

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 March 31, 2026

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   
Non-accelerated filer

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 May 8, 2026, the registrant had 16,050,320 shares of \$0.01 par value common stock outstanding.

VERU INC.  
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## 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 as a drug candidate that preserves muscle mass and augments fat loss in patients receiving a glucagon-like peptide-1 receptor agonist (“GLP-1 RA”) for greater amount and higher quality weight loss for the treatment of obesity 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, the potential suspension or termination of any such trials or 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, and the risk that the terms of any regulatory approval may limit the drug’s commercial potential;
- although we have sought and received feedback from the FDA on the designs of our clinical trials and intend to continue to do so, the FDA may ultimately disagree that our trials support approval;
- 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 that our business could be negatively impacted by disruptions at the FDA or other government agencies, including as a result of a shutdown of the U.S. government;
- 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;
- we may not receive any additional funds upon the exercise of outstanding warrants;
- our ability to maintain compliance with the continued listing requirements of the Nasdaq Stock Market LLC (“Nasdaq”);
- we need to secure significant funding to advance our drug candidates;
- we plan to prioritize the use of our current internal cash to the development of enobosarm, with a primary near-term focus on funding our PLATEAU Phase 2b clinical trial, and as a result advancement of sabizabulin as a treatment for slowing progression of or promoting regression of atherosclerosis disease will depend upon us securing additional funding;
- 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;

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- 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 obtain regulatory approval for or 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, licensing risks, and the Company's ability to fund any enforcement or defense of its intellectual property rights;
- 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;
- risks inherent in doing business on an international level, including currency risks, tariffs, regulatory requirements, political risks, export restrictions and other trade barriers, and including restrictions on the importation or sale of drug products;
- the risk of disruption of production at facilities of third parties on which we rely and/or of our ability to obtain supply product due to raw material shortages, labor shortages, manufacturing partner business changes, physical damage to third parties' facilities, product testing, transportation delays or regulatory or other governmental actions, and the duration and impact of any such disruptions;
- 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;
- we are subject to cybersecurity risks and the information technology systems on which we rely may be subject to data security or privacy incidents;
- 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.

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, in Part II, Item 1A, "Risk Factors" in this report, and in Part I, Item 1A, "Risk Factors", in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2025. 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

	March 31, 2026	September 30, 2025
<b>Assets</b>		
Current assets:		
Cash, cash equivalents, and restricted cash	\$ 27,596,820	\$ 15,794,562
Investments in equity securities	3,167,733	2,525,305
Prepaid expenses and other current assets	2,590,923	595,251
Total current assets	33,355,476	18,915,118
Property and equipment, net	308,421	364,808
Operating lease right-of-use assets	2,479,348	2,746,014
Goodwill	6,878,932	6,878,932
Other assets	60,549	930,847
Total assets	\$ 43,082,726	\$ 29,835,719
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,071,710	\$ 3,121,448
Accrued compensation	2,164,000	3,510,237
Accrued expenses and other current liabilities	382,876	394,529
Operating lease liability, short-term portion	770,257	758,946
Total current liabilities	5,388,843	7,785,160
Operating lease liability, long-term portion	2,063,089	2,358,018
Other liabilities	845,173	1,359,871
Total liabilities	8,297,105	11,503,049
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock; no shares issued and outstanding at March 31, 2026 and September 30, 2025	—	—
Common stock, par value \$0.01 per share; 308,000,000 shares authorized, 16,268,690 and 14,868,690 shares issued and 16,050,320 and 14,650,320 shares outstanding at March 31, 2026 and September 30, 2025, respectively	162,687	148,687
Additional paid-in-capital	367,799,164	343,286,502
Accumulated other comprehensive loss	—	—
Accumulated deficit	(325,369,625)	(317,295,914)
Treasury stock, 218,370 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	34,785,621	18,332,670
Total liabilities and stockholders' equity	\$ 43,082,726	\$ 29,835,719

See notes to unaudited condensed consolidated financial statements.

VERU INC.  
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,		Six Months Ended March 31,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	\$ 3,145,783	\$ 3,932,102	\$ 4,489,965	\$ 9,648,932
General and administrative	4,073,185	5,164,433	8,153,018	10,391,546
Total operating expenses	7,218,968	9,096,535	12,642,983	20,040,478
Gain on sale of ENTADFI® assets	—	974,303	—	1,669,519
Operating loss from continuing operations	(7,218,968)	(8,122,232)	(12,642,983)	(18,370,959)
Non-operating income (expenses):				
Gain on extinguishment of debt	—	—	—	8,624,778
Change in fair value of equity securities	3,931,416	—	3,811,338	(349,078)
Other income, net	195,002	269,839	406,516	432,963
Total non-operating income	4,126,418	269,839	4,217,854	8,708,663
Net loss from continuing operations	(3,092,550)	(7,852,393)	(8,425,129)	(9,662,296)
Net income (loss) from discontinued operations, net of taxes	351,418	(49,226)	351,418	(7,184,670)
Net loss	\$ (2,741,132)	\$ (7,901,619)	\$ (8,073,711)	\$ (16,846,966)
Net loss from continuing operations per basic and diluted common shares and pre-funded warrants outstanding	\$ (0.13)	\$ (0.54)	\$ (0.39)	\$ (0.66)
Net income (loss) from discontinued operations per basic and diluted common shares and pre-funded warrants outstanding	\$ 0.02	\$ (0.00)	\$ 0.02	\$ (0.49)
Net loss per basic and diluted common shares and pre-funded warrants outstanding	\$ (0.12)	\$ (0.54)	\$ (0.37)	\$ (1.15)
Basic and diluted weighted average common shares and pre-funded warrants outstanding	23,050,320	14,638,614	21,655,705	14,638,502

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, 2025	14,868,690	\$ 148,687	\$ 343,286,502	\$ —	\$ (317,295,914)	\$ (7,806,605)	\$ 18,332,670
Share-based compensation	—	—	757,605	—	—	—	757,605
Shares issued in connection with public offering of common stock, warrants, and pre-funded warrants, net of fees and costs	1,400,000	14,000	23,352,345	—	—	—	23,366,345
Net loss	—	—	—	—	(5,332,579)	—	(5,332,579)
Balance at December 31, 2025	16,268,690	\$ 162,687	\$ 367,396,452	—	\$ (322,628,493)	\$ (7,806,605)	\$ 37,124,041
Share-based compensation	—	—	402,712	—	—	—	402,712
Net loss	—	—	—	—	(2,741,132)	—	(2,741,132)
Balance at March 31, 2026	16,268,690	\$ 162,687	\$ 367,799,164	\$ —	\$ (325,369,625)	\$ (7,806,605)	\$ 34,785,621
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

See notes to unaudited condensed consolidated financial statements.

VERU INC.  
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended March 31,	
	2026	2025
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (8,073,711)	\$ (16,846,966)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	56,387	94,201
Noncash change in right-of-use assets	266,666	324,529
Noncash interest expense, net of interest paid	—	(168,556)
Gain on extinguishment of debt	—	(8,624,778)
(Gain) loss on sale of FC2 business	(351,418)	4,244,251
Gain on sale of ENTADFI® assets	—	(1,669,519)
Share-based compensation	1,160,317	4,897,948
Deferred income taxes	—	(1,915)
Change in fair value of derivative liabilities	—	3,138,316
Change in fair value of equity securities	(3,811,338)	349,078
Other	—	(57,915)
Changes in current assets and liabilities:		
Increase in accounts receivable	—	(657,253)
Decrease in inventories	—	863,928
Increase in prepaid expenses and other assets	(1,125,374)	(341,922)
Decrease in accounts payable	(1,564,436)	(1,673,105)
Decrease in accrued expenses and other liabilities	(1,357,890)	(2,586,373)
Decrease in operating lease liabilities	(283,618)	(353,399)
Net cash used in operating activities	(15,084,415)	(19,069,450)
<b>INVESTING ACTIVITIES</b>		
Proceeds from sale of FC2 business, net of costs	351,418	16,331,515
Cash proceeds from sale of ENTADFI® assets	—	1,669,519
Proceeds from sale of equity securities	3,168,910	393,217
Capital expenditures	—	(1,083)
Net cash provided by investing activities	3,520,328	18,393,168
<b>FINANCING ACTIVITIES</b>		
Payment on extinguishment of residual royalty agreement liabilities	—	(4,221,611)
Proceeds from sale of shares in public offering, net of commissions and costs	23,366,345	—
Net cash provided by (used in) financing activities	23,366,345	(4,221,611)
Net increase (decrease) in cash, cash equivalents, and restricted cash	11,802,258	(4,897,893)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF PERIOD	15,794,562	24,916,285
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF PERIOD	\$ 27,596,820	\$ 20,018,392
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ —	\$ 332,826

See notes to unaudited condensed consolidated financial statements.

VERU INC.  
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, 2025. The accompanying condensed consolidated balance sheet as of September 30, 2025 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three and six months ended March 31, 2026 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2026.

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, Aspen Park Pharmaceuticals, Inc. (APP) and PCHC Limited (formerly known as The Female Health Company Limited). PCHC 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”) were included in the consolidated financial statements through December 30, 2024. Veru International Holdco Inc. was a wholly owned subsidiary of the Company and was dissolved in December 2025. Veru International Holdco Inc. did not have any impact on the Company’s operations during the quarter ended December 31, 2025. Veru International Holdco Inc.’s wholly owned subsidiaries, Veru Biopharma Netherlands B.V., Veru Biopharma UK Limited, and Veru Biopharma Europe Limited were dissolved during fiscal 2024 and were included in the consolidated financial statements through the date of dissolution. All significant intercompany transactions and accounts have been eliminated in consolidation. The Company is a late clinical stage biopharmaceutical company focused on developing innovative medicines for the treatment of cardiometabolic and inflammatory diseases. Our drug development program includes enobosarm, an oral selective androgen receptor modulator, which is being developed as a next generation drug that makes weight reduction by GLP-1 RA drugs more tissue selective for loss of fat and preservation of lean mass, and sabizabulin, a microtubule disruptor, which is being developed for the treatment of inflammation in atherosclerotic cardiovascular disease. On December 30, 2024, the Company sold substantially all of the assets relating to its FDA-approved commercial product, the FC2 Female Condom® (Internal Condom). 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. All of the Company’s net revenues during the three and six months ended March 31, 2025 were derived from sales of FC2 and are included within discontinued operations. The Company had no net revenues during the six months ended March 31, 2026.

**Reverse stock split:** As described more fully in Note 9, 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 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 six months ended March 31, 2026 and 2025, comprehensive loss is equivalent to the reported net loss.

**Recent accounting pronouncements not yet adopted:** 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 ASU 2023-09 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, depreciation, 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.

In December 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements, which improves the guidance in Topic 270 by improving the navigability of the required interim disclosures and clarifying when that guidance is applicable. The amendments also provide additional guidance on what disclosures should be provided in interim reporting periods and adds to Topic 270 a principle that requires entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. ASU 2025-11 is effective for interim reporting periods within the Company's fiscal year ending September 30, 2029, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2025-11 on its 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 PCHC 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. Pursuant to an Escrow Agreement entered into under the terms of the Purchase Agreement, the \$54,000 retention amount is being held in escrow as of March 31, 2026 and is classified as restricted cash, included within cash, cash equivalents, and restricted cash on the accompanying condensed consolidated balance sheet.

The purchase price for the FC2 Business Sale was \$18.0 million in cash, subject to adjustment as set forth in the Purchase Agreement, which included a customary working capital adjustment subsequent to 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 were \$16.5 million, which is the \$18.0 million purchase price per the Purchase Agreement, net of costs incurred of \$1.4 million, and amounts allocated to the related transition services agreement of \$150,000 but excluding the change of control payment pursuant to the Residual Royalty Agreement of \$4.2 million (see Note 8 for additional information). The loss on sale of the FC2 business was \$4.1 million, which is the difference between net proceeds of \$16.5 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 disputed the calculation. This dispute was submitted to an accounting firm for binding resolution, and in September 2025 the accounting firm delivered its final determination, resolving all disputed matters in favor of the Company. As a result of the final determination, the Purchaser paid additional purchase price of approximately \$150,000 to us and approximately \$300,000 was released from escrow.

During the three months ended March 31, 2026, the Company recognized an additional gain on sale of the FC2 business of \$351,000, which is for net proceeds received from the Purchaser in the settlement of a dispute related to a pre-closing tax receivable and liability.

The FC2 Business Sale represented a strategic shift, which had a major effect on our operations and financial results. We 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 the six months ended March 31, 2025. We did not allocate any amounts for shared general and administrative operating support expense to discontinued operations. We did not have any discontinued operations during the three and six months ended March 31, 2026. 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 sheets as of March 31, 2026 or September 30, 2025.

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The following table presents results of discontinued operations for the three and six months ended March 31, 2026 and 2025:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2026	2025	2026	2025
Net revenues	\$ —	\$ —	\$ —	\$ 4,484,591
Cost of sales	—	—	—	2,900,514
Gross profit	—	—	—	1,584,077
Operating expenses	—	9,410	—	1,111,397
Gain (loss) on sale of FC2 business	351,418	(39,816)	351,418	(4,244,251)
Operating income (loss)	351,418	(49,226)	351,418	(3,771,571)
Non-operating expenses:				
Interest expense	—	—	—	(164,270)
Change in fair value of derivative liabilities	—	—	—	(3,138,316)
Other expense, net	—	—	—	(31,960)
Total non-operating expenses	—	—	—	(3,334,546)
Income (loss) before income taxes	351,418	(49,226)	351,418	(7,106,117)
Income tax expense	—	—	—	78,553
Net income (loss) from discontinued operations, net of taxes	<u>\$ 351,418</u>	<u>\$ (49,226)</u>	<u>\$ 351,418</u>	<u>\$ (7,184,670)</u>

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 six months ended March 31, 2026 and 2025 are comprised of the following:

	Six Months Ended March 31,	
	2026	2025
Total net cash used in operating activities from discontinued operations	\$ —	\$ (334,864)
Total net cash provided by investing activities from discontinued operations	\$ 351,418	\$ 16,330,432

**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 of March 31, 2026 and September 30, 2025, the Company has investments in equity securities consisting of 1,196 and 3,125 shares, respectively, of Series D Convertible Preferred Stock (the “ONCO Series D Preferred Stock”) of Onconetix, Inc. (“ONCO”) and a warrant to purchase 169,395 shares of common stock of ONCO (the “ONCO Warrant”). ONCO effected a 1-for-5 reverse stock split for all of its issued and outstanding shares of common stock on March 25, 2026. All ONCO common stock amounts presented have been retroactively adjusted for all periods presented. The ONCO Series D Preferred Stock and the ONCO Warrant were received on September 22, 2025 as a settlement of the ONCO Promissory Notes. See Note 15 for additional information. The Company has elected to measure the ONCO Series D Preferred Stock and the ONCO Warrant at fair value in accordance with ASC 825. The investments in the ONCO Series D Preferred Stock and the ONCO Warrant are classified within Level 3 of the fair value hierarchy because there is no market for these types of securities and the fair value is determined using significant unobservable inputs. The fair value of the ONCO Series D Preferred Stock and the ONCO Warrant have been determined using a Monte Carlo simulation model. This valuation model incorporates the contractual terms of the instruments and assumptions including the stock price of ONCO Common Stock, expected volatility, and a selected discount rate. Additionally, the ONCO Series D Preferred Stock and the ONCO Warrant were issued by ONCO as part of a Securities Purchase Agreement, which included the sale of 16,099 shares of Series D convertible preferred stock and warrants to purchase 872,565 shares of ONCO Common Stock to eleven institutional investors, for an aggregate purchase price of \$12.9 million. The valuation of the ONCO Series D Preferred Stock and ONCO Warrant at issuance included a calibration discount to the proceeds of the original transaction, which was done at arms’ length. The calibration discount was reduced to zero as of March 31, 2026 as the Company began to convert the ONCO Series D Preferred Stock during the three months ended March 31, 2026, which had the effect of increasing the fair value of the ONCO Series D Preferred Stock and the ONCO Warrant. The assumptions used in calculating the fair value of the financial instruments represent the Company’s best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, the use of different estimates or assumptions would result 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. The following table summarizes the significant unobservable inputs used in the Monte Carlo Simulations as of March 31, 2026 and September 30, 2025:

<b>Significant Unobservable Input</b>	<b>March 31, 2026</b>	<b>September 30, 2025</b>
ONCO Series D Preferred Stock		
Simulation Term (Years)	1.0	1.5
Expected Volatility	70.2%	72.5%
Discount Rate	25.0%	25.0%
Calibration Discount	0.0%	48.6%
ONCO Warrant		
Simulation Term (Years)	2.5	3.0
Equity Volatility	72.2%	68.6%
Calibration Discount	0.0%	48.6%

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The following table provides a reconciliation of the beginning and ending balance associated with the ONCO Series D Preferred Stock and the ONCO Warrant measured at fair value for the six months ended March 31, 2026 and 2025, which are presented as investments in equity securities on the accompanying consolidated balance sheet:

	Six Months Ended March 31,	
	2026	2025
<b>ONCO Series D Preferred Stock</b>		
Beginning balance	\$ 1,764,318	\$ —
Change in fair value of equity securities	2,818,551	—
Converted into ONCO common stock	(3,218,257)	—
Ending balance	<u>\$ 1,364,612</u>	<u>\$ —</u>
<b>ONCO Warrant</b>		
Beginning balance	\$ 760,987	\$ —
Change in fair value of equity securities	1,041,659	—
Ending balance	<u>\$ 1,802,646</u>	<u>\$ —</u>

During the three months ended March 31, 2026, the Company converted 1,929 shares of the ONCO Series D Preferred Stock into 771,091 shares of ONCO common stock and sold 770,772 shares of ONCO common stock for net proceeds of \$3.2 million. Subsequent to March 31, 2026, the Company converted the remaining outstanding 1,196 shares of ONCO Series D Preferred Stock into 1,041,743 shares of ONCO common stock and sold 1,042,062 shares of ONCO common stock for net proceeds of \$1.8 million.

The Company also had an investment in equity securities consisting of 28,549 shares of common stock of ONCO (the “ONCO Common Stock”), which were sold during the six months ended March 31, 2025 for net proceeds of \$0.4 million. The Company recognized a loss from the change in fair value of equity securities related to the ONCO Common Stock of \$0.3 million during the six months ended March 31, 2025.

The following is a summary of unrealized and realized gains and losses on equity securities recognized during the three and six months ended March 31, 2026 and 2025:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2026	2025	2026	2025
Net gains (losses) recognized during the period on equity securities	\$ 3,931,416	\$ —	\$ 3,811,338	\$ (349,078)
Less: net gains (losses) recognized during the period on equity securities sold during the period	1,954,544	—	2,081,146	(349,078)
Unrealized gains (losses) recognized during the reporting period on equity securities still held at the reporting date	<u>\$ 1,976,872</u>	<u>\$ —</u>	<u>\$ 1,730,192</u>	<u>\$ —</u>

**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 March 31, 2026 and September 30, 2025:

	Estimated Useful Life (in years)	March 31, 2026	September 30, 2025
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		(657,022)	(600,635)
Property and equipment, net		<u>\$ 308,421</u>	<u>\$ 364,808</u>

Depreciation expense was approximately \$28,000 and \$29,000 for the three months ended March 31, 2026 and 2025, respectively.

#### Note 7 – Goodwill

The carrying amount of goodwill at March 31, 2026 and September 30, 2025 was \$6.9 million. There was no change in the balance during the six months ended March 31, 2026 and 2025.

#### 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.

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. The loss associated with the change in fair value of the embedded derivatives was included within net loss from discontinued operations on the accompanying consolidated statement of operations for the three months ended December 31, 2024. It was included in discontinued operations because the related debt was required to be repaid as a result of the FC2 Business Sale.

At March 31, 2026 and September 30, 2025, there were no balances remaining related to the Residual Royalty Agreement liability.

## **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 March 31, 2026 and September 30, 2025. 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 March 31, 2026 and September 30, 2025, and there was no activity during the three and six months ended March 31, 2026 and 2025.

### 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 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.

### Shelf Registration Statements

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 March 31, 2026, \$33.3 million remained available under that shelf registration statement. That shelf registration statement expired on April 14, 2026. In April 2026, the Company filed a new shelf registration statement on Form S-3 (File No. 333-294911) with a capacity of \$200 million, which was declared effective by the SEC on April 15, 2026. This new shelf registration statement expires on April 15, 2029. Under current SEC regulations, because the aggregate market value of the Company's common stock held by non-affiliates (“public float”) is less than \$75 million, and for so long as the Company's public float remains less than \$75 million, the amount it can raise through primary public offerings of securities in any 12-month period using shelf registration statements is limited to an aggregate of one-third of the Company's public float.

### Common Stock

On October 31, 2025, we completed an underwritten public offering of (i) 1,400,000 shares of our common stock, (ii) pre-funded warrants to purchase up to 7,000,000 shares of our common stock, each representing the right to purchase one share of common stock at an exercise price of \$0.001, in lieu of common stock, (iii) accompanying Series A warrants to purchase up to 8,400,000 shares of our common stock at an exercise price of \$3.00, and (iv) accompanying Series B warrants to purchase up to 8,400,000 shares of our common stock at an exercise price of \$3.00, at a combined public offering price of \$3.00 per share of common stock, accompanying Series A warrant and accompanying Series B warrant. Net proceeds to the Company from this offering were approximately \$23.4 million, after deducting the underwriting discounts and commissions of \$1.5 million and costs payable by the Company of \$0.3 million. All of the securities in the offering were sold by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-270606) in effect at that time. The relative fair value allocated to the common stock, pre-funded warrants, accompanying Series A warrants and accompanying Series B warrants were \$1.7 million, \$8.4 million, \$8.5 million, and \$6.7 million, respectively.

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The following table summarizes the Company's pre-funded warrant activity for the six months ended March 31, 2026:

	<u>Pre-Funded Warrants</u>	<u>Weighted Average Exercise Price</u>
Outstanding at September 30, 2025	—	\$ —
Issued	7,000,000	\$ 0.001
Exercised	—	\$ —
Canceled/Expired	—	\$ —
Outstanding at March 31, 2026	<u>7,000,000</u>	<u>\$ 0.001</u>

Warrants

The following table summarizes the Company's warrant activity, excluding pre-funded warrants, for the six months ended March 31, 2026:

	<u>Warrants</u>	<u>Weighted Average Exercise Price</u>
Outstanding at September 30, 2025	—	\$ —
Issued	16,800,000	\$ 3.00
Exercised	—	\$ —
Canceled/Expired	—	\$ —
Outstanding at March 31, 2026	<u>16,800,000</u>	<u>\$ 3.00</u>

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 were registered pursuant to the Company's 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. The shelf registration statement on Form S-3 (File No. 333-270606) expired on April 14, 2026, and after that date the Company was unable to sell any common stock pursuant to the Lincoln Park Purchase Agreement because such sales would no longer be covered by an effective registration statement. The Company did not have plans to utilize the remaining capacity under the Lincoln Park Purchase Agreement and terminated the agreement effective May 12, 2026.

During the six months ended March 31, 2026 and 2025, we did not sell any shares under the Lincoln Park Purchase Agreement. Since inception of the Lincoln Park Purchase Agreement through March 31, 2026, we have sold 302,500 shares of common stock to Lincoln Park resulting in proceeds to the Company of \$3.1 million.

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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. As of March 31, 2026, the Company did not have plans to utilize the remaining capacity under the Lincoln Park Purchase Agreement and concluded that the deferred costs did not provide a probable future economic benefit. As such, during the three months ended March 31, 2026, the total remaining unamortized deferred costs of \$870,000 were written off and are included in general and administrative expenses on the accompanying unaudited condensed consolidated statements of operations for each of the three and six months ended March 31, 2026. The unamortized deferred costs related to the Lincoln Park Purchase Agreement of \$870,000 as of September 30, 2025 are included in other assets on the accompanying unaudited condensed consolidated balance sheets.

**Note 10 – Share-based Compensation**

We allocate share-based compensation expense to general and administrative expense and research and development expense based on the award holder's employment function. For the three and six months ended March 31, 2026 and 2025, we recorded share-based compensation expenses as follows:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2026	2025	2026	2025
General and administrative	\$ 311,852	\$ 1,618,958	\$ 905,058	\$ 3,623,674
Research and development	90,860	604,885	255,259	1,284,323
Discontinued operations	—	—	—	(10,049)
Share-based compensation	<u>\$ 402,712</u>	<u>\$ 2,223,843</u>	<u>\$ 1,160,317</u>	<u>\$ 4,897,948</u>

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 March 31, 2026, 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 12, 2026, the Company's stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 5.85 million. As of March 31, 2026, 3,914,259 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 March 31, 2026, 21,512 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 \$0 and \$0.1 million during the three months ended March 31, 2026 and 2025, respectively.

The following table outlines the weighted average assumptions for options granted during the three and six months ended March 31, 2026 and 2025:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2026	2025	2026	2025
<u>Weighted Average Assumptions:</u>				
Expected volatility	—	115.5%	116.6%	110.2%
Expected dividend yield	—	0.0%	0.0%	0.0%
Risk-free interest rate	—	4.1%	3.8%	3.6%
Expected term (in years)	—	6.0	6.0	6.0
Fair value of options granted	\$ —	\$ 3.88	\$ 2.20	\$ 6.28

During the three and six months ended March 31, 2026 and 2025, 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 March 31, 2026:

	Number of Shares	Exercise Price Per Share	Weighted Average		Aggregate Intrinsic Value
			Remaining Contractual Term (years)		
Outstanding at September 30, 2025	1,911,020	\$ 42.18			
Granted	350,700	\$ 2.55			
Exercised	—	\$ —			
Forfeited and expired	(171,742)	\$ 40.32			
Outstanding at March 31, 2026	<u>2,089,978</u>	\$ 35.68	5.81	\$	—
Exercisable at March 31, 2026	<u>1,436,000</u>	\$ 49.29	4.30	\$	—

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 March 31, 2026 of \$2.21, less the respective weighted average exercise price per share at period end.

As of March 31, 2026, the Company had unrecognized compensation expense of approximately \$1.9 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 2.1 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 March 31, 2026, 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 two years to less than five 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. The Company does not have any leases that have not yet commenced as of March 31, 2026.

The components of the Company’s lease costs were as follows for the three and six months ended March 31, 2026 and 2025:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2026	2025	2026	2025
Operating lease cost	\$ 186,232	\$ 186,233	\$ 372,465	\$ 372,466
Short-term lease cost	2,541	2,541	5,082	5,082
Variable lease cost	46,338	47,251	51,682	48,569
Total lease cost	\$ 235,111	\$ 236,025	\$ 429,229	\$ 426,117

The Company paid cash of \$389,000 and \$378,000 for amounts included in the measurement of operating lease liabilities during the six months ended March 31, 2026 and 2025, 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 March 31, 2026 and September 30, 2025.

Other information related to the Company’s leases as of March 31, 2026 and September 30, 2025 was as follows:

	March 31, 2026	September 30, 2025
<b>Operating Leases</b>		
Weighted-average remaining lease term (years)	3.9	4.4
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 has tail product liability insurance coverage for claims arising from the use of products it previously sold. The coverage amount is \$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.

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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”), and on October 2, 2025, the Purchaser filed an amended complaint in the Clear Future Lawsuit. The amended 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 amended complaint makes claims for fraud, breach of representations and warranties, and a declaratory judgment for indemnification. During the three months ended March 31, 2026, the parties settled the Purchaser’s claim that the Company is responsible to indemnify the Purchaser for a pre-closing tax liability. 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. The portion of the Balance that remained unpaid as of December 31, 2025 is being paid in equal monthly installments over 24 months, commencing in January 2026. \$1.0 million and \$2.6 million is included in accounts payable and \$0.8 million and \$1.4 million is included in other liabilities related to this agreement as of March 31, 2026 and September 30, 2025, respectively, on the accompanying condensed consolidated balance sheets.

#### **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:

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>March 31,</b>		<b>March 31,</b>	
	<b>2026</b>	<b>2025</b>	<b>2026</b>	<b>2025</b>
Income tax benefit at U.S. federal statutory rates	\$ (649,435)	\$ (1,649,002)	\$ (1,769,276)	\$ (2,029,082)
State income tax benefit, net of federal benefit	(102,054)	(127,680)	(278,029)	(157,109)
Non-deductible expenses	18,946	19,874	20,596	20,613
U.S. research and development tax credit	(137,696)	(197,911)	(254,453)	(428,708)
Other	5,255	—	13,407	—
Change in valuation allowance	864,984	1,954,719	2,267,755	2,594,286
Income tax expense	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

#### **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 and pre-funded warrants 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 outstanding warrants, 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 Notes 9 and 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 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.

As of September 22, 2025, an aggregate of \$8.8 million was payable to the Company under the ONCO Promissory Notes and related amendments. On September 22, 2025, the Company and ONCO entered into a Settlement Agreement and Release (the “Settlement Agreement”), whereby the Company agreed to accept a cash payment of \$6.3 million, 3,125 shares of ONCO Series D Preferred Stock and the ONCO Warrant to purchase 169,395 shares of ONCO’s common stock (such cash payment, shares of ONCO Series D Preferred Stock, and the ONCO Warrant, collectively, the “Settlement Amount”) in full satisfaction of all amounts due under the ONCO Promissory Notes, as amended by all preceding amendments, forbearance agreements, and waivers, in complete discharge of all obligations thereunder. The ONCO Promissory Notes and the Forbearance Agreement terminated upon payment of the Settlement Amounts. The Company received proceeds of \$3.2 million from the sale of shares of ONCO’s common stock acquired from the conversion of ONCO Series D Preferred Stock during the three months ended March 31, 2026 and \$1.8 million from the sale of shares of ONCO’s common stock acquired from the conversion of ONCO Series D Preferred Stock subsequent to March 31, 2026, and after such sales the Company no longer holds any shares of ONCO Series D Preferred Stock. There can be no assurances as to whether and when the Company will be able to receive any cash proceeds from the shares of ONCO Warrant or any shares of ONCO’s common stock that the Company might acquire upon exercise of the ONCO Warrant.

The Company determined that it was not probable, at the time of the transaction and until the Settlement Agreement was executed, 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 \$1.7 million during the six months ended March 31, 2025, for the nonrefundable consideration received during that period. The ONCO Promissory Notes are now settled so no additional gain from additional consideration is expected in future periods.

#### **Note 16 - Segments**

Operating segments are identified as components of an entity about which separate discrete financial information is available for evaluation by the CODM, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company’s CODM is Mitchell S. Steiner, M.D., our Chairman, President and Chief Executive Officer, who views the Company’s operations as one operating segment, which is focused on developing innovative medicines for the treatment of cardiometabolic and inflammatory diseases. The Company does not have revenue, incurs expenses primarily in the U.S., and manages the business activities on a consolidated basis.

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The accounting policies of the drug development segment are the same as those described in the summary of significant accounting policies.

The CODM assesses performance for the drug development segment and decides how to allocate resources based on net loss that is also reported on the income statement as consolidated net loss. The measure of segment assets is reported on the balance sheet as cash, cash equivalents, and restricted cash.

The Company has not generated any product revenue from continuing operations in the current period and expects to continue to incur significant expenses and operating losses for the foreseeable future as the Company advances its product candidates through all stages of development and clinical trials. As such, the CODM uses cash forecast models in deciding how to invest into the drug development segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results, net cash used in operating activities for the period and cash on hand are used in assessing performance of the segment.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the six months ended March 31, 2026 and 2025:

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>March 31,</b>		<b>March 31,</b>	
	<b>2026</b>	<b>2025</b>	<b>2026</b>	<b>2025</b>
<b>Operating expenses:</b>				
Research and development	\$ 3,145,783	3,932,102	4,489,965	\$ 9,648,932
General and administrative	4,073,185	5,164,433	8,153,018	10,391,546
Total operating expenses	7,218,968	9,096,535	12,642,983	20,040,478
<b>Other segment items:</b>				
Gain on sale of ENTADFI® assets	—	974,303	—	1,669,519
Gain on extinguishment of debt	—	—	—	8,624,778
Change in fair value of equity securities	3,931,416	—	3,811,338	(349,078)
Other income, net	195,002	269,839	406,516	432,963
Net income (loss) from discontinued operations, net of taxes	351,418	(49,226)	351,418	(7,184,670)
Net loss	<u>\$ (2,741,132)</u>	<u>(7,901,619)</u>	<u>(8,073,711)</u>	<u>\$ (16,846,966)</u>

The Company is a single operating segment and therefore the measure of segment net loss is the same as consolidated net loss and does not require reconciliation.

For the six months ended March 31, 2026 and 2025, net cash used in operating activities was \$15.1 million and \$19.1 million, respectively. The table below summarizes the significant asset categories regularly reviewed by the CODM as of March 31, 2026 and September 30, 2025:

	<b>2026</b>	<b>2025</b>
Cash, cash equivalents and restricted cash	\$ 27,596,820	\$ 15,794,562

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 innovative medicines for the treatment of cardiometabolic and inflammatory diseases. Our drug development program consists of two late-stage novel small molecules, enobosarm and sabizabulin. Enobosarm, an oral selective androgen receptor modulator ("SARM"), is being developed as a next generation drug that makes weight reduction by GLP-1 RA drugs more tissue selective for loss of fat and preservation of lean mass leading to improved body composition and physical function which is expected to result in clinically meaningful incremental weight reduction versus GLP-1 RA therapy alone. Sabizabulin, a microtubule disruptor, is being developed for the treatment of chronic inflammation related to 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 (the "FC2 Business").

**Obesity Program - Enobosarm**

Currently approved GLP-1 RA treatments in patients with obesity results in significant weight loss composed of reductions in both fat and lean (muscle) mass. In the scientific literature, 20-50% of the total weight loss was attributable to lean mass (muscle) loss. Older patients who have sarcopenic obesity have both obesity and low muscle mass and are potentially at the greatest risk for developing critically low muscle mass and physical function decline when taking a currently approved GLP-1 RA. According to the European Working Group on Sarcopenia in Older People 2 (EWGSOP2), sarcopenia is defined by reduced muscle strength/function as the primary diagnostic criterion, confirmed by low muscle quantity or quality, while impaired physical performance reflects disease severity. We believe there is an urgent unmet need for a drug that prevents the loss of muscle and physical function as well as increases the loss of fat for greater weight loss in at-risk sarcopenic obese older patients receiving GLP-1 RA for weight reduction.

Enobosarm is being developed for weight loss and as a treatment to preserve physical function as well as to augment fat loss resulting in incremental weight loss in patients with obesity receiving a GLP-1 RA for weight reduction. A Phase 2b, multicenter, double-blind, placebo-controlled, randomized, dose-finding QUALITY clinical trial was conducted to evaluate the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo in 168 patients with obesity ( $\geq 60$  years of age) receiving semaglutide (Wegovy®) for weight reduction. The primary endpoint for the QUALITY clinical trial was the percent change from baseline in total lean body mass, and the key secondary endpoints were the percent change from baseline in total body fat mass, total body weight, and physical function as measured by stair climb test at 16 weeks. After completing the efficacy dose-assessment portion of the Phase 2b QUALITY clinical trial, the participants continued into a Phase 2b maintenance extension trial where all patients stopped treatment with semaglutide, but continue taking placebo, enobosarm 3mg, or enobosarm 6mg monotherapy in a blinded fashion for 12 additional weeks. The Phase 2b extension clinical trial evaluated whether enobosarm can maintain muscle and prevent the fat and weight regain that generally occurs after discontinuing a GLP-1 RA.

***Phase 2b QUALITY Study Results During Active Weight Loss 16 Week Period***

In January 2025, the Company announced topline results for the Phase 2b QUALITY clinical trial:

- Primary endpoint was met with a statistically significant and a clinically meaningful benefit in the preservation of total lean body mass in 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 dose 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 a DXA scan 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 with 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%.
- Physical function was measured by the stair climb test, which is an activity of daily living. 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 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 44.3% 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 GLP-1 RA 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 is a novel drug candidate 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 portion during the 16 weeks of active weight loss 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.

#### ***Phase 2b QUALITY Study Results During the 12 Week Maintenance Extension Period***

After completing the efficacy dose-finding and active weight reduction 16 week 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 maintenance extension portion of the Phase 2b QUALITY clinical study:

As a point of reference, body weight loss at the end of the Phase 2b QUALITY study active weight loss period was similar across treatment groups with the semaglutide + placebo group losing an average of 11.88 lbs. After the 12-week maintenance extension study period where all treatment groups discontinued the use of 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 clinical trial 12 week maintenance extension period, 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 the use of 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 lean mass was preserved for a higher quality weight reduction compared to the placebo group.

#### *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. In a pilot pharmacokinetic study, the new modified release formulation resulted in a 25-33% reduction in maximum plasma concentration ( $C_{max}$ ), a delayed time to maximum plasma concentration ( $T_{max}$ ), a distinct secondary peak, and similar extent of absorption (AUC) compared to historical values for enobosarm immediate release capsules. The actual formulation, pharmacokinetic release profile(s), and method of manufacturing are the subjects of pending patent applications. If issued, the expiry for the new modified release oral enobosarm formulation patent is expected to be 2046.

#### **Development Plan: Planned Clinical Trials**

##### Regulatory Feedback

The regulatory landscape continues to evolve for muscle preservation drugs in the treatment of obesity. Based on FDA feedback on Veru's clinical development program for enobosarm received in September 2025, the FDA now guides that incremental weight loss with enobosarm added to GLP-1 RA treatment over the GLP-1 RA treatment alone is an acceptable primary endpoint to support the efficacy of enobosarm for approval.

In its feedback, the FDA stated that incremental weight loss with enobosarm of at least a 5% placebo-corrected weight loss at 52 weeks of maintenance treatment alone would support efficacy for approval. Alternatively, if incremental weight loss with enobosarm of  $<5\%$  is observed at 52 weeks of maintenance treatment with a clinically significant positive benefit, such as clinically beneficial preservation in physical function, a drug in combination with GLP-1 RA may be approvable. Physical function (stair climb assessment) improvement that is linked to a patient reported outcome of mobility/disability would also be acceptable. The FDA stated it may be reasonable to first establish efficacy in older adults who may be at greater risk of harm due to muscle loss, but the development should be expanded to younger patients with obesity. The FDA also confirmed that enobosarm 3mg is an acceptable dosage for future Veru clinical development.

On December 19, 2025, the FDA announced that total hip bone mineral density (BMD) assessed by DXA qualifies as a validated surrogate endpoint for drug development in postmenopausal women with osteoporosis at risk for fracture providing an alternative to fracture endpoints. It has been reported in the scientific literature that GLP-1 RA therapy reduces hip BMD, and recently, the Wegovy FDA label has been updated to include the observation of a greater number of hip and pelvic fractures in the SELECT cardiovascular trial in adults receiving semaglutide. The SELECT (Semaglutide Effects on Heart Disease and Stroke in Patients With Overweight or Obesity) cardiovascular trial is a completed clinical trial sponsored by Novo Nordisk A/S in over 17,000 subjects. In the SELECT trial, 4-5 times more fractures of the hip and pelvis were reported on Wegovy than on placebo in female patients and patients ages 75 and older. Enobosarm has been shown in published preclinical studies to have anabolic and anti-resorptive activities to increase bone mineral density in rat models of postmenopausal women and male osteoporosis.

#### Clinical Development Strategy

The clinical development program of enobosarm will take advantage of both the FDA regulatory clarity on the acceptable primary endpoint and on enobosarm's key attributes, preservation of muscle and physical function, and greater selective fat loss (100% fat loss and 0% lean mass weight loss), that were demonstrated in Veru's Phase 2 QUALITY study. Further, enobosarm's ability to improve body composition by preserving muscle, losing more fat, and increasing bone mineral density measured by DXA may also take advantage of hip BMD as a validated surrogate primary endpoint.

The Company is focusing its Phase 2b PLATEAU clinical study in older patients (age  $\geq 65$  yo) who have the most weight to lose (BMI  $\geq 35$ ). The weight loss plateau occurs when the patient with obesity stops losing weight while on a GLP-1 RA. In the SURMOUNT-1 clinical study conducted by Eli Lilly and Company, about 88% of patients with obesity receiving tirzepatide reached the weight loss plateau by 72 weeks. Unfortunately, 62.6% of these patients are still clinically overweight or have obesity at 72 weeks, and patients that had a baseline BMI  $\geq 35$  on average still had obesity. We believe treatment with semaglutide when combined with enobosarm, will lead to additional fat loss by preserving muscle and physical function and directly burning fat. Enobosarm's ability to directly and indirectly cause additional fat loss is expected to reset the weight loss plateau leading to incremental weight reduction, thereby increasing the number of patients who achieve and maintain a normal weight.

#### Currently Enrolling Phase 2b PLATEAU Clinical Study

On March 9, 2026, the Company announced it had enrolled its first patient in the Phase 2b PLATEAU clinical trial. Veru's PLATEAU clinical trial design is a double-blind, placebo-controlled study to evaluate the effect of enobosarm 3mg on total body weight, fat mass, lean mass and physical function, bone mineral density and safety in approximately 200 older patients (age  $\geq 65$  yo) who have obesity (BMI  $\geq 35$ ) and are initiating semaglutide (Wegovy) GLP-1 RA treatment for weight reduction. The primary efficacy endpoint of the study is the percent change from baseline in total body weight at 68 weeks. An interim analysis will be conducted at 36 weeks to assess the percent change from baseline in lean body mass, total fat mass, percentage body fat mass, percentage body lean mass, and total body mass, as measured by DXA scan. The key secondary endpoints for the overall study are total fat mass, total lean mass, physical function (stair climb test), mobility-disability assessment, bone mineral density, and patient reported outcome questionnaires for physical function (SF-36 PF-10, and IWQOL-lite CT physical function), HbA1c, and insulin resistance.

The Phase 2b PLATEAU clinical study is designed to assess the ability of enobosarm treatment to break through the weight loss plateau observed in patients with obesity receiving GLP-1 RA treatment to achieve clinically meaningful incremental weight reduction and preserve muscle mass and physical function by 68 weeks. An interim analysis for the clinical study after all patients are treated for 36 weeks is planned for the first quarter of calendar 2027.

Based on FDA regulatory feedback and qualification of BMD as an acceptable surrogate endpoint, results from the Phase 2b PLATEAU study may have three possible regulatory pathways to support efficacy for approval of enobosarm in combination with the GLP-1 RA. If incremental weight loss is  $\geq 5\%$ , the Phase 3 study could be in patients with obesity with a primary endpoint of total body weight, and key secondary endpoints for prespecified subgroups of physical function in sarcopenic patients (age  $\geq 65$  yo) with mobility disability and another for BMD in postmenopausal women with osteoporosis. If the incremental weight loss is  $< 5\%$ , the Phase 3 study could be in patients with obesity and mobility disability with a primary endpoint of physical function in sarcopenic obesity patients (age  $\geq 65$  yo) with mobility disability, and a key secondary endpoint could be BMD in a prespecified group of postmenopausal women with osteoporosis. Alternatively, the Phase 3 study could be in patients with obesity and osteoporosis with a primary endpoint of BMD in postmenopausal women with osteoporosis, and a key secondary endpoint of physical function in sarcopenic patients (age  $\geq 65$  yo) with mobility disability.

### **Atherosclerosis Inflammation Program - Sabizabulin**

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). 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 may not adequately address the current unmet medical need of atherosclerotic inflammation.

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 a novel small molecule that targets the colchicine binding site on  $\beta$ -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. Overall preclinical data from *in vitro* and *in vivo* inflammation studies show that sabizabulin treatment suppressed all cytokines and chemokines tested which includes IL-1 $\alpha$ , IL-1 $\beta$ , IL-6, IL-8, TNF- $\alpha$ , Interferon- $\gamma$ , and IP-10 (CXCL-10). In Phase 2 and 3 pulmonary inflammation COVID-19 clinical studies, sabizabulin has demonstrated broad anti-inflammatory activity resulting in a significant reduction in mortality. 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  $\leq$  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). Further, because sabizabulin has a different chemical structure than colchicine, it is not a substrate for CYP3A4 and P-glycoprotein thereby 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.

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 with a potentially better efficacy and safety profile like sabizabulin as a secondary treatment in combination with lipid lowering statin drugs to prevent and treat atherosclerotic CAD. Consequently, 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.

***Development Plan: Planned Clinical Trials.***

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. Initially, we plan to evaluate sabizabulin in a small Phase 2 dose finding proof of concept study to assess whether sabizabulin reduces blood levels of high sensitivity C-reactive protein, an important measurement of inflammation, in 45 patients with stable CAD following 3 months of treatment. 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 a wholly owned subsidiary of the Company (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, which included a customary working capital adjustment subsequent to 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 were \$16.5 million, which is the \$18.0 million purchase price per the Purchase Agreement after purchase price adjustments, net of costs incurred of \$1.4 million, and amounts allocated to the related transition services agreement of \$150,000 but excluding the change of control payment pursuant to the Residual Royalty Agreement of \$4.2 million (see Note 8 to the financial statements included in this report for additional information). The loss on sale of the FC2 Business is \$4.1 million, which is the difference between estimated net proceeds of \$16.5 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 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 disputed the calculation. This dispute was submitted to an accounting firm for binding resolution, and in September 2025 the accounting firm delivered its final determination, resolving all disputed matters in favor of the Company. As a result of the final determination, the Purchaser paid additional purchase price of approximately \$150,000 to us and approximately \$300,000 was released from escrow.

During the three months ended March 31, 2026, the Company recognized an additional gain on sale of the FC2 business of \$351,000, which is for net proceeds received from the Purchaser in the settlement of a dispute related to a pre-closing tax receivable and liability.

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 the three and six months ended March 31, 2025. We did not allocate any amounts for shared general and administrative operating support expense to discontinued operations. 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 March 31, 2026 or September 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 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.

As of September 22, 2025, an aggregate of \$8.8 million was payable to the Company under the ONCO Promissory Notes and related amendments. On September 22, 2025, the Company and ONCO entered into a Settlement Agreement and Release (the “Settlement Agreement”), whereby the Company agreed to accept a cash payment of \$6.3 million, 3,125 shares of ONCO’s Series D Convertible Preferred Stock (the “ONCO Series D Preferred Stock”) and a warrant to purchase 169,395 shares of ONCO’s common stock (the “ONCO Warrant”) (such cash payment, shares of ONCO Series D Preferred Stock, and the ONCO Warrant, collectively, the “Settlement Amount”) in full satisfaction of all amounts due under the ONCO Promissory Notes, as amended by all preceding amendments, forbearance agreements, and waivers, in complete discharge of all obligations thereunder. The ONCO Promissory Notes and the Forbearance Agreement terminated upon payment of the Settlement Amounts. The Company received proceeds of \$3.2 million from the sale of shares of ONCO’s common stock acquired from the conversion of ONCO Series D Preferred Stock during the three months ended March 31, 2026 and \$1.8 million from the sale of shares of ONCO’s common stock acquired from the conversion of ONCO Series D Preferred Stock subsequent to March 31, 2026, and after such sales the Company no longer holds any shares of ONCO Series D Preferred Stock. There can be no assurances as to whether and when the Company will be able to receive any cash proceeds from the shares of ONCO Warrant or any shares of ONCO’s common stock that the Company might acquire upon exercise of the ONCO Warrant.

**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 \$3.1 million and \$3.9 million for the three months ended March 31, 2026 and 2025, respectively, and \$4.5 million and \$9.6 million for the six months ended March 31, 2026 and 2025, respectively. 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 MARCH 31, 2026 COMPARED TO THREE MONTHS ENDED MARCH 31, 2025

Research and development expenses decreased to \$3.1 million in the three months ended March 31, 2026 from \$3.9 million in the same period in fiscal 2025. The decrease in research and development expenses is primarily due to reduced personnel costs, driven by lower share-based compensation expense.

General and administrative expenses were \$4.1 million in the three months ended March 31, 2026, which is a decrease from \$5.2 million in the three months ended March 31, 2025. The decrease is due primarily to a reduction in corporate personnel costs, due to reduced share-based compensation expense.

The Company recorded a gain on sale of ENTADFI assets of \$1.0 million in the three months ended March 31, 2025. The Company recognized a gain on sale of ENTADFI assets as nonrefundable consideration was received from the ONCO Promissory Notes. The ONCO Promissory Notes were settled in fiscal 2025 so no additional gain from additional consideration is expected in future periods. Refer to Note 15 to the financial statements included in this report for additional information.

The Company also recorded a gain from the increase in fair value of equity securities of \$3.9 million in the three months ended March 31, 2026. The increase in fair value was driven by realized gain from the conversion of the ONCO Series D Preferred Stock and sale of the underlying ONCO common stock and a change in the fair value of the remaining outstanding ONCO Series D Preferred Stock and the ONCO Warrants, driven by favorable provisions triggered by ONCO's reverse stock split on March 25, 2026.

Net income from discontinued operations, net of taxes, related to the FC2 business of \$351,000 for the three months ended March 31, 2026, which is an additional gain on the sale of the FC2 business for net proceeds received from the Purchaser in the settlement of a dispute related to a pre-closing tax receivable and liability. The net loss from discontinued operations of \$49,000 during the three months ended March 31, 2025 is due to changes in estimates made at the time the FC2 business was sold.

SIX MONTHS ENDED MARCH 31, 2026 COMPARED TO SIX MONTHS ENDED MARCH 31, 2025

Research and development expenses decreased to \$4.5 million in the six months ended March 31, 2026 from \$9.6 million in the same period in fiscal 2025. 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 fiscal 2025. The Company initiated the Phase 2b PLATEAU clinical study during the three months ended March 31, 2026. Personnel costs also decreased due primarily to reduced share-based compensation expense.

General and administrative expenses were \$8.2 million in the six months ended March 31, 2026, which is a decrease from \$10.4 million in the six months ended March 31, 2025. The decrease is due primarily to a reduction in corporate personnel costs, due to reduced share-based compensation expense.

The Company recorded a gain on sale of ENTADFI assets of \$1.7 million in the six months ended March 31, 2025. The Company recognized a gain on sale of ENTADFI assets as nonrefundable consideration was received from the ONCO Promissory Notes. The ONCO Promissory Notes were settled in fiscal 2025 so no additional gain from additional consideration is expected in future periods. Refer to Note 15 to the financial statements included in this report for additional information.

Gain on extinguishment of debt of \$8.6 million was recognized during the six months ended March 31, 2025, related to the termination of the Residual Royalty Agreement, in connection with the FC2 Business Sale. The gain was 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.

During the six months ended March 31, 2026, the Company also recorded a gain from the increase in fair value of equity securities of \$3.8 million compared to a loss from a decrease in fair value of equity securities of \$0.3 million during the six months ended March 31, 2025. The increase in fair value in the fiscal 2026 period was driven by realized gain from the conversion of the ONCO Series D Preferred Stock and sale of the underlying ONCO common stock and a change in the fair value of the remaining outstanding ONCO Series D Preferred Stock and the ONCO Warrants, driven by favorable provisions triggered by ONCO's reverse stock split on March 25, 2026.

Net income from discontinued operations, net of taxes, related to the FC2 business of \$351,000 for the six months ended March 31, 2026, which is an additional gain on the sale of the FC2 business for net proceeds received from the Purchaser in the settlement of a dispute related to a pre-closing tax receivable and liability. The Company recorded a net loss from discontinued operations, net of taxes, related to the FC2 business of \$7.2 million for the six months ended March 31, 2025. The net loss from discontinued operations during the six months ended March 31, 2025 is attributable to the operations of the FC2 business during that period and the recognition of the loss on sale of FC2, initially estimated as \$4.2 million for the six months ended March 31, 2025 and adjusted to \$4.1 million in a subsequent quarter during fiscal 2025.

#### Liquidity and Sources of Capital

##### ***Liquidity***

Our cash, cash equivalents, and restricted cash on hand at March 31, 2026 was \$27.6 million, compared to \$15.8 million at September 30, 2025. Restricted cash included in this balance is \$0.1 million at each of March 31, 2026 and September 30, 2025. At March 31, 2026, the Company had working capital of \$28.0 million and stockholders' equity of \$34.8 million compared to working capital of \$11.1 million and stockholders' equity of \$18.3 million as of September 30, 2025. The increase in working capital is primarily due to an increase in cash, cash equivalents, and restricted cash of \$11.8 million, an increase in prepaid expenses of \$2.0 million, a decrease in accrued compensation of \$1.3 million, and a decrease in accounts payable of \$1.0 million.

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 I, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2025 and Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q 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 \$15.1 million in the six months ended March 31, 2026. Cash used in operating activities included net loss of \$8.1 million, adjustments to reconcile net loss to net cash used in operating activities totaling a decrease of \$2.7 million and changes in operating assets and liabilities resulting in a decrease of \$4.3 million. Adjustments to net loss primarily consisted of \$3.8 million for the gain from the change in fair value of equity securities and \$1.2 million for share-based compensation. The decrease in cash from changes in operating assets and liabilities primarily included a decrease in accounts payable of \$1.6 million, a decrease in accrued expenses and other liabilities of \$1.4 million, and an increase in prepaid expenses and other assets of \$1.1 million.

Operating activities used cash of \$19.1 million in the six months ended March 31, 2025. Cash used in operating activities included net loss of \$16.8 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of \$2.5 million and changes in operating assets and liabilities resulting in a decrease of \$4.7 million. Adjustments to net loss primarily consisted of \$4.9 million for share-based compensation, \$4.2 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 \$1.7 million. The decrease in cash from changes in operating assets and liabilities included a decrease in accrued expenses and other current liabilities of \$2.6 million and a decrease in accounts payable of \$1.7 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 six months ended March 31, 2025 are outflows of \$0.3 million.

*Investing activities*

Net cash provided by investing activities was \$3.5 million during the six months ended March 31, 2026, and consisted of net proceeds from the sale of equity securities of \$3.2 million and net proceeds of \$0.4 million from the sale of the FC2 business for the settlement of a dispute related to a pre-closing tax receivable and liability.

Net cash provided by investing activities was \$18.4 million during the six months ended March 31, 2025, and consisted of net proceeds of \$16.3 million from the sale of the FC2 business, proceeds of \$1.7 million from the sale of ENTADFI assets, and proceeds of \$0.4 million from the sale of equity securities.

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 six months ended March 31, 2026 and 2025 are inflows of \$0.3 million and \$16.2 million, respectively, which consist of net proceeds from the sale of the FC2 business.

*Financing activities*

Net cash provided by financing activities in the six months ended March 31, 2026 was \$23.4 million, which consisted of proceeds from the sale of common stock and warrants in an underwritten public offering, net of commissions and costs, of \$23.4 million.

Net cash used in financing activities in the six months ended March 31, 2025 was \$4.2 million, which represented 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.

***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 during the three and six months ended March 31, 2025. The Company is not required to make any additional payments under the Residual Royalty Agreement.

*Equity Offering*

On October 31, 2025, we completed an underwritten public offering of (i) 1,400,000 shares of our common stock, (ii) pre-funded warrants to purchase up to 7,000,000 shares of our common stock, each representing the right to purchase one share of common stock at an exercise price of \$0.001, in lieu of common stock, (iii) accompanying Series A warrants to purchase up to 8,400,000 shares of our common stock, and (iv) accompanying Series B warrants to purchase up to 8,400,000 shares of our common stock, at a public offering price of \$3.00 per share of common stock, accompanying Series A warrant and accompanying Series B warrant. Net proceeds to the Company from this offering were approximately \$23.4 million after deducting underwriting discounts and commissions and costs paid by the Company. All of the securities 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. The shelf registration statement on Form S-3 (File No. 333-270606) expired in April 2026, and after that date the Company was unable to sell any securities pursuant to the Lincoln Park Purchase Agreement because such sales would no longer be covered by an effective registration statement. The Company did not have plans to utilize the remaining capacity under the Lincoln Park Purchase Agreement and terminated the agreement effective May 12, 2026.

During the six months ended March 31, 2026 and 2025, we did not sell any shares under the Lincoln Park Purchase Agreement. Since inception of the Lincoln Park Purchase Agreement through March 31, 2026, we sold 302,500 shares of common stock to Lincoln Park resulting in proceeds to the Company of \$3.1 million.

Fair Value Measurements

The Company has investments in equity securities consisting of the ONCO Series D Preferred Stock and the ONCO Warrant as of March 31, 2026 and September 30, 2025. The ONCO Series D Preferred Stock and the ONCO Warrant were received on September 22, 2025 as a settlement of the ONCO Promissory Notes. See Note 15 to the financial statements included in this report for additional information. The Company has elected to measure the ONCO Series D Preferred Stock and the ONCO Warrant at fair value in accordance with ASC 825. The investments in the ONCO Series D Preferred Stock and the ONCO Warrant are classified within Level 3 of the fair value hierarchy because there is no market for these types of securities and the fair value is determined using significant unobservable inputs. The fair value of the ONCO Series D Preferred Stock and the ONCO Warrant have been determined using a Monte Carlo simulation model. This valuation model incorporates the contractual terms of the instruments and assumptions including the stock price of ONCO Common Stock, expected volatility, and a selected discount rate. Additionally, the ONCO Series D Preferred Stock and the ONCO Warrant were issued by ONCO as part of a Securities Purchase Agreement, which included the sale of 16,099 shares of Series D convertible preferred stock and warrants to purchase 4,362,827 shares of ONCO Common Stock to eleven institutional investors, for an aggregate purchase price of \$12.9 million. The valuation of the ONCO Series D Preferred Stock and ONCO Warrant at issuance included a calibration discount to the proceeds of the original transaction, which was done at arms' length. The calibration discount was reduced to zero as of March 31, 2026 as the Company began to convert the ONCO Series D Preferred Stock during the three months ended March 31, 2026, which had the effect of increasing the fair value of the ONCO Series D Preferred Stock and the ONCO Warrant. The assumptions used in calculating the fair value of the financial instruments represent the Company's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, the use of different estimates or assumptions would result 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.

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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, 2025.

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

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the risks and uncertainties relating to the Company's business disclosed in Part I, Item 1A, "Risk Factors", in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2025. There have been no material changes from the risk factors disclosed in Part I, Item 1A, "Risk Factors", in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2025, except for the following additional risk factor. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations.

***We will need to raise additional capital to fund our operations and development programs in the future, and the SEC "baby shelf" rule may limit our ability to raise sufficient capital when needed.***

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. Our existing cash, cash equivalents, and restricted cash 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.

Under current SEC regulations, because our public float is less than \$75 million, and for so long as our public float remains less than \$75 million, the amount we can raise through primary public offerings of securities in any 12-month period using shelf registration statements is limited to an aggregate of one-third of our public float (referred to as the "baby shelf" rule). As of April 7, 2026, the aggregate market value of our outstanding common shares held by non-affiliates, or public float, was approximately \$38.5 million, which is calculated based on 14,480,292 shares of our outstanding common stock held by non-affiliates and a price of \$2.66 per share, the closing price of our common stock on February 26, 2026, which is the highest closing price of our common stock on the Nasdaq Capital Market within the prior 60 days of April 7, 2026. If our public float decreases, the amount of securities we may sell under our shelf registration statement may also decrease.

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 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.

Item 5. Other Information

Disclosure Pursuant to Item 1.02 of Form 8-K – Termination of a Material Definitive Agreement

On May 11, 2026, the Company delivered notice to Lincoln Park to terminate the Lincoln Park Purchase Agreement. Termination of the Lincoln Park Purchase is effective May 12, 2026, pursuant to Section 11 of the Lincoln Park Purchase Agreement. The Company is not subject to any termination penalties related to the termination of the Lincoln Park Purchase Agreement.

As a result of the termination of the Purchase Agreement, the Company will not issue or sell any additional shares of common stock under the Purchase Agreement. Since inception of the Purchase Agreement, the Company sold 302,500 shares of common stock to Lincoln Park resulting in proceeds to the Company of \$3.1 million.

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Item 6. Exhibits

<u>Exhibit Number</u>	<u>Description</u>
2.1	<a href="#">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).</a>
2.2	<a href="#">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).</a>
2.3	<a href="#">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).</a>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
3.3	<a href="#">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).</a>
3.4	<a href="#">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).</a>
3.5	<a href="#">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).</a>
3.6	<a href="#">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).</a>
3.7	<a href="#">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).</a>
3.8	<a href="#">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).</a>
3.9	<a href="#">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).</a>
3.10	<a href="#">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).</a>

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3.11	<a href="#">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).</a>
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits <a href="#">3.1</a> , <a href="#">3.2</a> , <a href="#">3.3</a> , <a href="#">3.4</a> , <a href="#">3.5</a> , <a href="#">3.6</a> , <a href="#">3.7</a> , <a href="#">3.8</a> , <a href="#">3.9</a> , and <a href="#">3.10</a> ).
4.2	<a href="#">Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.11).</a>
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a> *
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a> *
32.1	<a href="#">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).</a> *, **
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, 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: May 13, 2026

/s/ Mitchell S. Steiner

Mitchell S. Steiner

Chairman, Chief Executive Officer and President

DATE: May 13, 2026

/s/ Michele Greco

Michele Greco

Chief Financial Officer and Chief Administrative Officer

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: May 13, 2026

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

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: May 13, 2026

/s/Michele Greco

Michele Greco

Chief Financial Officer and Chief Administrative Officer

**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 March 31, 2026 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: May 13, 2026

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

Date: May 13, 2026

/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.