a price exceeding a specified amount. Among other things, the reports must explain the justifications for the price or price increase.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

Our business could be negatively impacted by disruptions at the FDA or other government agencies.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including the transition to a new administration; government budget and funding levels; statutory, regulatory and policy changes: the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees; and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and certain Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine operations.

We could experience misconduct by our employees.

We will be exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, marketing and promotional laws, rules, and policies, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws and regulations, to comply with anti-corruption laws, including the FCPA, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and prevent employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Coverage and reimbursement may not be available for our products.

Market acceptance and sales for our drug candidates will depend on coverage and reimbursement policies and may be affected by health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. We cannot be sure that coverage and reimbursement will be available for our drug candidates, if approved. We also cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our drug candidates.

We may not be able to gain and retain market acceptance for our drug candidates.

Physicians may not prescribe our drug candidates, if approved by the appropriate regulatory authorities for marketing and sale, which would prevent any such drug candidate from generating revenue. Market acceptance of our drug candidates by physicians, patients and payors, will depend on a number of factors, many of which are beyond our control, including the following:

- the clinical indications for which our drug candidates are approved, if at all;
- acceptance by physicians and payors of each product as safe and effective treatment;
- the cost of treatment in relation to alternative treatments;
- the relative convenience and ease of administration of our products in the treatment of the conditions for which they are intended;
- the availability and efficacy of competitive drugs;
- the effectiveness of our sales and marketing efforts;

- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid;
- limitations or warnings contained in a product's FDA or other applicable regulatory agency's approved labeling; and
- prevalence and severity of adverse side effects.

Even if the medical community accepts that our drug candidates are safe and efficacious for their approved indications, physicians may not immediately be receptive to the use or may be slow to adopt such products as an accepted treatment for the conditions for which they are intended. Without head-to-head comparative data, we will also not be able to promote our products as being superior to competing products. If our drug candidates, if approved, do not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from these products. In addition, our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.

In addition, even if our drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if:

- new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete;
- unforeseen complications arise with respect to use of our products; or
- sufficient third-party insurance coverage or reimbursement does not remain available.

Our drug products may be subject to governmental pricing controls.

In many foreign markets, including the countries in the EU, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our likelihood of launching a product and on the profitability of any marketed product.

Third parties may obtain FDA regulatory exclusivity to our detriment.

We plan to seek to obtain market exclusivity for our drug candidates and any other drug candidates we develop in the future. To the extent that patent protection is not available or has expired, FDA marketing exclusivity may be the only available form of exclusivity available for these proposed products. Marketing exclusivity can delay the submission or the approval of certain marketing applications. Potentially competitive products may also seek marketing exclusivity and may be in various stages of development, including some more advanced than our drug candidates. We cannot predict with certainty the timing of FDA approval or whether FDA approval will be granted, nor can we predict with certainty the timing of FDA approval for competing products or whether such approval will be granted. It is possible that competing products may obtain FDA approval with marketing exclusivity before we do, which could delay our ability to submit a marketing application or obtain necessary regulatory approvals, result in lost market opportunities with respect to our drug candidates and materially adversely affect our business, financial condition and results of operations.

Risks Related to Our Financial Position and Need for Capital

We have incurred net losses in recent fiscal years and expect to continue to incur losses for the foreseeable future.

We incurred a net loss of $37.8 million during the year ended September 30, 2024. Pharmaceutical product development is a speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. We expect to incur significant expenses until we are able to obtain regulatory approval and subsequently sell one or more of our drug candidates under development in significant quantities, which may not happen. We expect to devote most of our financial resources to research and development, including our non-clinical development activities and clinical trials. Our drug candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenue. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2024.

The report from our independent registered public accounting firm for the year ended September 30, 2024, includes an explanatory paragraph stating that our losses from operations and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern for a period of one year after the date the financial statements are issued. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. There can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, or that our cash resources will fund our operating plan for the period anticipated by the Company or that additional funding will be available on terms acceptable to us, or at all.

We will need to raise additional capital to fund our operations in the future. If we are unsuccessful in attracting new capital, we may not be able to continue operations or may be forced to sell assets to do so. Alternatively, capital may not be available to us on favorable terms, or if at all. If available, financing terms may lead to significant dilution of our stockholders' equity.

We are not profitable and have had negative cash flow from operations. We will need large amounts of capital to support our development and commercialization efforts for our drug candidates, including one or more Phase 3 pivotal clinical trials to evaluate the efficacy and the safety of enobosarm in preventing significant muscle wasting in obese patients receiving a GLP-1 therapeutic to treat obesity. Our existing cash and cash equivalents as of the date of this report may not be sufficient to fund our working capital needs and operating expenses. To obtain the capital necessary to fund our operations, we expect to finance our cash needs through public or private equity offerings, debt financing and/or other capital sources. Additional capital may not be available at such times or amounts as needed by us.

Even if capital is available, it might be available only on unfavorable terms. Any additional equity or convertible debt financing into which we enter could be dilutive to our existing stockholders. Any future debt financing into which we enter may impose covenants upon us that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, we may need to relinquish rights to our technologies or our products or grant licenses on terms that are not favorable to us. Our low stock price may make it more difficult to access equity capital markets and may increase the dilution to our shareholders if we raise capital through the sale of equity securities. If access to sufficient capital is not available as and when needed, our business will be materially impaired, and we may be required to cease operations, curtail one or more product development or commercialization programs, scale back or eliminate the development of business opportunities, or significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all of our assets. Any of these factors could harm our operating results.

The amount of additional financing that we will need to support our development and commercialization activities is uncertain.

We expect to incur significant expenditures over the next several years to support our preclinical and clinical development activities, particularly with respect to clinical trials for certain of our drug candidates and to commence the commercialization of our drug candidates. This may require us to obtain additional financing for our business until revenues from our current commercial operations independently fund our drug development programs. We may also need to obtain additional financing to complete the development of any additional drug candidates we might acquire or to pay other operating expenses.

Our future capital requirements will depend upon a number of factors, including:

- the size, complexity, results and timing of our development programs and clinical trials;
- our ability to successfully commercialize our drug candidates, if approved;
- our ability to obtain sufficient supply of the compounds necessary for our drug candidates at a reasonable cost;
- the time and cost involved in obtaining regulatory approvals;
- the time and cost involved in developing any required companion diagnostics for any of our product candidates, including enobosarm;
- the terms and timing of any potential future collaborations, licensing or other arrangements we may establish;

- cash requirements of any future acquisitions, in-licenses or the development of other drug candidates;
- our receipt of funds from other potential sources, including cash flow from licenses and sales;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- the costs involved in manufacturing and commercializing our drug candidates;
- the amount of sales or other revenues from drug candidates that we may commercialize, if any, including the selling prices for such drug candidates and the availability of adequate third-party coverage and reimbursement;
- regulatory changes;
- changes to federal, state or local health care or prescription drug programs;
- market and economic conditions; and
- competing technological and market developments.

These factors could result in variations from currently projected operating and liquidity requirements.

Unstable market and economic conditions may have serious adverse consequences on our ability to raise funds, which may cause us to delay, restructure or cease our operations.

From time to time, global and domestic credit and financial markets have experienced extreme disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates or inflation, and uncertainty about economic stability. In recent years, the COVID-19 pandemic, the Russia-Ukraine war and the Israel-Hamas war have created volatility and uncertainty. Recently, tensions in trading relations between the U.S. and other countries due to U.S. tariffs and retaliatory tariffs on U.S. goods could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in disruptions in global economic conditions and global financial markets. Our financing strategy may be adversely affected by an economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, it may make a debt or equity financing more difficult to complete, costlier, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms will have a material adverse effect on our business strategy and financial performance, and could require us to cease or delay our operations.

We may not receive any additional payments from ONCO in connection with the sale of our ENTADFI assets.

In April 2023, we sold our ENTADFI assets to ONCO and on September 29, 2023, we entered into an amendment to the Asset Purchase Agreement which provided that the promissory note for the $4 million installment of the purchase price due September 30, 2023 was deemed paid and fully satisfied upon (1) the payment to us of the sum of $1.0 million in immediately available funds on September 29, 2023, and (2) the issuance to us by October 3, 2023 of 3,000 shares of ONCO Preferred Stock. The shares of ONCO Preferred Stock held by the Company were converted into 142,749 shares of ONCO Common Stock on September 24, 2024, and during the three months ended December 31, 2024, the Company sold all 142,749 shares of ONCO Common Stock for net proceeds of $0.4 million. Under the Asset Purchase Agreement, ONCO was obligated to pay an additional $10 million in installments in our fiscal year 2024 pursuant to the ONCO Promissory Notes, plus up to an additional $80 million in milestone payments based on ONCO’s net sales from ENTADFI business after closing.

There is uncertainty as to whether and when we will receive any future installment payments of purchase price under the ONCO Promissory Notes or sales milestone payments under the Asset Purchase Agreement, and there is a risk of a future default by ONCO in performing its payment obligations, and we do not have a security interest in any of ONCO's assets and accordingly would be an unsecured creditor in the event that ONCO defaulted. We received payment of $1.0 million on September 29, 2023 and total payments of $0.3 million during the year ended September 30, 2024 from ONCO pursuant to the ONCO Promissory Notes. We have entered into the Forbearance Agreement with ONCO, relating to certain defaults under the ONCO Promissory Notes, and have also agreed to extend the due dates for the ONCO Promissory Notes to August 14, 2025. ONCO is required to make the Required Payments towards the outstanding balance of the ONCO Promissory Notes during the period prior to the new due date. There can be no assurance as to (1) whether and when we will receive any payments pursuant to the terms of the Forbearance Agreement or otherwise under the ONCO Promissory Notes or any sales milestone payments under the Asset Purchase Agreement, and (2) the extent of the risk of a future default by ONCO in performing its payment or other obligations under the Forbearance Agreement and the ONCO Promissory Notes. If ONCO fails to pay the outstanding ONCO Promissory Notes when due or an event of default under the ONCO Promissory Notes or the Forbearance Agreement otherwise occurs, we may, among other things, declare the full amount outstanding to be due and sue to collect the ONCO Promissory Notes, which actions may force ONCO into bankruptcy. There can be no assurance as to whether we would be able to collect any amounts due under the ONCO Promissory Notes if ONCO files for bankruptcy.

Risks Related to Our Business

We may experience competition, especially for enobosarm as a treatment for metabolic diseases, if approved.

We are engaged in the marketing and development of products in industries, including the pharmaceutical industry, that are highly competitive. The pharmaceutical industry is also characterized by extensive research and rapid technological progress. Potential competitors with respect to our drug candidates in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies. Many of our competitors have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we have. We may be unable to compete successfully against current and future competitors, and competitive pressures could have a negative effect on our net revenues and profit margins.

The market for treatments relating to obesity, including treatments relating to muscle atrophy and muscle weakness in patients receiving a GLP-1 RA, is highly competitive and includes major pharmaceutical companies. Such competitors may have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we have. We may be unable to compete successfully against current and future competitors, and competitive pressures could have a negative effect on our net revenues and profit margins. In addition, if we believe that a competitor's development activities infringe on our intellectual property rights relating to enobosarm, we may lack the resources to file infringement claims, which can be expensive and time-consuming.

An inability to identify or complete future acquisitions could adversely affect our future growth.

We intend to pursue acquisitions of new products, technologies, and/or businesses that enable us to leverage our competitive strengths. While we continue to evaluate potential acquisitions, we may not be able to identify and successfully negotiate suitable acquisitions, obtain financing for future acquisitions on satisfactory terms, obtain regulatory approval for acquisitions where required, or otherwise complete acquisitions in the future. An inability to identify or complete future acquisitions could limit our future growth. Similarly, any use of our equity or a convertible debt security in any acquisition would be dilutive to our stockholders and may affect the market price of our shares.

We may experience difficulties in integrating strategic acquisitions.

The integration of acquired companies and their operations into our operations involves a number of risks, including:

- the acquired business may experience losses or we may assume liabilities from the acquired company that could adversely affect our profitability;
- unanticipated costs relating to the integration of acquired businesses may increase our expenses;
- possible failure to accomplish the strategic objectives for an acquisition;
- the loss of key personnel of the acquired business;
- difficulties in achieving planned cost-savings and synergies may increase our expenses or decrease our net revenues;
- diversion of management's attention could impair their ability to effectively manage our business operations;
- the acquired business may require significant expenditures for product development or regulatory approvals;
- the acquired business may lack adequate internal controls or have other issues with its financial systems;
- there may be regulatory compliance or other issues relating to the business practices of an acquired business;
- we may record goodwill and nonamortizable intangible assets that are subject to impairment testing on a regular basis and potential impairment charges and we may also incur amortization expenses related to intangible assets; and
- unanticipated management or operational problems or liabilities may adversely affect our profitability and financial condition.

Additionally, we may borrow funds or issue equity to finance strategic acquisitions. Debt leverage resulting from future acquisitions could adversely affect our operating margins and limit our ability to capitalize on future business opportunities. Such borrowings may also be subject to fluctuations in interest rates. Equity issuances may dilute our existing shareholders and adversely affect the market price of our shares.

We may be subject to claims or investigations relating to The Pill Club's business practices with respect to sales of FC2.

The Pill Club was one of the largest customers of our FC2 business, accounting for 44% of our net revenues in fiscal 2022 and 43% of our net revenues in fiscal 2021. On February 7, 2023, the California Attorney General announced a settlement with The Pill Club over a number of alleged improper actions by The Pill Club, including alleged overbilling for FC2. Although we were not involved in the business practices that were the subject of the California Attorney General's allegations, it is possible that the California Attorney General or another governmental authority may investigate or assert claims against us in connection with The Pill Club's practices with respect to sales of FC2. Any such claims or investigations could have a material adverse effect on our reputation, business, results of operations and financial condition. Any such claims or investigations, regardless of the outcome, would be costly and time-consuming.

It is unlikely that we will collect any amount of our accounts receivable with The Pill Club.

We have a concentration of accounts receivable at The Pill Club, with $3.9 million of accounts receivable as of June 30, 2025. On April 18, 2023, The Pill Club filed for Chapter 11 bankruptcy and its assets were sold in June 2023 to satisfy a secured creditor. After the FC2 Business Sale, we retained our claims against The Pill Club for these receivables that have been filed with The Pill Club bankruptcy estate and we will continue to pursue payment for as much of the receivables as possible but based on the amount of the claims of other unsecured creditors and the limited assets remaining in The Pill Club bankruptcy estate it is unlikely that we will recover any of these receivables. We recorded in fiscal 2023 and maintain as of June 30, 2025 an allowance for credit losses of $3.9 million due to The Pill Club's Chapter 11 bankruptcy filing in April 2023.

We are subject to significant payment obligations pursuant to the resolution of a dispute with a supplier.

A supplier had claimed that we owe approximately $10 million for products and services relating to our efforts to commercialize sabizabulin under an emergency use authorization. We disputed the amount we owe, and to resolve this dispute we agreed to pay the supplier a total of $8.3 million, consisting of $2.3 million paid in February 2024, $3.5 million payable in 48 equal monthly installments between March 31, 2024 and January 31, 2028, and $2.5 million payable in an amount equal to 25% of payments pursuant to the ONCO Promissory Notes, provided that if this amount is not paid in full by December 31, 2025, we must pay the balance in 24 equal monthly installments commencing in January 2026. If we lack sufficient cash to pay amounts due to this supplier when due, we may need to raise additional capital, curtail one or more product development or commercialization programs, scale back or eliminate the development of business opportunities, or significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all of our assets.

Uncertainty and adverse changes in the general economic conditions may negatively affect our business.

If general economic conditions, including continued or worsening inflation or supply chain challenges, recessionary pressures, rising interest rates, labor shortages, and rising unemployment, in the U.S. and other global markets in which we operate decline, or if consumers fear that economic conditions will decline, consumers may reduce expenditures for products such as our potential products. Adverse changes may occur as a result of adverse global or regional economic conditions, fluctuating oil prices, supply chain problems, inflation, political instability, declining consumer confidence, a pandemic, unemployment, fluctuations in stock markets, contraction of credit availability, tariffs and trade tensions, or other factors affecting economic conditions generally. These changes may negatively affect the sales or development of future products, increase the cost, and decrease the availability of financing, or increase costs associated with producing and distributing our potential drug candidates.

Material adverse or unforeseen legal judgments, fines, penalties, or settlements could have an adverse impact on our profits and cash flows.

We may, from time to time, become a party to legal proceedings incidental to our business, including, but not limited to, alleged claims relating to product liability, environmental compliance, patent infringement, commercial disputes, securities laws, antitrust and competition laws, regulatory or administrative actions, corporate matters and employment matters. The current and future use of our drug candidates by us and potential collaborators in clinical trials, and the sale of any approved products in the future, may expose us to product liability claims. We will face an inherent risk of product liability claims as a result of the clinical testing of our drug candidates and will face an even greater risk if we obtain FDA approval and commercialize our drug candidates in the U.S. or other additional jurisdictions or if we engage in the clinical testing of proposed new products or commercialize any additional products. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products or drug candidates, if approved.

Regardless of the merits or eventual outcome, product liability claims may result in any of the following:

- the inability to commercialize our drug candidates;
- difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed;
- labeling, marketing, or promotional restrictions;
- product recalls or withdrawals;
- decreased demand for our products or products that we may develop in the future;
- loss of revenue;
- injury to reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients; and
- a decline in the value of our shares.

Litigation could require us to record reserves or make payments which could adversely affect our profits and cash flows. Even the successful defense of legal proceedings may cause us to incur substantial legal costs, may divert management's attention and resources away from our business, may prevent us or our partners from achieving or maintaining market acceptance of the affected product and may substantially increase the costs of commercializing our future products and impair the ability to generate revenues from the commercialization of these products either by us or by our strategic alliance partners.

We currently maintain limited general commercial liability insurance coverage. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or for liabilities in excess of our insurance limits, our assets may not be sufficient to cover such claims and our business operations could be impaired.

We have been named a defendant in stockholder class actions. These, and potential similar or related lawsuits or investigations, could result in substantial legal fees, fines, penalties or damages and may divert management's time and attention from our business.

On December 5, 2022, a putative securities class action complaint was filed in federal district court for the Southern District of Florida against us certain of our current officers and directors. The amended complaint alleges that certain public statements about sabizabulin as a treatment for COVID-19 between March 1, 2021 and March 2, 2023 violated Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, and seeks monetary damages. We and certain of our offices and directors are also parties to four derivative actions asserting state law claims primarily in connection with the issues and claims asserted in the securities class action.

These legal proceedings and any other similar or related legal proceedings are subject to inherent uncertainties, and the actual costs to be incurred relating to these matters will depend upon many unknown factors. The outcome of these legal proceedings is uncertain, and we could be forced to expend significant resources in the defense of these actions, and we may not prevail. Although we have insurance coverage for these actions, we have a $5 million retention amount, which means that we are responsible for the first $5 million of costs or damages relating to these actions, and as a result must pay for any defense costs ourselves up to such retention amount before any insurance coverage will apply. Monitoring and defending against legal actions is time-consuming for management and detracts from our ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with these matters. We are also generally obligated, to the extent permitted by law, to indemnify our current and former directors and officers who are named as defendants in these and similar actions. We are not currently able to estimate the possible cost to us from these matters, as these actions are currently at an early stage and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. Decisions adverse to our interests in these actions could result in the payment of substantial damages, and could have a material adverse effect on our cash flow, results of operations and financial position. These and additional legal proceedings may also increase the costs of, or result in adverse changes in, our director and officer insurance coverage, and if we are unable in the future to obtain an acceptable level of director and officer insurance coverage we may face challenges in recruiting or retaining qualified independent directors or officers.

Our business and operations would suffer if we sustain cyber-attacks or other privacy or data security incidents that result in security breaches.

Our information technology may be subject to cyber-attacks, security breaches or computer hacking. Experienced computer programmers and hackers may be able to penetrate our security controls and misappropriate or compromise sensitive personal, proprietary or confidential information, create system disruptions or cause shutdowns. They also may be able to develop and deploy malicious software programs that attack our systems or otherwise exploit any security vulnerabilities. Our systems and the data stored on those systems may also be vulnerable to security incidents or security attacks, acts of vandalism or theft, misplaced or lost data, human errors, or other similar events that could negatively affect our systems and our data, as well as the data of our business partners. Further, third parties, such as hosted solution providers, that provide services to us, could also be a source of security risk in the event of a failure of their own security systems and infrastructure.

The costs to eliminate or address the foregoing security threats and vulnerabilities before or after a cyber-incident could be significant. Our remediation efforts may not be successful and could result in interruptions, delays or cessation of service, and loss of existing or potential suppliers or customers. In addition, breaches of our security measures and the unauthorized dissemination of sensitive personal, proprietary or confidential information about us, our business partners, participants in our clinical trials or other third parties could expose us to significant potential liability and reputational harm. In addition, the loss of clinical trial data from completed or ongoing or planned clinical trials as a result of a data security incident or other systems failure could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. As threats related to cyber-attacks develop and grow, we may also find it necessary to make additional investments to protect our data and infrastructure, which may impact our profitability. As a global enterprise, we could also be negatively impacted by existing and proposed laws and regulations, as well as government policies and practices related to cybersecurity, data privacy, data localization and data protection such as GDPR and the California Consumer Privacy Act.

We will need to increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.

Our management, personnel, systems and facilities currently in place may not be adequate to support our business plan and future growth. We will need to further expand our scientific, sales and marketing, managerial, operational, financial and other resources to support our planned research, development and commercialization activities.

Our need to manage our operations, growth and various projects effectively requires that we:

- improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- manage our commercialization activities for our drug candidates effectively and in a cost-effective manner;
- manage our relationship with our partners related to the commercialization of our drug candidates;
- manage our clinical trials effectively;
- manage our internal manufacturing operations effectively and in a cost-effective manner while increasing production capabilities for our current drug candidates to commercial levels; and
- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. Because we rely on consultants for certain functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals.

Uncertainties in the interpretation and application of tax rules in the various jurisdictions in which we operate could materially affect our deferred tax assets, tax obligations and effective tax rate.

We are subject to a variety of taxes and tax collection and remittance obligations in the U.S. and foreign jurisdictions. Additionally, at any point in time, we may be under examination for value added, sales-based, payroll, product, import or other non-income taxes. We may recognize additional tax expense, be subject to additional tax liabilities, incur losses and penalties, due to changes in laws, regulations, administrative practices, principles, assessments by authorities and interpretations related to tax, including tax rules in various jurisdictions. We compute our income tax provision based on enacted tax rates in the countries in which we operate. As tax rates vary among countries, a change in earnings attributable to the various jurisdictions in which we operate could result in an unfavorable change in our overall tax provision. Changes in enacted tax rates and the assumptions and estimates we have made, as well as actions we may take, could result in a write down of deferred tax assets or otherwise materially affect our tax obligations or effective tax rate, which could negatively affect our financial condition and results of operations.

Our effective tax rate may be negatively impacted if we are unable to realize deferred tax assets or by future changes to tax laws in jurisdictions in which we operate.

We are subject to income taxes in the U.S., the U.K. and other global jurisdictions. Our effective tax rate could be adversely affected by changes in the valuation of deferred tax assets and liabilities. We recognize deferred tax assets and liabilities based on the differences between the consolidated financial statement carrying amounts and the tax basis of assets and liabilities. Significant judgment is required in determining our provision for income taxes. We regularly review our deferred tax assets for recoverability and establish a valuation allowance if it is more likely than not that some portion or all of a deferred tax asset will not be realized. If we are unable to generate sufficient future taxable income, if there is a material change in the actual effective tax rates, or if there is a change to the time period within which the underlying temporary differences become taxable or deductible, we could be required to increase our valuation allowance against our deferred tax assets, which could result in a material increase in our effective tax rate. Changes in tax laws or tax rulings could have a material impact on our effective tax rate. Jurisdictions in which we operate, including the U.S. and the UK, may consider changes to existing tax laws. Such changes could increase our tax obligations in those countries where we do business. Any changes in the taxation of our activities in such jurisdictions may result in a material increase in our effective tax rate.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of September 30, 2024, we had federal and state net operating loss carryforwards of approximately $164.2 million and $70.0 million, respectively, of which $28.6 million and $35.6 million, respectively, if not utilized to offset taxable income in future periods, will begin to expire in 2025 and will completely expire in 2044. Under the Internal Revenue Code of 1986, as amended (the "Code") and the regulations promulgated thereunder, including, without limitation, the consolidated income tax return regulations, various corporate ownership changes could limit our ability to use our net operating loss carryforwards and other tax attributes to offset our income.

An "ownership change" (generally a 50% change in equity ownership over a three-year period) under Section 382 of the Code could limit our ability to offset, post-change, our U.S. federal taxable income. Section 382 of the Code imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change net operating loss carryforwards and certain recognized built-in losses.

There are risks and uncertainties associated with the sale of the FC2 business, including those related to outstanding litigation or other claims by or disputes with the Purchaser of the FC2 business, which could result in substantial legal fees or damages and may divert management's time and attention from our business.

On December 30, 2024, we sold the FC2 business to Clear Future, Inc. (the "Purchaser"), for aggregate consideration of $18.0 million, less specified deductions and subject to a customary working capital adjustment. We estimate that the proceeds to us after deducting a change of control payment due to SWK Funding LLC ("SWK") pursuant to the Residual Royalty Agreement, dated as of March 5, 2018 (the "Royalty Agreement"), between the Company and SWK, together with other customary transaction fees for a transaction of this type, is approximately $12.5 million, subject to adjustment as set forth in the Purchase Agreement. As a result of the adjustment provisions in the Purchase Agreement, we could receive proceeds that are less than we anticipate.

The Purchase Agreement contains a provision for an adjustment to the purchase price, including an adjustment based on the working capital of the FC2 business as of the closing date. The Purchaser was required to deliver its purchase price adjustment calculation within 90 days after the closing date. The Purchaser delivered its calculation in April 2025 and we have disputed its calculation. This dispute has been submitted to an accounting firm for binding resolution pursuant to the terms of the Purchase Agreement.

The sale of the FC2 business required us to separate and allocate specific assets to the business, including some shared assets. We could face disputes with the Purchaser regarding whether or not certain assets were included in the sale. Moreover, we agreed, for a period of time after the sale pursuant to a Transition Services Agreement, to continue to perform certain services that we historically performed for the FC2 business, and we also undertook other customary obligations associated with a disposition of a business by means of asset sale. The attention of our management may be directed toward closing or post-closing matters relating to the sale of the FC2 business, including the services required by the Transition Services Agreement, and their focus may be diverted from the day-to-day business operations of our company.

We have also agreed to indemnify the Purchaser against certain losses suffered as a result of certain breaches of our representations, warranties, covenants and agreements in the Purchase Agreement and related documents. Any event that results in a right for the Purchaser to seek indemnity from us could result in substantial liability to us and could adversely affect our financial position and results of operations. On August 5, 2025, the Purchaser filed a complaint in the Superior Court of the State of Delaware (the "Clear Future Lawsuit") alleging that we breached certain representations and warranties in the Purchase Agreement and otherwise made false representations relating to a customer relationship. The complaint makes claims for fraud, breach of representations and warranties, indemnification and breach of contract. Although our potential exposure to the Purchaser for any claims of breach of these representations and warranties is limited to $54,000 except in the case of fraud, we may incur substantial legal fees and costs and such limit will not apply if the Purchaser prevails in its claims for fraud. In June 2025, the Purchaser delivered a demand for indemnification under the Purchase Agreement, which alleged that we are responsible to indemnify the Purchaser for a pre-closing tax liability of approximately $137,000.

We may incur significant legal and other fees and costs to resolve these disputes with the Purchaser. In addition, monitoring and defending against the Clear Future Lawsuit and any other legal claims or resulting litigation or other dispute resolution processes is time-consuming for management and detracts from our ability to fully focus our internal resources on our business activities. We are not currently able to estimate the possible cost to us from these matters, as these matters are currently at an early stage and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. Decisions adverse to our interests in these actions could result in the payment of substantial damages, and could have a material adverse effect on our cash flow, results of operations and financial position.

Risks Relating to Our Intellectual Property

We may be unable to protect the proprietary nature of the intellectual property covering our products.

Our commercial success depends in part on our ability to obtain and maintain intellectual property rights to our products, drug candidates and technology as well as successfully defending these rights against third party challenges. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and profitability. The patent positions of pharmaceutical products are highly uncertain. The legal principles applicable to patents are in transition due to changing court precedent and legislative action and we cannot be certain that the historical legal standards surrounding questions of validity will continue to be applied or that current defenses relating to issued patents in these fields will be sufficient in the future. Changes in patent laws in the United States, such as the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States and we may encounter significant problems in protecting our proprietary rights in these countries. We are limited in protecting our proprietary rights from unauthorized use by third parties by the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets.

These risks include the possibility of the following:

- the patent applications that we have filed may fail to result in issued patents in the United States or in foreign countries;
- patents issued or licensed to us or our partners may be challenged or discovered to have been issued on the basis of insufficient, incomplete or incorrect information, and thus held to be invalid or unenforceable;
- the scope of any patent protection may be too narrow to exclude competitors from developing or designing around these patents;
- we or our licensor was not the first to make the invention covered by an issued patent or pending patent application;
- we or our licensor was not the first inventor to file a patent application for the technology in the United States or was not the first to file a patent application directed to the technology abroad;

- we may fail to comply with procedural, documentary, fee payment and other similar provisions during the patent application process, which can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights;
- future drug candidates or our proprietary technologies may not be patentable or legal decisions may limit patent-eligible subject matter;
- others may claim rights or ownership with regard to patents and other proprietary rights that we hold or license;
- delays in development, testing, clinical trials and regulatory review may reduce the period of time during which we could market our drug candidates under patent protection;
- we may fail to timely apply for patents on our technologies or products; and
- inability to control patent prosecution, maintenance, or enforcement of any in-licensed intellectual property.

We cannot predict whether third parties will assert these claims against us or our strategic partners or against the licensors of technology licensed to us, or whether those claims will harm our business. In addition, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we or our partners were to face infringement claims or challenges by third parties relating to our drug candidates, an adverse outcome could subject us to significant liabilities to such third parties and force us or our partners to curtail or cease the development of some or all of our drug candidates, which could adversely affect our business, financial condition, results of operations and prospects.

Our or our licensors' patents may expire or be invalidated, found to be unenforceable, narrowed or otherwise limited or our or our licensors' patent applications may not result in issued patents or may result in patents with narrow, overbroad, or unenforceable claims.

Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection for our drug candidates, as well as the methods for treating patients in the prescribed indications using these drug candidates. We will be able to protect our drug candidates and the methods for treating patients in the indications using these drug candidates from unauthorized use by third parties only to the extent that we or our licensors own or control such valid and enforceable patents or trade secrets.

Even if our drug candidates and the methods for treating patients for prescribed indications using these drug candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Our and our licensor's ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensor, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

While we will apply for patents covering our technologies and products, as we deem appropriate, many third parties may already have filed patent applications or have received patents in our areas of product development. These entities' applications, patents and other intellectual property rights may conflict with our patent applications or other intellectual property rights and could prevent us from obtaining patents, could call into question the validity of any of our patents, if issued, or could otherwise adversely affect our ability to develop, manufacture, commercialize or market our products. In addition, if third parties file patent applications which include claims covering any technology to which we have rights, we may have to participate in interference, derivation or other proceedings with the USPTO, or foreign patent regulatory authorities to determine our rights in the technology, which may be time-consuming and expensive. Moreover, issued patents may be challenged in the courts or in post-grant proceedings at the USPTO, or in similar proceedings in foreign countries. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims.

If we or our licensors or strategic partners fail to obtain and maintain patent protection for our products, or our proprietary technologies and their uses, companies may be dissuaded from collaborating with us. In such event, our ability to commercialize our drug candidates or future drug candidates, if approved, may be threatened, we could lose our competitive advantage and the competition we face could increase, all of which could adversely affect our business, financial condition, results of operations and prospects.

In addition, mechanisms exist in much of the world permitting some form of challenge by generic drug marketers to patents prior to, or immediately following, the expiration of any regulatory exclusivity, and generic companies are increasingly employing aggressive strategies, such as "at risk" launches and compulsory licensing to challenge relevant patent rights.

Our business also may rely on unpatented proprietary technology, know-how, and trade secrets. If the confidentiality of this intellectual property is breached, it could adversely impact our business.

We may not have sufficient intellectual property protection for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness.

The value of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness will depend in part on our ability to obtain and maintain intellectual property rights to this drug candidate as well as successfully defend these rights against third party challenges. We have existing composition of matter and polymorph composition of matter issued patents with the last patent terms expiring in 2028 and 2029 as well as a pending provisional patent method of use application related to the use of enobosarm in weight management, with the longest patent term, if issued, being for the method of use application which would expire in 2044, if issued. This method of use patent application may fail to result in an issued patent, may be challenged, or may result in patent protection that may be too narrow to exclude competitors from developing or designing around any issued patent. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and profitability.

We are dependent in part on some license relationships.

We have acquired by license intellectual property and technology relating to our sabizabulin and enobosarm drug candidates and might enter into additional licenses in the future. Licenses to which we are a party contain, and we expect that any future licenses will contain, provisions requiring up-front, milestone and royalty payments to licensors. If we fail to comply with these obligations or other obligations to a licensor, that licensor might have the right to terminate the license on relatively short notice, in which event we would not be able to commercialize the drug candidates that were covered by the license. Also, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates.

We may face claims that our intellectual property infringes on the intellectual property rights of third parties. If we infringe intellectual property rights of third parties, it may increase our costs or prevent us from being able to commercialize our product candidates.

Our success depends, in part, on not infringing the patents and proprietary rights of other parties and not breaching any license, collaboration or other agreements we enter into with regard to our technologies and products. Numerous United States and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we intend to develop drugs. Patent applications are confidential when filed and remain confidential until publication, approximately 18 months after initial filing, while some patent applications remain unpublished until issuance. As such, there may be other third-party patents and pending applications of which we will be unaware with claims directed towards composition of matter, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products or drug candidates. Therefore, we cannot know with certainty the nature or existence of every third-party patent filing. We cannot be sure that we or our partners will be free to manufacture or market our drug candidates as planned or that us or our licensors' and partners' patents will not be opposed or litigated by third parties. If any third-party patent was held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods of treatment related to the use or manufacture of any of our drug candidates, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. We may not be able to obtain a license to such patent on favorable terms or at all. Failure to obtain such license may have a material adverse effect on our business.

There is a risk that we are infringing the proprietary rights of third parties because numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields that are the focus of our development and manufacturing efforts. Others might have been the first to make the inventions covered by each of our or our licensor’s pending patent applications and issued patents and/or might have been the first to file patent applications for these inventions. In addition, because patent applications take many months to publish and patent applications can take many years to issue, there may be currently pending applications, unknown to us or our licensor, which may later result in issued patents that cover the production, manufacture, synthesis, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, synthesis, commercialization, formulation or use of our product candidates may infringe existing patents of which we are not aware. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management’s attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.

There is a substantial amount of litigation involving intellectual property in the pharmaceutical industry. If a third party asserts that we infringe its patents or other proprietary rights, we could face a number of risks that could adversely affect our business, financial condition, results of operations and prospects, including the following:

- infringement and other intellectual property claims would be costly and time-consuming to defend, whether or not we are ultimately successful, and could delay the regulatory approval process, consume our capital and divert management's attention from our business;
- we may have to pay substantial damages for past infringement if a court determines that our products or technologies infringe a competitor's patent or other proprietary rights;
- a court may prohibit us from selling or licensing our technologies or future products unless a third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties or lump sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license; or
- we may need to redesign our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We cannot predict whether third parties will assert these claims against us or our strategic partners or against the licensors of technology or other intellectual property licensed to us, or whether those claims will harm our business. In addition, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we or our partners were to face infringement claims or challenges by third parties relating to our drug candidates, an adverse outcome could subject us to significant liabilities to such third parties and force us or our partners to curtail or cease the development of some or all of our drug candidates, which could adversely affect our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of our competitors.

As is common in the pharmaceutical industry, we will employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Such claims may lead to material costs for us, or an inability to protect or use valuable intellectual property rights, which could adversely affect our business, financial condition, results of operations and prospects.

We may need to file lawsuits or take other actions to protect or enforce our intellectual property rights.

We may be subject to competition from third parties with products in the same class of products as our drug candidates or products with the same active pharmaceutical ingredients as our drug candidates in those jurisdictions in which we have no patent protection. Even if patents are issued to us or our licensor regarding our drug candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid or unenforceable, lack of utility, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create non-infringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing another less burdensome pathway to approval.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights, generally.

In addition, in an infringement proceeding, a court may decide that one of our patents or one of our licensor's patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents, or those of our licensors, do not cover the technology in question or on other grounds. An adverse result in any litigation or defense proceedings could put one or more of our patents, or those of our licensors, at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications, or those of our licensors, at risk of not issuing. Moreover, we may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries in which the laws may not protect those rights as fully as in the United States or in those countries in which we do not file national phase patent applications. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. The occurrence of any of the above could adversely affect our business, financial condition, results of operations and prospects.

We may fail to protect the confidentiality of commercially sensitive information.

We also rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Risks Related to Ownership of Our Common Stock

Ownership in our common stock is highly concentrated and your ability to influence corporate matters may be limited as a result.

As of August 7, 2025, our executive officers and directors collectively beneficially owned approximately 15.3% of the outstanding shares of our common stock, including approximately 6.8% beneficially owned by Mitchell Steiner, M.D., our Chairman, President and Chief Executive Officer, and 6.2% beneficially owned by Harry Fisch, M.D., our Vice Chairman and Chief Corporate Officer. These shareholders may have the ability to exert significant influence over the outcome of shareholder votes, including votes concerning director elections, amendments to our Amended and Restated Articles of Incorporation and other significant corporate transactions. In addition, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders. The interests of such stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

If our stock price declines, we may be subject to delisting from the Nasdaq Capital Market.

Rule 5550(a)(2) of the Nasdaq Listing Rules requires the closing bid price of our common stock to be greater than $1.00 per share. On August 29, 2024, we received a letter (the “Original Deficiency Letter”) from The Nasdaq Stock Market, LLC ("Nasdaq") notifying us that we had fallen below compliance with this listing standard and providing us with a period of 180 calendar days from the date of notification to regain compliance with the minimum bid price requirement, which was subsequently extended to August 25, 2025. On August 8, 2025, we effected a 1-for-10 reverse stock split of all of our issued and outstanding shares of common stock (the “Reverse Stock Split”). In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock after the Reverse Stock Split must exceed $1.00 per share for a period of ten consecutive trading days.

Even if we regain compliance with the minimum bid price requirement, if the closing bid price of our common stock subsequently is less than $1.00 per share for 10 consecutive trading days, we may receive another deficiency letter from Nasdaq stating that our common stock will be delisted unless we are able to regain compliance with the minimum bid price requirement. We cannot assure you that our stock price will continue to trade above $1.00 per share or otherwise meet the Nasdaq listing requirements and therefore our common stock may in the future be subject to delisting. The continuing effect of the Reverse Stock Split on the market price of our common stock cannot be predicted with any certainty, and the history of similar reverse stock splits for companies in like circumstances is varied.

If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq's listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our shares;
- reduced liquidity for our shares;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our shares;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We incurred charges to earnings in fiscal 2020 and in fiscal 2023 resulting from the APP Acquisition, and additional charges to earnings resulting from the APP Acquisition in the future may cause our operating results to suffer.

Under the acquisition method of accounting in accordance with ASC 805, *Business Combinations*, we allocated the total purchase price of the APP Acquisition to APP's net tangible assets and intangible assets based on their respective fair values as of the date of the APP Acquisition and recorded the excess of the purchase price over those fair values as goodwill. Management's estimates of the fair value of such assets was based upon assumptions that they believed to be reasonable but that will be inherently uncertain. Impairment of goodwill, among other factors, could result in material charges that would cause our financial results to be negatively impacted.

The restatements of our prior financial statements may affect stockholder and investor confidence in us or harm our reputation, and may subject us to additional risks and uncertainties, including increased costs and the increased possibility of legal proceedings and regulatory inquiries, sanctions or investigations.

Subsequent to the filing of our Form 10-Q for the quarter ended June 30, 2023 on August 10, 2023 (the "Original Form 10-Q"), we reached a determination to restate certain financial information and related footnote disclosures in our previously issued consolidated financial statements in the Original Form 10-Q. In addition, subsequent to the filing of the Original Form 10-K for the year ended September 30, 2023 on December 8, 2023, we reached a determination to restate certain financial information and related footnote disclosures in our previously issued consolidated financial statements in the Original Form 10-K. As a result of the restatements, we have incurred, and may continue to incur, unanticipated costs for accounting and legal fees in connection with, or related to, such restatements. In addition, such restatements could subject us to a number of additional risks and uncertainties, including the increased possibility of legal proceedings and inquiries, sanctions or investigations by the SEC or other regulatory authorities, which effect may be compounded by having two restatements in close proximity. Any of the foregoing may adversely affect our reputation, the accuracy and timing of our financial reporting, or our business, results of operations, liquidity and financial condition, or cause stockholders, investors, members and customers to lose confidence in the accuracy and completeness of our financial reports or cause the market price of our common stock to decline.

We previously had identified two material weaknesses in our internal control over financial reporting, and determined that they resulted in our internal control over financial reporting and disclosure controls and procedures not being effective, as of September 30, 2023. Although we have remediated these material weaknesses, we may identify additional material weaknesses or other deficiencies in the future or otherwise fail to maintain an effective system of internal controls, including disclosure controls and procedures, and this could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations.

SEC rules define a material weakness as a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a registrant's financial statements will not be prevented or detected on a timely basis. We are required to annually provide management's attestation on internal control over financial reporting. We are also required to disclose significant changes made to our internal control procedures on a quarterly basis and any material weaknesses identified by our management in our internal control over financial reporting during the course of related assessments.

Management previously had identified material weaknesses in our internal control over financial reporting as of September 30, 2023 related to: (1) its controls over applying technical accounting guidance to nonrecurring events and transactions, specific to the evaluation of information that was known or knowable at the time of the transaction or event, and (2) its management review control over its estimate of research and development expenses associated with activities conducted by third-party service providers. Management determined that such material weaknesses resulted in the Company's internal control over financial reporting and disclosure controls and procedures not being effective as of September 30, 2023. During the quarter ended September 30, 2024, we successfully completed the testing necessary to conclude that these material weaknesses have been remediated.

Effective internal controls are necessary for us to provide reliable financial statements and prevent or detect fraud. Although the material weaknesses in internal control over financial reporting described above have been remediated, any new material weaknesses or other deficiencies identified in the future or any deficiencies in our disclosure controls and procedures, if not timely remediated, could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. We can provide no assurance that the remediation measures we have taken will be effective at preventing or avoiding potential future significant deficiencies or material weaknesses in our internal controls.

If we identify any new deficiencies in the future, the accuracy and timing of our financial reporting may be adversely affected, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, we could be subject to sanctions or investigations by the SEC, or other regulatory authorities, and we may not be able to source external financing for our capital needs on acceptable terms or at all. Each of the foregoing items could adversely affect our business, results of operations, financial condition, and the market price and volatility of our common stock. In addition, we have expended, and expect to continue to expend, significant resources, including accounting-related costs and significant management oversight, in order to assess, implement, maintain, remediate and improve the effectiveness of our internal control over financial reporting and our general control environment.

In addition, as a result of the material weaknesses described above and other matters raised or that may in the future be raised by the SEC, we face the potential for litigation or other disputes which may include, among others, claims invoking the federal and state securities laws, contractual claims or other claims arising from the deficiencies in our internal control over financial reporting described above, the preparation of our financial statements and the restatement described above. Any such litigation or dispute, whether successful or not, could have a material adverse effect on our business, results of operations, liquidity and financial condition.

We are a "smaller reporting company" and will be able to avail ourselves of reduced disclosure requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors.

We are a "smaller reporting company," as defined in the Exchange Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "smaller reporting companies," including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer a "smaller reporting company." We will remain a "smaller reporting company" until (a) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day of our most recently completed second fiscal quarter is $250 million or more and we reported annual net revenues as of our most recently completed fiscal year is $100 million or more, or (b) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day of our most recently completed second fiscal quarter is $700 million or more, regardless of annual revenue.

There are provisions in our charter documents and Wisconsin law that might prevent or delay a change in control of our company.

We are subject to a number of provisions in our charter documents and Wisconsin law that may discourage, delay, or prevent a merger or acquisition that a shareholder may consider favorable. These provisions include the following:

- the authority provided to our Board of Directors in our Amended and Restated Articles of Incorporation to issue preferred stock without further action by our shareholders;
- the provision under Wisconsin law that permits shareholders to act by written consent only if such consent is unanimous;
- the provision under Wisconsin law that requires for a corporation such as us, that was formed before January 1, 1973, the affirmative vote of the holders of at least two-thirds of the outstanding shares of our voting stock to approve an amendment to our articles of incorporation, a merger submitted to a vote of our shareholders, or a sale of substantially all of our assets;

- advance notice procedures for nominations of candidates for election as directors and for shareholder proposals to be considered at shareholders' meetings; and
- the Wisconsin control share acquisition statute and Wisconsin's "fair price" and "business combination" provisions which limit the ability of an acquiring person to engage in certain transactions or to exercise the full voting power of acquired shares under certain circumstances.

The trading price of our common stock has been volatile, and investors in our common stock may experience substantial losses.

The trading price of our common stock has been volatile and may continue to be volatile. The trading price of our common stock could decline or fluctuate in response to a variety of factors, including:

- our failure to meet market expectations for our performance;
- the timing of announcements by us or our competitors concerning significant product developments, acquisitions, or financial performance;
- adverse results or delays in our clinical trials for our drug candidates;
- changes in laws or regulations applicable to our business;
- competition from new products that may emerge;
- actual or anticipated fluctuations in our financial condition or operating results;
- substantial sales of our common stock;
- the market reaction to the Reverse Stock Split;
- issuance of new or updated research reports from securities analysts;
- announcement or expectation of additional debt or equity financing efforts;
- additions or departures of key personnel;
- general stock market conditions;
- attacks by short sellers or substantial short interest in our common stock; or
- other economic or external factors.

You may be unable to sell your stock at or above your purchase price.

A substantial number of shares may be sold in the market, which may depress the market price for our common stock.

Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, including upon the exercise of stock options, shares of common stock we may issue under our current common stock purchase agreement with Lincoln Park, including 302,500 shares of common stock that we have issued under our current common stock purchase agreement with Lincoln Park through the date of this report. These shares can be freely sold in the public market upon issuance.

Additionally, sales of our common stock by our executive officers or directors, even when done during an open trading window under our policies with respect to insider sales, may adversely impact the trading price of our common stock. Although we do not expect that the relatively small volume of such sales will itself significantly impact the trading price of our common stock, the market could react negatively to the announcement of such sales, which could in turn affect the trading price of our common stock.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our shareholders' sole source of gain.

We have not declared or paid cash dividends on our common stock since May 2014. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be our shareholders' sole source of gain for the foreseeable future.

Item 6. Exhibits

Exhibit Number	Description
2.1	Asset Purchase Agreement, dated as of April 19, 2023, between the Company and Blue Water Vaccines Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on April 20, 2023).
2.2	Amendment to Asset Purchase Agreement, dated as of September 29, 2023, between the Company and Onconetix, Inc. (formerly known as Blue Water Vaccines Inc.) (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on October 2, 2023).
2.3	Stock and Asset Purchase Agreement, dated as of December 30, 2024, among Veru Inc., The Female Health Company Limited and Clear Future, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on January 3, 2025).
3.1	Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Form SB-2 Registration Statement (File No. 333-89273) filed with the SEC on October 19, 1999).
3.2	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 27,000,000 shares (incorporated by reference to Exhibit 3.2 to the Company's Form SB-2 Registration Statement (File No. 333-46314) filed with the SEC on September 21, 2000).
3.3	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 35,500,000 shares (incorporated by reference to Exhibit 3.3 to the Company's Form SB-2 Registration Statement (File No. 333-99285) filed with the SEC on September 6, 2002).
3.4	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 38,500,000 shares (incorporated by reference to Exhibit 3.4 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 15, 2003).
3.5	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 3 (incorporated by reference to Exhibit 3.5 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 17, 2004).
3.6	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 4 (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).
3.7	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company changing the corporate name to Veru Inc. and increasing the number of authorized shares of common stock to 77,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on August 1, 2017).
3.8	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 154,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 29, 2019).
3.9	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 308,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on July 28, 2023).
3.10	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company effecting the Reverse Stock Split (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on August 12, 2025).

3.11	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 4, 2018).
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, and 3.10).
4.2	Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.11).
10.1	Limited Waiver, dated as of June 30, 2025, between the Company and Onconetix, Inc. *
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002). *, **
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, formatted in iXBRL (Inline Extensible Business Reporting Language): (1) the Unaudited Condensed Consolidated Balance Sheets, (2) the Unaudited Condensed Consolidated Statements of Operations, (3) the Unaudited Condensed Consolidated Statements of Stockholders' Equity, (4) the Unaudited Condensed Consolidated Statements of Cash Flows and (5) the Notes to the Unaudited Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as iXBRL and contained in Exhibit 101).

* Filed herewith

** This certification is not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

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.

VERU INC.

DATE: August 12, 2025

/s/ Mitchell S. Steiner
Mitchell S. Steiner
Chairman, Chief Executive Officer and President

DATE: August 12, 2025

/s/ Michele Greco
Michele Greco
Chief Financial Officer and Chief Administrative Officer

Exhibit 10.1

WAIVER

This **LIMITED WAIVER**, dated as of June 30, 2025 ("**Limited Waiver**"), is made by **ONCONETIX, INC** (the "**Company**") and **VERU INC.** (the "**Holder**").

WHEREAS, reference is hereby made to a certain Promissory Note, dated as of April 19, 2023, and which was originally due on April 19, 2024 (the "**April 2024 Promissory Note**");

WHEREAS, reference is hereby made to a certain Promissory Note, dated as of April 19, 2023, which was originally due on September 30, 2024 ("**September 2024 Promissory Note**" and together with the April 2024 Promissory Note, the "**Promissory Notes**");

WHEREAS, on April 24, 2024, the Borrower and Holder entered into a certain Forbearance Agreement, which was further amended on September 19, 2024 and November 26, 2024 (the "**A&R Forbearance Agreement**") to, among other things, extend the maturity date of the April 2024 Promissory Note to March 31, 2025 and extend the September 2024 Promissory Note to June 30, 2025;

WHEREAS, on March 31, 2025, the Holder extended the date by which the Company shall pay the April 2024 Promissory Note to April 14, 2025;

WHEREAS, on April 23, 2025, the Holder extended the date by which the Company shall pay the April 2024 Promissory Note to June 30, 2025;

WHEREAS, as of the date hereof, the Company is unable to repay the Promissory Notes;

WHEREAS, the Company is seeking to secure financing to generate sufficient cash to fulfill all applicable obligations to the Holder pursuant to the A&R Forbearance Agreement; and

WHEREAS, the Holder has agreed to a limited waiver as more fully set forth in this Limited Waiver.

NOW, THEREFORE, in consideration of the premises set forth above and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. **Definitions**. Capitalized terms used and not defined in this Limited Waiver shall have the respective meanings given to them in the A&R Forbearance Agreement.

2. **Limited Waiver**. This Limited Waiver shall be deemed to be effective as of June 30, 2025. The Holder hereby waives and extends the date by which the Company shall pay the Promissory Notes to July 31, 2025.

3. **No Modifications**. Nothing contained in this Limited Waiver shall be deemed or construed to amend, supplement or modify the A&R Forbearance Agreement or otherwise affect the rights and obligations of any party thereto, all of which remain in full force and effect, subject only to this Limited Waiver.

4. **Execution**. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Limited Waiver as of the date first set forth above.

ONCONETIX, INC.

By: /s/ Karina M. Fedasz
Name: Karina M. Fedasz
Title: Interim Chief Executive Officer and Interim Chief Financial Officer

VERU INC.

By: /s/ Michael J. Purvis
Name: Michael J. Purvis
Title: EVP, General Counsel

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mitchell S. Steiner, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Veru Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 12, 2025

/s/Mitchell S. Steiner
Mitchell S. Steiner
Chairman, Chief Executive Officer and President

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michele Greco, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Veru Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 12, 2025

/s/Michele Greco
Michele Greco
Chief Financial Officer and Chief Administrative Officer

Exhibit 32.1

Certification of Periodic Financial Report
Pursuant to 18 U.S.C. Section 1350

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Veru Inc. (the "Company") certifies that the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2025 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and information contained in that Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2025

/s/Mitchell S. Steiner
Mitchell S. Steiner
Chairman, Chief Executive Officer and President

Date: August 12, 2025

/s/Michele Greco
Michele Greco
Chief Financial Officer and
Chief Administrative Officer

This certification is made solely for purpose of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose.