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, 2024

OR

☐ 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: 001-41294

Onconetix, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**83-2262816**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
201 E. Fifth Street, Suite 1900 Cincinnati, OH	**45202**
(Address of principal executive offices)	(Zip Code)

(513) 620-4101
(Registrant's telephone number, including area code)

Not Applicable
(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 exchange on which registered**
Common stock, $0.00001 par value	**ONCO**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of May 20, 2024, the registrant had 22,327,701 shares of common stock, $0.00001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Report") contains forward-looking statements that reflect our current expectations and views of future events. The forward-looking statements are contained principally in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Readers are cautioned that known and unknown risks, uncertainties and other factors, including those over which we may have no control and others listed in the "Risk Factors" section of this Report, may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations and repay indebtedness;
- our ability to commercialize or monetize ENTADFI and Proclarix and integrate the assets and commercial operations acquired in the share exchange with Proteomedix AG ("Proteomedix");
- the successful development of our commercialization capabilities, including sales and marketing capabilities.
- our ability to maintain the necessary regulatory approvals to market and commercialize our products;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current products;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;

- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated, or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- our reliance on third parties, including manufacturers and logistics companies;
- the success of competing therapies or diagnostics and products that are or become available;
- our ability to successfully compete against current and future competitors;
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract, motivate and retain key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our products;
- market acceptance of our products, the size and growth of the potential markets for our current products, and our ability to serve those markets; and
- Disruptions in the business of Onconetix or Proteomedix, which could have an adverse effect on their respective businesses and financial results.

These forward-looking statements involve numerous risks and uncertainties. Although we believe that our expectations expressed in these forward-looking statements are reasonable, our expectations may later be found to be incorrect. Our actual results of operations or the results of other matters that we anticipate herein could be materially different from our expectations. Important risks and factors that could cause our actual results to be materially different from our expectations are generally set forth in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and other sections in this Report. You should thoroughly read this Report and the documents that we refer to with the understanding that our actual future results may be materially different from and worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements.

The forward-looking statements made in this Report relate only to events or information as of the date on which the statements are made in this Report. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this Report and the documents that we refer to in this Report and have filed as exhibits to this Report, completely and with the understanding that our actual future results may be materially different from what we expect.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

ONCONETIX, INC.
Condensed Consolidated Balance Sheets

	March 31, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets		
Cash	$ 4,463,870	$ 4,554,335
Accounts receivable, net	252,792	149,731
Inventories	396,312	364,052
Prepaid expenses and other current assets	1,181,723	770,153
Total current assets	6,294,697	5,838,271
Prepaid expenses, long-term	7,792	17,423
Property and equipment, net	56,763	60,654
Deferred offering costs	366,113	366,113
Operating right of use asset	109,360	148,542
Intangible assets, net	21,453,555	25,410,887
Goodwill	46,743,319	55,676,142
Total assets	**$ 75,031,599**	**$ 87,518,032**
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 4,251,394	$ 5,295,114
Accrued expenses	1,936,014	2,199,867
Notes payable, net of debt discounts of $198,699 and $381,627 at March 31, 2024 and December 31, 2023, respectively	10,406,394	9,618,373
Note payable – related party, net of debt discount of $225,226 and $0 at March 31, 2024 and December 31, 2023, respectively	4,774,774	—
Operating lease liability, current	62,480	74,252
Contingent warrant liability	2,641	2,641
Total current liabilities	21,433,697	17,190,247
Note payable	110,871	118,857
Subscription agreement liability – related party	637,600	864,000
Pension benefit obligation	321,132	556,296
Operating lease liability, net of current portion	46,880	74,290
Deferred tax liability, net	2,743,246	3,073,781
Total liabilities	25,293,426	21,877,471
Commitments and Contingencies (see Note 10)		
Series B Convertible Redeemable Preferred stock, $0.00001 par value, 2,700,000 shares authorized at March 31, 2024 and December 31, 2023; 2,696,729 shares issued and outstanding at March 31, 2024 and December 31, 2023	64,236,085	64,236,085
Stockholders' equity (deficit)		
Series A Convertible Preferred stock, $0.00001 par value, 10,000 shares authorized at March 31, 2024 and December 31, 2023; 3,000 shares issued and outstanding at March 31, 2024 and December 31, 2023; Liquidation preference of $3,000,000 at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.00001 par value, 250,000,000 shares authorized at March 31, 2024 and December 31, 2023; 22,845,100 and 22,841,975 shares issued at March 31, 2024 and December 31, 2023, respectively; 22,327,701 and 22,324,576 shares outstanding at March 31, 2024 and December 31, 2023, respectively	228	228
Additional paid-in-capital	49,452,674	49,428,809
Treasury stock, at cost; 517,399 shares of common stock at March 31, 2024 and December 31, 2023	(625,791)	(625,791)
Accumulated deficit	(67,904,766)	(56,786,194)
Accumulated other comprehensive income (loss)	(2,455,546)	2,380,920
Total Onconetix stockholders' deficit	(21,533,201)	(5,602,028)
Non-controlling interest	7,035,289	7,006,504
Total stockholders' equity (deficit)	(14,497,912)	1,404,476
Total liabilities, convertible redeemable preferred stock, and stockholders' equity (deficit)	**$ 75,031,599**	**$ 87,518,032**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ONCONETIX, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Revenue	$ 700,433	$ —
Cost of revenue	511,433	—
Gross profit	189,000	—
Operating expenses		
Selling, general and administrative	3,736,450	1,766,022
Research and development	48,964	1,082,237
Impairment of goodwill	5,192,000	—
Impairment of ENTADFI assets	2,293,576	—
Total operating expenses	11,270,990	2,848,259
Loss from operations	(11,081,990)	(2,848,259)
Other income (expense)		
Interest expense – related party	(225,063)	—
Interest expense	(187,993)	—
Change in fair value of subscription agreement liability – related party	226,400	—
Other income	28,507	—
Change in fair value of contingent warrant liability	—	1,615
Total other income (expense)	(158,149)	1,615
Loss before income taxes	(11,240,139)	(2,846,644)
Income tax benefit	121,567	—
Net loss	**$ (11,118,572)**	**$ (2,846,644)**
Net loss per share, basic and diluted	$ (0.50)	$ (0.18)
Weighted average number of common shares outstanding, basic and diluted	22,147,598	15,910,415
Other comprehensive loss		
Net loss	$ (11,118,572)	$ (2,846,644)
Foreign currency translation	(4,991,144)	—
Change in pension benefit obligation	154,678	—
Total comprehensive loss	$ (15,955,038)	$ (2,846,644)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ONCONETIX, INC.
Condensed Consolidated Statements of Convertible Redeemable Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)

	Series B Preferred Stock		Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Other Comprehensive Income	Total Onconetix Equity (Deficit)	Non-controlling Interest	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount		Shares	Amount					
Balance at December 31, 2023	**2,696,729**	**$64,236,085**	**3,000**	**$ —**	**22,841,975**	**$ 228**	**$49,428,809**	**(517,399)**	**$(625,791)**	**$ (56,786,194)**	**$ 2,380,920**	**$ (5,602,028)**	**$ 7,006,504**	**$ 1,404,476**
Issuance of restricted stock	—	—	—	—	3,125	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	23,865	—	—	—	—	23,865	28,785	52,650
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	(4,991,144)	(4,991,144)	—	(4,991,144)
Changes in pension benefit obligation	—	—	—	—	—	—	—	—	—	—	154,678	154,678	—	154,678
Net loss	—	—	—	—	—	—	—	—	—	(11,118,572)	—	(11,118,572)	—	(11,118,572)
Balance at March 31, 2024	**2,696,729**	**$64,236,085**	**3,000**	**$ —**	**22,845,100**	**$ 228**	**$49,452,674**	**(517,399)**	**$(625,791)**	**$ (67,904,766)**	**$ (2,455,546)**	**$ (21,533,201)**	**$ 7,035,289**	**$ (14,497,912)**

	Series B Preferred Stock		Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Other Comprehensive Income	Total Onconetix Equity (Deficit)	Non-controlling Interest	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount		Shares	Amount					
Balance at December 31, 2022	**—**	**$ —**	**—**	**$ —**	**15,724,957**	**$ 157**	**$42,331,155**	**(459,729)**	**$(566,810)**	**$ (19,376,500)**	**$ —**	**$ 22,388,002**	**$ —**	**$ 22,388,002**
Exercise of pre-funded warrants	—	—	—	—	646,640	7	(7)	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	185,578	—	—	—	—	185,578	—	185,578
Purchase of treasury shares	—	—	—	—	—	—	—	(32,638)	(33,454)	—	—	(33,454)	—	(33,454)
Net loss	—	—	—	—	—	—	—	—	—	(2,846,644)	—	(2,846,644)	—	(2,846,644)
Balance at March 31, 2023	**—**	**$ —**	**—**	**$ —**	**16,371,597**	**$ 164**	**$42,516,726**	**(492,367)**	**$(600,264)**	**$ (22,223,144)**	**$ —**	**$ 19,693,482**	**$ —**	**$ 19,693,482**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ONCONETIX, INC.
Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Cash flows from operating activities		
Net loss	$ (11,118,572)	$ (2,846,644)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of goodwill	5,192,000	—
Impairment of ENTADFI assets	2,293,576	—
Amortization of debt discounts	182,928	—
Amortization of debt discount – related party	174,774	—
Depreciation and amortization	206,700	1,698
Change in fair value of subscription agreement liability – related party	(226,400)	—
Net periodic pension benefit	(58,404)	—
Stock-based compensation	52,650	185,578
Interest accrued on note payable – related party	50,000	—
Change in fair value of contingent warrant liability	—	(1,615)
Deferred tax benefit	(121,567)	—
Changes in operating assets and liabilities:		
Accounts receivable	(116,763)	—
Inventories	(36,974)	—
Prepaid expenses and other current assets	(419,530)	(321,961)
Other noncurrent assets	(7,750)	23,117
Accounts payable	(1,017,428)	(1,237,493)
Accrued expenses	(261,303)	(214,311)
Net cash used in operating activities	(5,232,063)	(4,411,631)
Cash flows from investing activities		
Net advances to related parties	—	(34,452)
Purchases of property and equipment	(4,578)	(1,819)
Net cash used in investing activities	(4,578)	(36,271)
Cash flows from financing activities		
Proceeds from issuance of note payable – related party	5,000,000	—
Proceeds from issuance of note payable	678,550	—
Payment of financing costs	(400,000)	—
Principal payment of note payable	(73,457)	—
Payment of deferred offering costs		(15,500)
Purchase of treasury shares	—	(33,454)
Net cash provided by (used in) financing activities	5,205,093	(48,954)
Effect of exchange rate changes on cash	(58,917)	—
Net decrease in cash	(90,465)	(4,496,856)
Cash, beginning of period	4,554,335	25,752,659
Cash, end of period	$ 4,463,870	$ 21,255,803
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 4,405	$ —
Noncash investing and financing activities:		
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 339,593
Deferred offering costs previously included in prepaid expenses	$ —	$ (11,020)
Exercise of pre-funded warrants	$ —	$ 7

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Note 1 — Organization and Basis of Presentation

Organization and Nature of Operations

Onconetix, Inc. (formerly known as Blue Water Biotech, Inc. and Blue Water Vaccines Inc.) (the "Company" or "Onconetix") was formed on October 26, 2018, and is a commercial stage biotechnology company focused on the research, development, and commercialization of innovative solutions for men's health and oncology.

On December 15, 2023, Onconetix acquired 100% of the issued and outstanding voting equity interests in Proteomedix AG, a Swiss company ("Proteomedix"), and its related diagnostic product Proclarix. As a result of this transaction, Proteomedix became a wholly owned subsidiary of Onconetix (see Note 5). In April 2023, the Company acquired ENTADFI, a Food and Drug Administration ("FDA")-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia.

Historically, the Company's focus was on the research and development of transformational vaccines to prevent infectious diseases worldwide, until the third quarter of 2023, at which time the Company halted its efforts on vaccine development activities to focus on commercialization activities for ENTADFI and pursue other potential acquisitions. However, in light of (i) the time and resources needed to continue pursuing commercialization of ENTADFI, and (ii) the Company's cash runway and indebtedness, the Company has now determined to pause its commercialization of ENTADFI, as it explores strategic alternatives to monetize ENTADFI, such as a potential sale of the ENTADFI assets. To that end, the Company has engaged an investment advisor to assist with a potential sale or other transaction of the ENTADFI assets.

Basis of Presentation and Principles of Consolidation

The Company's condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and include the accounts of Onconetix and its 100% wholly owned subsidiary, Proteomedix, since the acquisition date of December 15, 2023. All significant intercompany balances and transactions have been eliminated in consolidation.

Unaudited Interim Consolidated Financial Statements

The accompanying condensed consolidated balance sheet as of March 31, 2024, and the condensed consolidated statements of operations and comprehensive loss, the condensed consolidated statements of convertible redeemable preferred stock and stockholders' equity (deficit), and the condensed consolidated statements of cash flows for the three months ended March 31, 2024 and 2023 are unaudited. These unaudited interim consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements, and in management's opinion, include all adjustments, consisting of only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2024 and its results of operations and comprehensive loss and its cash flows for the three months ended March 31, 2024 and 2023. The financial data and the other financial information disclosed in the notes to these condensed consolidated financial statements related to the three month period are also unaudited. Operating results for the three months ended March 31, 2024, are not necessarily indicative of the results that may be expected for the year ending December 31, 2024, any other interim periods, or any future year or period. The unaudited condensed consolidated financial statements included in this Report should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, which includes a broader discussion of the Company's business and the risks inherent therein.

Note 2 — Going Concern and Management's Plans

The Company's operating activities to date have been devoted to seeking licenses, engaging in research and development activities, potential asset and business acquisitions, and expenditures associated with the commercial launch of ENTADFI and the commercialization of Proclarix.

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of March 31, 2024, the Company had cash of approximately $4.5 million, a working capital deficit of approximately $15.1 million and an accumulated deficit of approximately $67.9 million. During the three months ended March 31, 2024, the Company used approximately $5.2 million in cash for operating activities. In addition, as of May 15, 2024, the Company's cash balance was approximately $1.9 million. The Company believes that its current cash balance is only sufficient to fund its operations into the third quarter of 2024 and this raises substantial doubt about the Company's ability to continue as a going concern within one year from the date of the issuance of these consolidated financial statements, and indicates that the Company is unable to meet its contractual commitments and obligations as they come due in the ordinary course of business. The Company will require significant additional capital in the short-term to fund its continuing operations, satisfy existing and future obligations and liabilities, including the remaining payments due for the acquisition of the ENTADFI assets, payment due on debentures, in addition to funds needed to support the Company's working capital needs and business activities. These business activities include the commercialization of Proclarix, and the development and commercialization of the Company's future product candidates. In addition, as discussed more fully in Note 5, if stockholder approval is not obtained by January 1, 2025 with respect to the conversion of the Series B Convertible Redeemable Preferred Stock issued in connection with the acquisition of Proteomedix, these shares become redeemable for cash at the option of the holders, and the Company currently does not have sufficient cash to redeem such shares. Based on the closing price of $0.156 for the Company's common stock as of May 17, 2024, the Series B Convertible Redeemable Preferred Stock would be redeemable for approximately $42.1 million.

Management's plans for funding the Company's operations include generating product revenue from sales of Proclarix, which may still be subject to further successful commercialization activities within certain jurisdictions. In addition, the Company has paused commercialization activities for ENTADFI and it is exploring strategic alternatives for its monetization, such as a potential sale of the ENTADFI assets. Management's plans also include attempting to secure additional required funding through equity or debt financings if available. However, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all. This creates significant uncertainty that the Company will have the funds available to be able to sustain its operations and expand commercialization of Proclarix. If the Company is unable to secure additional capital, it may be required to curtail any future clinical trials, development and/or commercialization of future product candidates, and it may take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations.

Because of historical and expected operating losses and net operating cash flow deficits, there is substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the condensed consolidated financial statements, which is not alleviated by management's plans. The condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. These condensed consolidated financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty.

Note 3 — Summary of Significant Accounting Policies

During the three months ended March 31, 2024, there were no changes to the Company's significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2023. Selected significant accounting policies are discussed in further detail below:

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. The most significant estimates in the Company's consolidated financial statements relate to accounting for acquisitions, valuation of inventory, the useful life of the amortizable intangible assets, estimates of future cash flows used to evaluate impairment of intangible assets, assumptions related to the pension benefit obligation, assumptions related to the related party subscription agreement liability, the valuation of preferred stock, and accounting for income taxes. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. As of March 31, 2024 and December 31, 2023, the Company was operating in one segment: commercial. Management's determination of its operating segments is consistent with the financial information regularly reviewed by the CODM for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods.

Note 3 — Summary of Significant Accounting Policies (cont.)

Fair Value Measurements

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. U.S. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). These tiers include:

- Level 1, defined as observable inputs such as quoted prices (unadjusted) for identical instruments in active markets;
- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement. Financial instruments, including cash, inventory, accounts receivable, accounts payable, accrued liabilities, operating lease liabilities, and notes payable are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments.

The fair value of the contingent warrant liability and the related party subscription agreement liability are valued using significant unobservable measures and other fair value inputs, and are therefore classified as Level 3 financial instruments.

The fair value of financial instruments measured on a recurring basis is as follows as of March 31, 2024, and December 31, 2023:

	As of March 31, 2024			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Contingent warrant liability	$ 2,641	—	—	$ 2,641
Subscription agreement liability – related party	$ 637,600	—	—	$ 637,600
Total	$ 640,241	$ —	$ —	$ 640,241

	As of December 31, 2023			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Contingent warrant liability	$ 2,641	—	—	$ 2,641
Subscription agreement liability – related party	$ 864,000	—	—	$ 864,000
Total	$ 866,641	$ —	$ —	$ 866,641

During the year ended December 31, 2023, in connection with the acquisition of Proteomedix, the Company recorded intangible assets, which were recognized at fair value (see Note 5). Additionally, as a result of the impairment losses recorded during the three months ended March 31, 2024 on the Company's ENTADFI asset group and goodwill recognized in connection with the Proteomedix acquisition, the related assets were recorded at fair value as of March 31, 2024 (see Note 4). None of the Company's other non-financial assets or liabilities are recorded at fair value on a non-recurring basis as of March 31, 2024 and December 31, 2023. There were no transfers between levels during the periods presented.

Note 3 — Summary of Significant Accounting Policies (cont.)

The following table summarizes the activity for the related party subscription agreement liability, using unobservable Level 3 inputs, for the three months ended March 31, 2024:

	Subscription Agreement Liability
Balance at December 31, 2023	$ 864,000
Change in fair value	(226,400)
Balance at March 31, 2024	$ 637,600

Revenue Recognition

The following is a description of principal activities from which the Company generates its revenue:

Product

The Company derives revenue through sales of its products, which includes Proclarix, its diagnostic product, directly to end users and to distributors. The Company sells its products to customers, including laboratories, hospitals, medical centers, doctors and distributors. The Company considers customer purchase orders, which in some cases are governed by master sales agreements or standard terms and conditions, to be the contracts with a customer. For each contract, the Company considers the promise to transfer products, each of which is distinct, to be the identified performance obligations. In determining the transaction price, the Company evaluates whether the price is subject to refund or adjustment to determine the net consideration to which it expects to be entitled. The Company fulfills its performance obligation applicable to product sales once the product is transferred to the customer.

Development Services

Proteomedix provides a range of services to life sciences customers referred to as "Development Services" including testing for biomarker discovery, assay design and development. These Development Services are performed under individual statement of work ("SOW") arrangements with specific deliverables defined by the customer. Development Services are generally performed on a time and materials basis. During the performance and through completion of the service to the customer in accordance with the SOW, the Company has the right to bill the customer for the agreed upon price and recognizes the Development Services revenue over the period estimated to complete the SOW. The Company generally identifies each SOW as a single performance obligation.

Completion of the service and satisfaction of the performance obligation under a SOW is typically evidenced by access to the data or test made available to the customer or any other form or applicable manner of delivery defined in the SOW. However, for certain SOWs under which work is performed pursuant to the customer's highly customized specifications, the Company has the enforceable right to bill the customer for work completed, rather than upon completion of the SOW. For those SOWs, the Company recognizes revenue over a period of time during which the work is performed based on the expended efforts (inputs). As the performance obligation under the SOW is satisfied, any amounts earned as revenue and billed to the customer are included in accounts receivable.

During the three months ended March 31, 2024, the Company recorded approximately $0.7 million of revenue generated by Proteomedix. Approximately $0.1 million of revenue was generated from Proclarix product sales and approximately $0.6 million of revenue was generated from development services.

The Company's revenue was generated from the following geographic regions during the three months ended March 31, 2024:

	European Union	Non-European Union	United States
Development services	100%	-%	-%
Product sales	-%	14%	86%

The Company had the following customer concentrations for its revenue during the three months ended March 31, 2024:

	Development services	Product sales
Customer A	100%	-%
Customer B	-%	86%

Any revenues earned but not yet billed to the customer as of the date of the condensed consolidated financial statements are recorded as contract assets and are included in prepaid expenses and other current assets in the accompanying condensed consolidated financial statements. These amounts as of March 31, 2024 and December 31, 2023 are not significant. Amounts recorded in contract assets are reclassified to accounts receivable in our condensed consolidated financial statements when the customer is invoiced according to the billing schedule in the contract. Accounts receivable was approximately $253,000 and $150,000 as of March 31, 2024 and December 31, 2023, respectively.

In relation to customer contracts, the Company incurs costs to fulfill a contract, but does not incur costs to obtain a contract. These costs to fulfill a contract do not meet the criteria for capitalization and are expensed as incurred.

New Accounting Pronouncements

There were no new accounting pronouncements issued since the Company's filing of the Annual Report on Form 10-K for the year ended December 31, 2023, which could have a significant effect on the accompanying condensed consolidated financial statements.

Note 4 — Balance Sheet Details

Inventories

Inventories primarily relate to ENTADFI product and consisted of the following as of March 31, 2024, and December 31, 2023:

	March 31, 2024	December 31, 2023
Raw materials	$ 135,198	$ 139,208
Work-in-process	256,148	194,805
Finished goods	4,966	30,039
Total	**$ 396,312**	**$ 364,052**

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of March 31, 2024, and December 31, 2023:

	March 31, 2024	December 31, 2023
Prepaid insurance	$ 796,282	$ 122,004
Prepaid regulatory fees	208,367	312,551
Prepaid research and development	89,195	89,195
Prepaid professional fees	—	70,708
Prepaid other	87,879	175,695
Total	**$ 1,181,723**	**$ 770,153**

Intangible Assets

Intangible assets, which were recorded during the year ended December 31, 2023 in connection with the ENTADFI and Proteomedix acquisitions (see Note 5), is comprised of customer relationships, product rights for developed technology, and a trade name, and consisted of the following as of March 31, 2024, and December 31, 2023:

	Balance at December 31, 2023	Impairment	Foreign Currency Translation	Balance at March 31, 2024
Gross basis:				
Trade name	$ 9,312,739	$ —	$ (625,714)	$ 8,687,025
Product rights for developed technology	14,182,157	(2,276,194)	(731,386)	11,174,577
Customer relationships	1,952,803	—	(131,207)	1,821,596
Total intangible assets, gross	**$ 25,447,699**	**$ (2,276,194)**	**$ (1,488,307)**	**$ 21,683,198**

Note 4 — Balance Sheet Details (cont.)

	Balance at December 31, 2023	Amortization	Foreign Currency Translation	Balance at March 31, 2024
Accumulated amortization:				
Product rights for developed technology	$ (31,213)	$ (170,929)	$ 7,430	$ (194,712)
Customer relationships	(5,599)	(30,664)	1,332	(34,931)
Total intangible assets, accumulated amortization	**$ (36,812)**	**$ (201,593)**	**$ 8,762**	**$ (229,643)**
Intangible assets, net	**$ 25,410,887**			**$ 21,453,555**

The finite lived intangible assets held by the Company, which includes customer relationships and product rights for developed technology, are being amortized over their estimated useful lives, which is 15 years for customer relationships, and 15 and 6 years for product rights for developed technology related to Proclarix and ENTADFI, respectively. Amortization expense related to intangible assets was approximately $202,000 for the three months ended March 31, 2024, of which approximately $171,000 and $31,000 was recorded as cost of revenue and selling, general, and administrative expenses, respectively, in the accompanying condensed consolidated statements of operations and comprehensive loss.

During the year ended December 31, 2023, the Company determined that there were certain triggering events that indicated that the carrying amount of the assets recorded in connection with the ENTADFI acquisition (see Note 5) were not fully recoverable and recorded an impairment charge of $14.7 million during the year ended December 31, 2023.

During the three months ended March 31, 2024, the Company became aware of a new competitor that received approval by the FDA for a combined finasteride-tadalafil capsule, which is a direct competitor product to ENTADFI. This was determined to be a triggering event that could result in a decrease in future expected cash flows, and thus indicated the carrying amount of the ENTADFI asset group may not be fully recoverable. The Company performed an undiscounted cash flow analysis over the ENTADFI asset group and determined that the carrying value of the asset group is not recoverable. The Company then estimated the fair value of the asset group to measure the impairment loss for the period. Significant assumptions used to determine this non-recurring fair value measurement included projected sales driven by market share and product sales price estimates, associated expenses, growth rates, the discount rate used to measure the fair value of the net cash flows associated with this asset group, as well as Management's estimates of an expected sales price for the asset group, and the probability of each potential strategic alternative taking place.

The Company recorded an impairment charge of $2.3 million during the three months ended March 31, 2024, which was allocated on a pro rata basis across the assets within the asset group as follows: approximately $2.3 million and less than $18,000 was allocated to the product rights intangible asset and other assets, respectively. After recording the impairment charges, the long-lived assets in the ENTADFI asset group have a remaining carrying amount of approximately $1.0 million and $3.3 million as of March 31, 2024 and December 31, 2023, respectively.

Future annual amortization expense related to the Company's finite lived intangible assets is as follows as of March 31, 2024:

Years ending December 31,	
2024	$ 598,786
2025	968,457
2026	968,457
2027	968,457
2028	968,457
Thereafter	8,293,916
Total	**$ 12,766,530**

Note 4 — Balance Sheet Details (cont.)

As of March 31, 2024, the weighted-average remaining amortization period for intangible assets was approximately 14.07 years.

Trade names, which do not have legal, regulatory, contractual, competitive, economic, or other factors that limit the useful lives are considered indefinite lived assets and are not amortized but are tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. The Company tested its trade name for impairment as of March 31, 2024, as a result of certain triggering events discussed below. The Company determined that there was no impairment of its trade name as of March 31, 2024. As of March 31, 2024 and December 31, 2023, $8.7 million and $9.3 million, respectively, of intangible assets relate to a trade name that has been identified as having an indefinite life.

Goodwill

Goodwill was recorded during the year ended December 31, 2023, in connection with the Proteomedix acquisition (see Note 5), and was assigned solely to the Proteomedix reporting unit. During the three months ended March 31, 2024, the Company's stock price and market capitalization declined, and the Company determined that this was an indicator of a potential impairment of its goodwill, and accordingly, as of March 31, 2024, the Company performed a quantitative analysis to identify and measure the amount of impairment loss to be recognized, if any. To perform its quantitative test, the Company compared the fair value of the reporting unit to its carrying value, and determined that the fair value of the reporting unit was less than its carrying value. The Company measured the amount of the impairment charge as the excess of the carrying value over the fair value of the reporting unit, and recorded a corresponding impairment charge to its goodwill of approximately $5.2 million during the three months ended March 31, 2024. The fair value estimate of the Proteomedix reporting unit was derived from a combination of an income approach and a market approach, and a reconciliation to the Company's market capitalization. Under the income approach, the Company estimated the fair value of the reporting unit based on the present value of estimated future cash flows, which the Company considers to be a Level 3 unobservable input in the fair value hierarchy. The Company prepared cash flow projections based on management's estimates of future revenue and operating costs, taking into consideration the historical performance and the current macroeconomic, industry, and market conditions. The Company based the discount rate on the weighted-average cost of capital considering Company-specific characteristics and changes in the reporting unit's projected cash flows. Under the market approach, the Company estimated the fair value of the reporting unit based on revenue market multiples derived from comparable companies with similar characteristics as the reporting unit, as well as an estimated control premium.

Goodwill consisted of the following as of March 31, 2024 and December 31, 2023:

Balance as of December 31, 2023	$ 55,676,142
Impairment loss	(5,192,000)
Foreign currency translation	(3,740,823)
Balance as of March 31, 2024	**$ 46,743,319**

Accrued Expenses

Accrued expenses consisted of the following as of March 31, 2024, and December 31, 2023:

	March 31, 2024	December 31, 2023
Accrued compensation	$ 568,559	$ 487,579
Accrued research and development	463,506	616,707
Accrued professional fees	445,569	550,415
Other accrued expenses	264,593	265,849
Accrued implementation fees	93,787	93,787
Accrued franchise taxes	50,000	60,530
Accrued interest – related party	50,000	—
Accrued deferred offering costs	—	125,000
Total	**$ 1,936,014**	**$ 2,199,867**

Note 5 — Acquisitions

ENTADFI

On April 19, 2023, the Company and Veru, Inc. ("Veru") entered into an Asset Purchase Agreement (the "Veru APA"). Pursuant to, and subject to the terms and conditions of, the Veru APA, the Company purchased substantially all of the assets related to Veru's ENTADFI product ("ENTADFI") (the "Transaction") for a total possible consideration of $100 million.

In accordance with the Veru APA, the Company agreed to provide Veru with initial consideration totaling $20.0 million, consisting of (i) $6.0 million paid upon the closing of the Transaction on April 19, 2023, (ii) an additional $4.0 million in the form of a non-interest bearing note payable due on September 30, 2023, and (iii) an additional $10.0 million in the form of two $5.0 million non-interest bearing notes payable, each due on April 19, 2024 and September 30, 2024.

Additionally, the terms of the Veru APA require the Company to pay Veru up to an additional $80.0 million based on the Company's net sales of ENTADFI after closing (the "Milestone Payments"). The Milestone Payments are payable as follows: (i) $10.0 million is payable upon the first time the Company achieves net sales from ENTADFI of $100.0 million during a calendar year, (ii) $20.0 million is payable upon the first time the Company achieves net sales from ENTADFI of $200.0 million during a calendar year, and (3) $50.0 million is payable upon the first time the Company achieves net sales from ENTADFI of $500.0 million during a calendar year.

In connection with the Transaction, the Company also assumed royalty and milestone obligations under an asset purchase agreement for tadalafil-finasteride combination entered into by Veru and Camargo Pharmaceutical Services, LLC on December 11, 2017 (the "Camargo Obligations"). The Camargo Obligations assumed by the Company include a 6% royalty on all sales of tadalafil-finasteride and sales milestone payments of up to $22.5 million, payable to Camargo as follows: (i) $5.0 million is payable upon the first time the Company achieves net sales from ENTADFI of $100.0 million during a calendar year, (ii) $7.5 million is payable upon the first time the Company achieves net sales from ENTADFI of $200.0 million during a calendar year, and (3) $10.0 million is payable upon the first time the Company achieves net sales from ENTADFI of $300.0 million during a calendar year.

On September 29, 2023, the Company entered into an amendment to the Veru APA (the "Veru APA Amendment"), which provides that the $4.0 million note payable originally due on September 30, 2023 was deemed paid and fully satisfied upon (1) the payment to the Seller of $1.0 million in cash on September 29, 2023, and (2) the issuance to the Seller of 3,000 shares of Series A Convertible Preferred Stock (the "Series A Preferred Stock") of the Company (see Note 9). Pursuant to the Veru APA Amendment, the Series A Preferred Stock will convert to common stock of the Company one year from the date of issuance if the required stockholder approval is obtained. The Series A Preferred Stock, which was issued to the Seller on October 3, 2023 is initially convertible, in the aggregate, into 5,709,935 shares of the Company's common stock, subject to adjustment and certain stockholder approval limitations specified in the Certificate of Designations. Pursuant to the Veru APA Amendment, the Company agreed to use commercially reasonable efforts to obtain such stockholder approval by December 31, 2023, however, such shareholder approval has not yet been obtained. The Company also agreed to include the shares of common stock issuable upon conversion of the Series A Preferred Stock in the next resale registration statement filed with the SEC.

Subsequent to March 31, 2024, the Company entered into a Forbearance Agreement with Veru, specifically related to the note payable that was due on April 19, 2024 (see Note 15).

Also, in connection with the Transaction, and pursuant to the Veru APA, the Company entered into non-competition and non-solicitation agreements (the "Non-Competition Agreements") with two of Veru's key stockholders and employees (the "Restricted Parties"). The Non-Competition Agreements generally prohibit the Restricted Parties from either directly or indirectly engaging in the Restricted Business (as such term is defined in the Veru APA) for a period of five years from the closing of the Transaction.

The acquisition of ENTADFI has been accounted for as an asset acquisition in accordance with ASC 805-50 because substantially all of the fair value of the assets acquired is concentrated in a single asset, the ENTADFI product rights. The ENTADFI products rights consist of trademarks, regulatory approvals, and other records, and are considered a single asset as they are inextricably linked.

Note 5 — Acquisitions (cont.)

The following table summarizes the aggregate consideration transferred for the assets acquired by the Company in connection with the Veru APA:

	Consideration Transferred
Consideration transferred at closing	$ 6,000,000
Fair value of notes payable issued	12,947,000
Transaction costs	79,771
Total consideration transferred	**$ 19,026,771**

The fair value of the non-interest bearing notes payable was estimated using a net present value model using discount rates averaging 8.2%. The resulting fair value is being accreted to the face value of the notes, through the respective maturity dates. Management evaluated the Milestone Payments and determined that at the close of the Transaction, they are not considered probable, and as such, the Company did not recognize any amount related to the Milestone Payments in the consideration transferred.

Management evaluated the Camargo Obligations and determined that at the close of the Transaction, the related sales milestone payments are not considered probable, and as such, the Company did not recognize any related liability at the date of the Transaction. In addition, royalties under the Camargo Obligations will be recorded as cost of sales, as the related sales are generated and recognized.

The following table summarizes the assets acquired with the Veru APA:

	Assets Recognized
Inventory	$ 1,120,000
ENTADFI Intangible	17,906,771
Total fair value of identifiable assets acquired	**$ 19,026,771**

In accordance with ASC 805-50, the acquired inventory was recorded at fair value. The remaining consideration transferred was allocated to the ENTADFI intangible asset, which will be amortized over its estimated useful life, starting when ENTADFI sales begin. Acquired inventory is comprised of work-in-process and raw materials. The fair value of work-in-process inventory was determined based on an estimated sales price of the finished goods, adjusted for costs to complete the manufacturing process, costs of the selling effort, a reasonable profit allowance for the remaining manufacturing and selling effort, and an estimate of holding costs, and resulted in a fair value adjustment of approximately $0.3 million. The fair value of raw materials was determined to approximate replacement cost.

The Company recorded an impairment charge on the ENTADFI asset group of approximately $2.3 million during the three months ended March 31, 2024 (see Note 4). In addition, during the fourth quarter of 2023, the Company recorded an impairment charge of approximately $14.7 million on the ENTADFI asset group, as well as an impairment charge on the ENTADFI acquired inventory of approximately $1.2 million, which included impairment of 100% of the acquired work-in-process inventory.

Note 5 — Acquisitions (cont.)

WraSer:

On June 13, 2023 (the "Execution Date"), the Company entered into an asset purchase agreement with WraSer, LLC, and affiliates (the "WraSer Seller") (the "WraSer APA"). Pursuant to, and subject to the terms and conditions of, the WraSer APA, on the WraSer Closing Date (as defined below) the Company was to purchase six FDA-approved pharmaceutical assets across several indications, including cardiology, otic infections, and pain management (the "WraSer Assets").

Under the terms of the WraSer APA, the Company was to purchase the WraSer Assets for (i) $3.5 million in cash at signing of the WraSer APA; (ii) $4.5 million in cash on the later of (x) 90 days after the signing of the WraSer APA or (y) the date that all closing conditions under the WraSer APA are met or otherwise waived (the "WraSer Closing Date"); (iii) 1.0 million shares of the Company's common stock (the "Closing Shares") issuable on the WraSer Closing Date, and (iv) $500,000 in cash one year from the WraSer Closing Date.

In conjunction with the WraSer APA, the Company and the WraSer Seller entered into a Management Services Agreement (the "MSA") on the Execution Date. Pursuant to the terms of the MSA, the Company would act as the manager of the WraSer Seller's business during the period between the Execution Date and the WraSer Closing Date. During this period, the Company would make advances to WraSer, if needed. If, on the WraSer Closing Date, the WraSer Seller's cash balance is in excess of the target amount ("Cash Target") specified in the MSA, the Company would apply that excess to the $4.5 million cash payment due upon closing. Conversely, if there is a shortfall, the Company would be required to remit the difference to the WraSer Seller over time.

The WraSer APA could be terminated prior to the closing upon agreement with all parties or upon breach of contract of either party, uncured within 20 days of notice. If the WraSer APA was terminated upon agreement with all parties or upon uncured breach of contract by the Company, the initial $3.5 million payment would be retained by the WraSer Seller. If it was determined that there is an uncured breach of contract by the WraSer Seller, and the WraSer APA was terminated, the Company would have an unsecured claim against WraSer for the $3.5 million payment made by the Company upon execution of the WraSer APA. The closing of the transaction was subject to certain customary closing conditions, including submission of the FDA transfer documentation to transfer ownership of the acquired product regulatory approvals to the Company.

Management evaluated the terms of the WraSer APA and the WraSer MSA, and determined that, at the Execution Date, control under the provisions of ASC 805, *Business Combinations* ("ASC 805"), did not transfer to the Company; if the transaction closes, control will transfer then, and the acquisition date will be the closing date. Management further evaluated the requirements pursuant to ASC 810, *Consolidations*, and determined based on the terms of the MSA, and the Company's involvement in the WraSer Seller's business, that the WraSer Seller is a variable interest entity ("VIE") to the Company. Management determined that the Company is not the primary beneficiary of the VIE as the WraSer APA and MSA do not provide the Company with the power to direct the activities of the VIE that most significantly impact the VIE's economic performance. While the Company was involved in the day-to-day business activities of the VIE until WraSer filed for relief under Chapter 11 of the U.S. Bankruptcy Court (see below), the WraSer Seller had to approve substantially all business activities and transactions that significantly impact the economic performance of WraSer during the term of the MSA. Additionally, the Company is not required to absorb the losses of WraSer if the WraSer APA does not close. As such, the Company was not required to consolidate WraSer in the Company's financial statements as of March 31, 2024 and December 31, 2023.

The Company recorded the initial $3.5 million payment as a deposit. The Company does not have any liabilities recorded as of March 31, 2024 and December 31, 2023 associated with its variable interest in the WraSer Seller, and its exposure to the WraSer Seller's losses is limited to no more than the shortfall, if any, of the Cash Target amount of approximately $1.1 million compared to the WraSer Seller's cash balance on the WraSer Closing Date.

Note 5 — Acquisitions (cont.)

On September 26, 2023, WraSer and its affiliates filed for relief under chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court. On October 4, 2023, the parties agreed to amend the WraSer APA, which was subject to court approval. Shortly after its bankruptcy filing, WraSer filed a motion seeking approval of the WraSer APA as amended. The amendment, among other things, eliminates the $500,000 post-closing payment due June 13, 2024 and staggers the $4.5 million cash payment that the Company would otherwise have to pay at closing to: (i) $2.2 million to be paid at closing, (ii) $2.3 million, to be paid in monthly installments of $150,000 commencing January 2024 and (iii) 789 shares of Series A Preferred Stock to be paid at closing. The amendment also reduced the number of products the Company was acquiring by excluding pain medications and including only (i) Ciprofloxacin 0.3% and Fluocinolone 0.025% Otic Solution, under the trademark OTOVEL and its Authorized Generic Version approved under US FDA NDA No. 208251, (ii) Ciprofloxacin 0.2% Otic solution, under the trademark CETRAXAL, and (iii) Vorapaxar Sulfate tablets under the trademark Zontivity approved under US FDA NDA N204886.

In October 2023, WraSer alerted the Company that its sole manufacturer for the active pharmaceutical ingredient ("API") for Zontivity, the key driver for the WraSer acquisition, would no longer manufacture the API for Zontivity. The Company believes that this development constituted a Material Adverse Effect under the WraSer APA and the WraSer MSA, enabling the Company to terminate the WraSer APA and the WraSer MSA. On October 20, 2023, the Company filed a motion for relief from the automatic stay in the Bankruptcy Court so that the Company can exercise the termination rights under the WraSer APA, as amended. On December 18, 2023, the Bankruptcy Court entered into an Agreed Order lifting the automatic stay to enable the Company to exercise its rights to terminate the WraSer APA and the WraSer MSA. On December 21, 2023, the Company filed a Notice with the Bankruptcy Court terminating the WraSer APA and the WraSer MSA. WraSer has advised the Company that it does not believe that a Material Adverse Effect occurred. In addition, WraSer recently filed a plan of reorganization that indicates it may seek damages from the Company due to the termination of the APA and MSA. Due to the WraSer bankruptcy filing and the Company's status as an unsecured creditor of WraSer, it is unlikely that the Company will recover the $3.5 million initial payment made, or any costs and resources in connection with services provided by the Company under the WraSer MSA, and therefore the Company recorded a loss on impairment for the $3.5 million deposit during the year ended December 31, 2023.

Proteomedix

On December 15, 2023 (the "Acquisition Date"), Onconetix entered into a Share Exchange Agreement (the "Share Exchange Agreement") with Proteomedix and each of the holders of outstanding capital stock or Proteomedix convertible securities (other than Proteomedix stock options) (collectively the "Sellers"), pursuant to which the Company acquired 100% of the outstanding common shares and voting interest of Proteomedix, through the issuance of 3,675,414 shares of common stock and 2,696,729 shares of Series B Convertible Preferred Stock (the "PMX Transaction").

Subject to any requirements related to the Committee on Foreign Investment in the United States, upon approval by the requisite vote of stockholders of Onconetix at the Special Meeting of the Stockholders ("Stockholder Approval"), each share of Series B Convertible Redeemable Preferred Stock ("Series B Preferred Stock") shall automatically convert into 100 shares of common stock in accordance with the terms of the Series B Certificate of Designation (the "Conversion"). If Stockholder Approval is not obtained by January 1, 2025, Onconetix may, at the option of the holders, be obligated to cash settle the Series B Preferred Stock. The Series B Preferred Stock outstanding as a result of the PMX Transaction is convertible into 269,672,900 shares of common stock.

Note 5 — Acquisitions (cont.)

The consummation (the "Closing") of the PMX Transaction was subject to customary closing conditions and the agreement to enter into a subscription agreement (see Note 8) with Altos Ventures, a shareholder of Proteomedix, prior to the closing of the PMX Transaction (the "PMX Investor").

In addition, each option to purchase shares of Proteomedix (each, a "Proteomedix Stock Option") outstanding immediately before the Closing, whether vested or unvested, remains outstanding until the Conversion unless otherwise terminated in accordance with its terms. At the Conversion, each outstanding Proteomedix Stock Option, whether vested or unvested, shall be assumed by Onconetix and converted into the right to receive (a) an option to acquire shares of common stock (each, an "Assumed Option") or (b) such other derivative security as Onconetix and Proteomedix may agree, subject in either case to substantially the same terms and conditions as were applicable to such Proteomedix Stock Option immediately before the Closing. Each Assumed Option shall: (i) represent the right to acquire a number of shares of common stock equal to the product of (A) the number of Proteomedix common shares that were subject to the corresponding Proteomedix Option immediately prior to the Closing, multiplied by (B) the Exchange Ratio (as defined in the Share Exchange Agreement"); and (ii) have an exercise price (as rounded down to the nearest whole cent) equal to the quotient of (A) the exercise price of the corresponding Proteomedix Option, divided by (B) the Exchange Ratio.

Management determined that the PMX Transaction was a business combination as defined within ASC 805, and that Onconetix was the accounting acquirer. The Company determined that Onconetix was the accounting acquirer based on the guidance contained within ASC 805-10. The significant factors that led to the Company's conclusion were (i) the Company obtained 100% of the outstanding common stock and voting interest of PMX, (ii) at closing of the PMX Transaction, the PMX shareholders were issued approximately 17% of Onconetix's outstanding common stock and none of the former PMX shareholders held more than 5% of Onconetix's common stock individually, (iii) the composition of executive management and the governing body did not change sufficiently to give PMX or its former shareholders control over these functions within Onconetix, and (iv) Onconetix was significantly larger when considering both total assets and operations. As a result, the Company has applied purchase accounting as of the Closing of the PMX Transaction. The assets, liabilities, and non-controlling interest of Proteomedix were recognized at fair value as of the Closing and the results of its operations have been included within Onconetix's condensed consolidated statements of operations and comprehensive loss from that date forward.

Proteomedix is a healthcare company whose mission is to transform prostate cancer diagnosis. Proteomedix has identified novel biomarker signatures with utility in prostate cancer diagnosis, prognosis and therapy management. The Company expects Proteomedix's diagnostic expertise to complement its existing prostate related treatment portfolio.

The assets acquired and liabilities assumed are recognized provisionally in the accompanying condensed consolidated balance sheets at their estimated fair values as of the acquisition date. The initial accounting for the business combination is not complete as the Company is in the process of obtaining additional information for the valuation of acquired intangible assets and deferred tax liabilities. The provisional amounts are subject to change to the extent that additional information is obtained about the facts and circumstances that existed as of the acquisition date. Under U.S. GAAP, the measurement period shall not exceed one year from the acquisition date and the Company will finalize these amounts no later than December 15, 2024. The estimated fair values as of the acquisition date are based on information that existed as of the acquisition date. During the measurement period the Company may adjust provisional amounts recorded for assets acquired and liabilities assumed to reflect new information that the Company has subsequently obtained regarding facts and circumstances that existed as of the acquisition date.

Note 5 — Acquisitions (cont.)

The acquisition-date fair value of the consideration transferred totaled approximately $65.1 million, which consisted of the following:

	Consideration Transferred
Common stock	$ 875,484
Series B Preferred Stock	64,236,085
Total consideration transferred	**$ 65,111,569**

The fair value of the Company's common shares issued as consideration was based on the closing price of the Company's common stock as of the Acquisition Date. The fair value of the Series B Preferred Stock issued as consideration was based on the underlying fair value of the number of common shares that the Series B Preferred Stock converts into, also based on the closing price of the Company's common stock as of the Acquisition Date.

The fair value of the Proteomedix stock options assumed as part of the PMX Transaction was determined using a Black-Scholes option pricing model with the following significant assumptions:

Exercise price	$1.15 – 28.83
Stock price	$128.11
Term (years)	0.17 – 3.59
Expected stock price volatility	90%
Risk-free rate of interest	4.07% – 5.47%

The following table summarizes the preliminary estimated fair values of the assets acquired and liabilities assumed at the acquisition date:

	Net Assets Recognized
Cash	$ 1,056,578
Accounts receivable	87,445
Inventories	80,593
Prepaid expenses and other current assets	114,615
Right of use asset	149,831
Property and equipment, net	39,779
Trade name	9,018,000
Customer relationships	1,891,000
Product rights for developed technology	10,541,000
Goodwill	53,914,055
Total assets acquired	76,892,896
Accounts payable	(234,029)
Accrued expenses	(732,814)
Operating lease liability	(149,831)
Deferred tax liability	(2,994,669)
Pension benefit obligation	(548,384)
Note payable	(115,096)
Total liabilities assumed	(4,774,823)
Net assets	72,118,073
Less non-controlling interest	(7,006,504)
Net assets acquired	**$ 65,111,569**

Note 5 — Acquisitions (cont.)

The goodwill recognized as a result of the PMX Transaction is attributable primarily to expected synergies and the assembled workforce of Proteomedix. None of the goodwill is expected to be deductible for income tax purposes.

The fair values of the acquired tangible and intangible assets were determined using variations of the cost, income approach using the excess earnings, lost profits and relief from royalty methods. The income approach valuation methodology used for the intangible assets acquired in the PMX Transaction makes use of Level 3 inputs.

The trade name intangible asset represents the value of the Proclarix™ brand name and was valued using a relief from royalty method under an income approach. A royalty rate of 6% was utilized in determining the fair value of this intangible asset. The fair value of this asset was determined based on a cash flow model using forecasted revenues and expenses specifically tied to Proclarix™. Those cash flows were then discounted at 10% determined by the use of a weighted average return on assets analysis. The life of this intangible asset was determined to be indefinite as the branded name will persist beyond the life of the product rights and customer relationships.

The customer relationship intangible assets represent the value of the existing customer contract with Labcorp (see Note 6) and was valued using the lost profits method under the income approach. The fair value of this asset was determined based on a cash flow model using forecasted revenues specifically tied to Proteomedix's Labcorp contract. Those cash flows were then discounted at 10% determined by the use of a weighted average return on assets analysis. The estimated useful life of this asset was determined by reference to the estimated life of the product rights associated with the Labcorp contract.

The product rights for developed technology acquired in the PMX Transaction represents know-how and patented intellectual property held by PMX pertaining to its commercial-ready prostate cancer diagnostic system, Proclarix™. The fair value of this asset was determined based on a cash flow model based on forecasted revenues and expenses specifically tied to Proclarix™. Those cash flows were then discounted at 8% for the period prior to patent expiration and 16% for the period thereafter. The discount rates were determined by the use of a weighted average return on assets analysis. The estimated useful life of the product rights was determined based on the underlying patent's remaining life.

The fair value of the non-controlling interest in Proteomedix is estimated to be $7.0 million and represents the fair value of the vested Proteomedix stock options outstanding as of the Acquisition Date. The fair value of the non-controlling interest was valued using the methodology applicable to the Proteomedix stock options disclosed above. As Proteomedix was a private company as of the Acquisition Date, the fair value measurement is based on significant inputs that are not observable in the market and thus represents a Level 3 measurement as defined in ASC 820, *Fair Value Measurement*.

The Company recognized approximately $1.5 million of acquisition related costs that were expensed during 2023, including the fair value of the related party subscription agreement liability, which was a closing condition for the PMX Transaction (see Note 8).

The following summary, prepared on a pro forma basis, presents the Company's unaudited consolidated results of operations for the three months ended March 31, 2023, as if the PMX Transaction had been completed as of January 1, 2023. The pro forma results below include the impact of amortization of intangible assets. This pro forma information is presented for illustrative purposes only, is not necessarily indicative of future results of operations and does not include any impact of transaction synergies. In addition, the pro forma results are not necessarily indicative of the results of operations that actually would have been achieved had the PMX Transaction been consummated as of that date:

	Unaudited For the Three Months Ended March 31, 2023
Revenue	$ 1,011,714
Net loss	2,576,001

Note 6 — Significant Agreements

Services Agreement

On July 21, 2023, the Company, entered into a Licensing and Services Master Agreement ("Master Services Agreement") and a related statement of work with a vendor, pursuant to which the vendor was to provide to the Company commercialization services for the Company's products, including recruiting, managing, supervising and evaluating sales personnel and providing sales-related services for such products, for fees totaling up to $29.1 million over the term of the statement of work. The statement of work had a term through September 6, 2026, unless earlier terminated in accordance with the Master Services Agreement and the statement of work. On July 29, 2023, a second statement of work was entered into with the same vendor for certain subscription services providing prescription market data access to the Company. The fees under the second statement of work totaled approximately $800,000, and the term was through July 14, 2025. On October 12, 2023, the Company terminated the Master Services Agreement and the statements of work. The Company had approximately $1.5 million and $1.8 million recorded in related accounts payable as of March 31, 2024 and December 31, 2023, respectively, which includes amounts due for early termination of the contract.

Laboratory Corporation of America

On March 23, 2023, Proteomedix entered into a license agreement Laboratory Corporation of America ("Labcorp") pursuant to which Labcorp has the exclusive right to develop and commercialize Proclarix, and other products developed by Labcorp using Proteomedix's intellectual property covered by the license, in the United States ("Licensed Products"). In consideration for granting Labcorp an exclusive license, Proteomedix received an initial license fee in the mid-six figures upon signing of the contract. Additionally, Proteomedix is entitled to royalty payments of between 5% and 10% on the net sales recognized by Labcorp of any Licensed Products plus milestone payments as follows:

- After the first sale of Proclarix as a laboratory developed test, Labcorp will pay an amount in the mid-six figures,
- after Labcorp achieves a certain amount in the low seven figures in net sales of Licensed Products, Labcorp will pay Proteomedix an amount in the low seven figures,
- after a certain amount in the mid-seven figures in net sales of Licensed Products, Labcorp will pay Proteomedix an amount in the low seven figures.

The total available milestone payments available under the terms of this contract is $2.5 million of which $0.5 million has been paid to Proteomedix.

Labcorp is wholly responsible for the cost, if any, of research, development and commercialization of Licensed Products in the United States but has the right to offset a portion of those costs against future royalty and milestone payments. Additionally, Labcorp may deduct royalties or other payments made to third parties related to the manufacture or sale of Licensed Products up to a maximum amount of any royalty payments due to Proteomedix.

The license agreement and related royalty payment provisions expire during 2038, which approximates the expiration of the last patent covered by the license agreement. Labcorp has the right to terminate the license agreement for any reason by providing 90 days written notice to Proteomedix. Either party may terminate the license agreement due to a material breach of the terms of the license agreement with 30 days' notice, provided such breach is not cured within the foregoing 30 day period. Finally, Proteomedix may terminate the license agreement with 60 days' notice in the event Labcorp fails to make any undisputed payment due, provided that Labcorp does not remit the payment within the foregoing 60 day period.

As of March 31, 2024, the sale of Licensed Products by Labcorp under the license agreement has not commenced. The Company has sold product to Labcorp for their use in internal trials of the test.

Notes 7 — Notes Payable

Veru Notes Payable

In connection with the Veru APA (see Note 5), the Company executed three non-interest bearing notes payable (the "Notes") in the principal amounts of $4.0 million, $5.0 million and $5.0 million with initial maturity dates of September 30, 2023, April 19, 2024, and September 30, 2024, respectively. In accordance with the Notes, no principal payments are due until maturity; however, the Company may voluntarily prepay the Notes with no penalty. Additionally, in an Event of Default, as defined in the Notes, the unpaid principal amount of the Notes will accrue interest at a rate of 10.0% per annum.

The Company imputed interest on the Notes using an average discount rate of 8.2% and recorded a debt discount of approximately $1.1 million at the issuance date. The debt discount is reflected as a reduction in the carrying amount of the Notes and amortized to interest expense through the respective maturity dates, using the effective interest method. The Company recorded approximately $0.4 million of associated interest expense during the three months ended March 31, 2024. The unamortized debt discount as of March 31, 2024 was approximately $0.2 million.

On September 29, 2023, the Company and the note holder entered into an amendment to the Veru APA, which provided that the $4.0 million note payable originally due on September 30, 2023 was deemed paid and fully satisfied upon (1) the payment to the Seller of $1.0 million in cash on September 29, 2023, and (2) the issuance to the Seller by October 3, 2023 of 3,000 shares of Series A Preferred Stock of the Company (see Note 5). In connection with the Veru APA Amendment, the Company recorded an extinguishment loss on the note payable of approximately $490,000 during the year ended December 31, 2023, which represented the difference between the fair value of the Series A Preferred Stock that was issued to settle the debt and the carrying value of the note payable as of September 29, 2023.

Future minimum principal payments on the Notes as of March 31, 2024, includes $10 million in principal payments that were due in 2024. Subsequent to March 31, 2024, the Company entered into a Forbearance Agreement related to the $5.0 million note payable that was due on April 19, 2024, which, among other things, now allows for the Company to repay the principal amount of the note by March 31, 2025 (see Note 15).

Related Party Debenture

On January 23, 2024, the Company issued a non-convertible debenture (the "Debenture") to the PMX Investor, a related party, in the principal sum of $5.0 million, in connection with the Subscription Agreement discussed in Note 8. The Debenture has an interest rate of 4.0% per annum, and the principal and accrued interest was originally payable in full upon the earlier of (i) the closing under the Subscription Agreement and (ii) June 30, 2024. The due date of the related party debenture was extended to October 31, 2024 (see Note 15). Additionally, the $5.0 million subscription amount under the Subscription Agreement shall be increased by the amount of interest payable under the Debenture.

In connection with the issuance of the Debenture, the Company incurred approximately $0.4 million in financing fees, which is recorded as a debt discount, and reflected as a reduction in the carrying amount of the Debenture. The debt discount is amortized to interest expense through the maturity date. The Company recorded approximately $0.2 million of interest expense on the Debenture during the three months ended March 31, 2024 which includes accrued interest and amortization of the debt discount. The unamortized debt discount as of March 31, 2024 was approximately $0.2 million.

As of March 31, 2024, the Company has recorded accrued interest of $50,000 on the Debenture, which is included in accrued expenses in the accompanying condensed consolidated balance sheets.

Notes 7 — Notes Payable (cont.)

Insurance Financing

During the three months ended March 31, 2024, the Company obtained financing for certain Director & Officer liability insurance policy premiums. The agreement assigns the lender a first priority lien on and security interest in the financed policies and any additional premium required in the financed policies.

The total premiums, taxes and fees financed are approximately $0.7 million, with an annual interest rate of 7.79%. In consideration of the premium payment by the lender to the insurance companies or the agent or broker, the Company unconditionally promised to pay the lender the amount financed plus interest and other charges permitted under the agreement. At March 31, 2024, the Company recognized approximately $0.6 million as an insurance financing note payable, which is included in the current portion of notes payable in the accompanying condensed consolidated balance sheets. The Company will pay the insurance financing through monthly installment payments of approximately $78,000, with the last payment for the note due on November 17, 2024.

PMX Note Payable

The Company also assumed an obligation in the amount of 100,000 CHF, in connection with the Proteomedix acquisition. This obligation relates to a loan from an investor that was advanced to Proteomedix in March 2010. This loan bears no interest, is unsecured and may be cancelled by the Company at its discretion, however it is the intent of the Company to repay this loan in the future. The loan payable, in the amount of approximately $111,000, is included in the long term note payable in the accompanying condensed consolidated balance sheets as of March 31, 2024.

Note 8 — Subscription Agreement

On December 18, 2023, the Company entered into a subscription agreement (the "Subscription Agreement") with the PMX Investor, who became a stockholder of Onconetix at the closing of the PMX Transaction (see Notes 5 and 11), for the sale of 20 million units, each comprised of 1 share of common stock and 0.30 pre-funded warrants (the "Units") at $0.25 per Unit. The Subscription Agreement includes a make-whole provision which requires the issuance of additional shares of common stock in the event that the 270-day volume weighted average price after the closing of the Subscription Agreement, is below $0.25. The Subscription Agreement will only close upon obtaining Stockholder Approval for certain transactions involving the Company's Series B Preferred Stock, as further described in Note 5.

The Subscription Agreement is accounted for as a liability in accordance with ASC 480, *Distinguishing Liabilities from Equity*, ("ASC 480"), as the make-whole provision could result in a variable number of shares being issued upon settlement. The related party subscription agreement liability is measured at fair value at the commitment date and at each subsequent reporting period, with changes in fair value recorded as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. As of March 31, 2024 and December 31, 2023, the fair value of the related party subscription agreement liability is estimated to be approximately $638,000 and $864,000, respectively, and the change in fair value of the related party subscription agreement liability for the three months ended March 31, 2024 was a decrease of approximately $226,000. The fair value was determined using a Monte-Carlo option pricing model, and as of March 31, 2024 and December 31, 2023, the Company estimated a 35% and a 55.0% probability, respectively, that the Subscription Agreement will close. The significant assumptions used in the Monte-Carlo model, which utilizes Level 3 inputs (see Note 3), are as follows as of March 31, 2024 and December 31, 2023:

	March 31, 2024	December 31, 2023
Exercise price	$ 0.25	$ 0.25
Term (years)	1.12	1.2
Expected stock price volatility	95%	95%
Risk-free rate of interest	4.95%	4.64%

Note 9 — Convertible Redeemable Preferred Stock and Stockholders' Equity

Authorized Capital

As of March 31, 2024 and December 31, 2023, the Company is authorized to issue 250,000,000 shares and 10,000,000 shares of common stock and preferred stock, respectively, with a par value of $0.00001 for both common stock and preferred stock. As of March 31, 2024 and December 31, 2023, the Company had designated and authorized the issuance of up to 1,150,000 shares, 10,000 shares, and 2,700,000 shares of Series Seed Preferred Stock, Series A Preferred Stock, and Series B Preferred Stock, respectively.

Preferred Stock

Series Seed Convertible Preferred Stock

The Company has 1,150,000 shares of preferred stock designated as Series Seed Preferred Stock ("Series Seed") and there are no shares of Series Seed outstanding as of March 31, 2024 and December 31, 2023.

Series A Convertible Preferred Stock

On September 29, 2023, the Company filed a Certificate of Designations of Rights and Preferences of Series A Preferred Stock of the Company (the "Series A Certificate of Designations") with the State of Delaware to designate and authorize the issuance of up to 10,000 shares of Series A Preferred Stock.

On October 3, 2023, the Company issued 3,000 shares of Series A Convertible Preferred Stock in exchange for the settlement of $3.0 million in notes payable due to Veru, Inc. (see Notes 5 and 7). The maximum number of shares that the Series A Preferred Stock is convertible into, based on the Conversion Price as of March 31, 2024, is approximately 5,709,935 shares of the Company's common stock. There are 3,000 shares of Series A Convertible Stock outstanding as of March 31, 2024 and December 31, 2023.

Series B Convertible Preferred Stock

On December 15, 2023, the Company filed a Certificate of Designations of Rights and Preferences of Series B Convertible Preferred Stock of the Company (the "Series B Certificate of Designations") with the State of Delaware to designate and authorize the issuance of up to 2,700,000 shares of Series B Preferred Stock.

On December 15, 2023, in connection with the PMX Transaction, as part of the purchase consideration, the Company issued 2,696,729 shares of Series B Convertible Preferred Stock (see Note 5). The Series B Preferred Stock is initially convertible into approximately 269,672,900 shares of the Company's common stock, upon Shareholder Approval as defined in the Series B Certificate of Designation.

The Company evaluated the terms of the Series B Preferred Stock, and in accordance with the guidance of ASC 480, the Series B Preferred Stock is classified as temporary equity in the accompanying consolidated balance sheets, as the shares may be redeemable by the holders for cash, upon certain conditions that are not within the control of the Company. Additionally, the Company does not control the actions or events necessary to deliver the number of required shares upon exercise by the holders of the conversion feature. The Series B Preferred Stock was recorded at its fair value as of the issuance date (see Note 5). The Series B Preferred Stock is not currently redeemable or probable of becoming redeemable because it is subject to, among other things, Stockholder Approval as described above, and therefore the carrying amount is not currently accreted to its redemption value as of March 31, 2024.

Note 9 — Convertible Redeemable Preferred Stock and Stockholders' Equity (cont.)

Common Stock

As of March 31, 2024 and December 31, 2023 there were 22,845,100 and 22,841,975 shares of common stock issued, respectively, and 22,327,701 and 22,324,576 shares of common stock outstanding, respectively.

Treasury Stock

On November 10, 2022, the Board approved a stock repurchase program (the "Repurchase Program") to allow the Company to repurchase up to 5.0 million shares of common stock with a maximum price of $1.00 per share, with discretion to management to make purchases subject to market conditions. On November 18, 2022, the Board approved an increase to the maximum price to $2.00 per share. There is no expiration date for this program.

There were no repurchases of common stock during the three months ended March 31, 2024. During the three months ended March 31, 2023, the Company repurchased 32,638 shares of common stock at an average price of $1.03 per share, for an aggregate of approximately $33,500. Shares that are repurchased are classified as treasury stock pending future use and reduce the number of shares outstanding used in calculating earnings per share. As of March 31, 2024, there are approximately 4.5 million shares remaining, that can be repurchased under the Repurchase Program.

At the Market Offering Agreement

On March 29, 2023, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC, as sales agent (the "Agent"), to create an at-the-market equity program under which it may sell up to $3,900,000 of shares of the Company's common stock (the "Shares") from time to time through the Agent (the "ATM Offering"). Under the ATM Agreement, the Agent will be entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of Shares under the ATM Agreement. The Company has no obligation to sell, and the Agent is not obligated to buy or sell, any of the Shares under the Agreement and may at any time suspend offers under the Agreement or terminate the Agreement. The ATM Offering will terminate upon the termination of the ATM Agreement as permitted therein.

Note 9 — Convertible Redeemable Preferred Stock and Stockholders' Equity (cont.)

Deferred offering costs associated with the ATM Agreement are reclassified to additional paid in capital on a pro-rata basis when the Company completes offerings under the ATM Agreement. Any remaining deferred costs will be expensed to the statements of operations should the planned offering be abandoned.

As of March 31, 2024, no shares have been sold under the ATM Offering, and the Company has recorded approximately $0.3 million of deferred offering costs in its condensed consolidated balance sheets at both March 31, 2024 and December 31, 2023.

Warrants

The following summarizes the Company's outstanding warrants, excluding contingent warrants issuable upon exercise of the outstanding warrants issued in the August 2022 and August 2023 offerings, as of March 31, 2024 and December 31, 2023:

Description	Number of Shares	Exercise Price	Expiration Date
April 2022 Offering Placement Agent Warrants	70,849	$ 8.46875	4/19/2026
August 2022 Private Placement Warrants	2,486,214	2.546	8/11/2027
August 2022 Offering Placement Agent Warrants	220,997	3.394	8/11/2027
August 2023 Inducement Warrants	4,972,428	1.09	8/2/2027
August 2023 Offering Placement Agent Warrants	149,173	1.3625	8/2/2027
Total warrants outstanding	7,899,661	1.68	

As of March 31, 2024, the Company had outstanding warrants, which are fully vested and exercisable into 7,899,661 shares of common stock, of which the common stock had a fair value of $0.15 per share, based on the closing trading price on that day.

Additionally, as of March 31, 2024 and December 31, 2023, the value of contingent warrants issuable upon exercise of the August 2022 private placement and August 2023 inducement warrants was approximately $3,000, and the maximum number of warrants issuable upon settlement of the contingent warrants was 447,519.

Onconetix Equity Incentive Plans

The Company's 2019 Equity Incentive Plan (the "2019 Plan") was adopted by its board of directors and by its stockholders on July 1, 2019. The Company has reserved 1,400,000 shares of common stock for issuance pursuant to the 2019 Plan.

On February 23, 2022 the Company's board of directors adopted the Company's 2022 Equity Incentive Plan (the "2022 Plan"), which is the successor and continuation of the Company's 2019 Plan. Under the 2022 Plan, the Company may grant stock options, restricted stock, restricted stock units, stock appreciation rights, and other forms of awards to employees, directors, and consultants of the Company. In May 2023, the number of shares of common stock reserved for issuance under the 2022 Plan was increased to 3,150,000. Stock-based awards granted during the three months ended March 31, 2024 and 2023 were all granted under the 2022 Plan. As of March 31, 2024, there are 1,252,617 shares available for issuance under the 2022 Plan.

Note 9 — Convertible Redeemable Preferred Stock and Stockholders' Equity (cont.)

Stock Options

The following summarizes activity related to the Company's stock options under the 2019 Plan and the 2022 Plan for the three months ended March 31, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2023	1,904,830	$ 1.63	8.4
Granted	—	—	—
Forfeited / cancelled	(537,965)	0.99	—
Exercised	—	—	—
Outstanding as of March 31, 2024	1,366,865	1.88	7.7
Options vested and exercisable as of March 31, 2024	908,224	$ 1.90	7.0

There were no stock options granted during the three months ended March 31, 2024. The fair value of options granted in 2023 was estimated using the following assumptions:

	For the Three Months Ended March 31, 2023
Exercise price	$1.05 – 1.29
Term (years)	5.00 – 10.00
Expected stock price volatility	113.1% – 119.5%
Risk-free rate of interest	3.5% – 3.6%

The weighted average grant date fair value of stock options granted during the three months ended March 31, 2023 was $1.08. The aggregate fair value of stock options that vested during the three months ended March 31, 2024 and 2023 was approximately $83,000 and $272,000, respectively.

Note 9 — Convertible Redeemable Preferred Stock and Stockholders' Equity (cont.)

Restricted Stock

On May 9, 2023, the Board's Compensation Committee approved the issuance of restricted stock, granted under the Company's 2022 Plan, to the Company's executive officers, employees, and certain of the Company's consultants. The restricted shares granted totaled 487,500, of which 150,000, 75,000, and 150,000 were granted to the Company's former CEO, former CFO, and former CBO, respectively. All of the restricted shares granted vest as follows: 50% in January 2024, 25% in August 2024, and 25% in August 2025. In addition, on May 31, 2023, the Board's Compensation Committee approved the issuance of 25,440 shares of restricted stock, granted to the Company's non-executive Board members, with full vesting on May 31, 2024. Further, on February 14, 2024, in connection with the appointment of a non-executive Board member, the Company issued 3,125 shares of restricted stock, with full vesting on June 14, 2024.

The following summarizes activity related to the Company's restricted stock awards granted under the 2022 Plan for the three months ended March 31, 2024:

	Number of Shares	Weighted Average Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2023	256,580	$ 1.03
Granted	3,125	0.17
Vested	(118,750)	1.03
Nonvested as of March 31, 2024	140,955	$ 0.98

Proteomedix Stock Option Plan

Proteomedix sponsors a stock option plan (the "PMX Option Plan") which provides common stock option grants to be granted to certain employees and consultants, as was determined by the board of directors of Proteomedix. In connection with the PMX Transaction, the Company assumed the PMX Option Plan (see Note 5).

Generally, options issued under the PMX Option Plan have a term of less than 11 years and provide for a four-year vesting period during which the grantee must remain in the service of Proteomedix. Stock options issued under the PMX Option Plan are measured at fair value using the Black-Scholes option pricing model.

There was no activity under the PMX Option Plan for the three months ended March 31, 2024. As of March 31, 2024, there were 58,172 and 57,546 stock options outstanding and vested, respectively, with a weighted average exercise price of $3.46 and $3.16, respectively, and a weighted average remaining contractual life of 5.11 years and 5.02 years, respectively. As of March 31, 2024 there were 57,546 stock options exercisable at a weighted average exercise price of $3.16 and a weighted average remaining contractual life of 5.02 years.

Note 9 — Convertible Redeemable Preferred Stock and Stockholders' Equity (cont.)

Stock-Based Compensation

Stock-based compensation expense related to stock options and restricted stock, for the three months ended March 31, 2024 and 2023 was as follows:

	For the Three Months Ended March 31,	
	2024	**2023**
Selling, general and administrative	$ 51,184	$ 99,207
Research and development	1,466	86,371
Total	**$ 52,650**	**$ 185,578**

Note 10 — Commitments and Contingencies

Office Leases

Proteomedix leases office and lab space in Zurich Switzerland, which requires lease payments of approximately $74,000 for the years ended December 31, 2024 and 2025, and which is insignificant to the Company's condensed consolidated financial statements.

The Company entered into a short-term lease in Palm Beach, Florida with an unrelated party, with a commencement date of May 1, 2022, for approximately $14,000 per month. The lease, which was personally guaranteed by the Company's former CEO, ended on April 30, 2023. During the three months ended March 31, 2023, the Company incurred rent expense on this lease of approximately $48,000, and variable lease expense of approximately $4,000.

Litigation

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. As of March 31, 2024, the Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. However, as discussed in Note 5, on December 21, 2023, the Company filed a notice with the Bankruptcy Court terminating the WraSer APA and the WraSer MSA, after having determined that a Material Adverse Effect had occurred. WraSer has advised the Company that it does not believe that a Material Adverse Effect occurred, and they recently filed a plan of reorganization that indicates it may seek damages from the Company due to the termination of the WraSer APA and WraSer MSA.

Registration Rights Agreements

In connection with private placements consummated in April 2022 and August 2022, the Company entered into Registration Rights Agreements with the purchasers. Upon the occurrence of any Event (as defined in each Registration Rights Agreement), which, among others, prohibits the purchasers from reselling the securities for more than ten consecutive calendar days or more than an aggregate of fifteen calendar days during any 12-month period, and should the registration statement cease to remain continuously effective, the Company would be obligated to pay to each purchaser, on each monthly anniversary of each such Event, an amount in cash, as partial liquidated damages and not as a penalty, equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such purchaser in the private placements. As of March 31, 2024, the Company determined that the likelihood of the Company incurring liquidated damages pursuant to the Registration Rights Agreements is remote, and as such, no accrual of these payments is required as of March 31, 2024.

Note 10 — Commitments and Contingencies (cont.)

Milestone and Royalty Obligations

The Company has entered into various license agreements with third parties that obligate the Company to pay certain development, regulatory, and commercial milestones, as well as royalties based on product sales. As of March 31, 2024, the Company terminated all license agreements, except for its license agreement with Children's Hospital Medical Center ("CHMC"), which could require the Company to pay CHMC milestone payments of up to an aggregate of $59.75 million. As of March 31, 2024, the Company evaluated the likelihood of the Company achieving the specified milestones and generating product sales, and determined the likelihood is not yet probable and as such, no accrual of these payments is required as of March 31, 2024.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not been required to defend any action related to its indemnification obligations. However, during the third quarter of 2023, the Company received a claim from its former CEO and a former accounting employee requesting advancement of certain expenses. The Company recorded approximately $209,000 in related expenses during the year ended December 31, 2023, of which approximately $159,000 was paid through reduction of the outstanding related party receivable due from the former CEO (see Note 11). The Company recorded a related accrual of approximately $50,000, which was included in accrued expenses at December 31, 2023, and which was paid subsequent to year end and accordingly there is no related accrual as of March 31, 2024. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is not estimable at this time.

Note 11 — Related Party Transactions

During 2022 the Company entered into a lease agreement that was personally guaranteed by the Company's former CEO. The lease expired on April 30, 2023 (see Note 9).

During the year ended December 31, 2023, the Company's Audit Committee completed a review of the Company's expenses due to certain irregularities identified with regards to the related party balance. Based on the results of the review, it was determined that the Company paid and recorded within selling, general and administrative expenses, personal expenditures of the Company's former CEO and an accounting employee who was also the former CEO's assistant, during 2022 and during the first three quarters of 2023. The Company evaluated the receivable, which was approximately $363,000, after recording a recovery of approximately $159,000, and which represented the total of the items identified as personal in nature for which the Company did not anticipate recovery from the related party. During 2023, the Company recorded a corresponding reserve for the full amount, resulting in a net related party receivable balance of $0 as of March 31, 2024 and December 31, 2023.

On December 18, 2023, the Company entered into the Subscription Agreement with the PMX Investor, a 5% stockholder of the Company as of March 31, 2024 (see Note 8). During the three months ended March 31, 2024, the Company issued a non-convertible debenture in the principal amount of $5.0 million to the PMX Investor, in connection with the Subscription Agreement (see Notes 7 and 8).

On February 6, 2024, the Company appointed Thomas Meier, PhD, as a member of the Company's board of directors. Dr. Meier provides consulting services to Proteomedix, through a consulting agreement that was effective January 4, 2024. The Company recorded approximately $6,000 in related expenses during the three months ended March 31, 2024, which is included in accrued expenses in the condensed consolidated balances sheets as of March 31, 2024.

A former director of the Company, who served on the Company's Scientific Advisory Board until August 2023, serves on the Advisory Board for the Cincinnati Children's Hospital Medical Center Innovation Fund, which is affiliated with CHMC. The Company has an exclusive license agreement with CHMC.

Note 12 — Income Taxes

The Company's tax provision for interim periods is determined using an estimate of the annual effective tax rate, adjusted for discrete items arising in that quarter. In each quarter, management updates the estimate of the annual effective tax rate, and any changes are recorded in a cumulative adjustment in that quarter. The quarterly tax provision and quarterly estimate of the annual effective tax rate are subject to significant volatility due to several factors, including management's ability to accurately predict the portion of income (loss) before income taxes in multiple jurisdictions, and the effects of acquisitions and the integration of those acquisitions.

For the three months ended March 31, 2024, the Company recorded an income tax benefit of approximately $0.1 million. This tax benefit is related to the Company's deferred foreign taxes resulting from the Proteomedix acquisition, and yielded an effective tax rate of 21.3% for Proteomedix for the three months ended March 31, 2024. There was no income tax provision or benefit recorded for the three months ended March 31, 2023.

The Company has incurred net operating losses for all of the periods presented and has not reflected any benefit in the accompanying condensed consolidated financial statements for its U.S. net operating loss carryforwards and only a partial benefit for its Swiss net operating loss carryforwards due to uncertainty around utilizing these tax attributes within their respective carryforward periods. The Company has recorded a full valuation allowance against its U.S. deferred tax assets as it is not more likely than not that such assets will be realized in the near future. During 2023, the Company recognized a foreign deferred tax liability related to the acquisition of Proteomedix (see Note 5). A partial valuation allowance has been recognized against the Company's Swiss deferred tax assets that are not more likely than not expected to be realizable.

The Company's policy is to recognize interest expense and penalties related to income tax matters as income tax expense. For the three months ended March 31, 2024 and 2023, the Company has not recognized any interest or penalties related to income taxes.

Note 13 — Net Loss Per Share

Basic net loss per share is computed by dividing the net income or loss applicable to common shares by the weighted average number of common shares outstanding during the period. The weighted average number of shares of common stock outstanding includes pre-funded warrants because their exercise requires only nominal consideration for delivery of shares; it does not include any potentially dilutive securities or any unvested restricted shares of common stock. Certain restricted shares, although classified as issued and outstanding at March 31, 2024, are considered contingently returnable until the restrictions lapse and will not be included in the basic net loss per share calculation until the shares are vested. Unvested shares of the Company's restricted stock do not contain non-forfeitable rights to dividends and dividend equivalents. Diluted earnings per share is computed using the weighted average number of common shares and, if dilutive, potential common shares outstanding during the period. Potential common shares consist of the Company's warrants, options, and restricted shares. Diluted net loss per share is computed by giving effect to all potential shares of common stock, including warrants, stock options, and unvested restricted shares, to the extent they are dilutive.

The two-class method is used to determine earnings per share based on participation rights of participating securities in any undistributed earnings. Each share of preferred stock that includes rights to participate in distributed earnings is considered a participating security and the Company uses the two-class method to calculate net income available to the Company's common stockholders per common share — basic and diluted.

The following securities were excluded from the computation of diluted shares outstanding due to the losses incurred in the periods presented, as they would have had an anti-dilutive impact on the Company's net loss:

	Three Months Ended March 31,	
	2024	**2023**
Options to purchase shares of common stock	1,366,865	1,469,102
Warrants	7,899,661	5,264,274
Unvested shares of restricted stock	140,955	—
Common stock issuable upon conversion of Series A preferred stock	5,709,935	—
Total	**15,117,416**	**6,733,376**

Note 14 — Defined Benefit Plan

Proteomedix sponsors a defined benefit pension plan (the "Swiss Plan") covering certain eligible employees. The Swiss Plan provides retirement benefits based on years of service and compensation levels.

The following significant actuarial assumptions were used in calculating the benefit obligation and the net periodic benefit cost as of March 31, 2024 and December 31, 2023:

	March 31, 2024	December 31, 2023
Discount rate	1.45%	1.45%
Expected long-term rate of return on plan assets	1.45%	1.45%
Rate of compensation increase	3.00%	3.00%

Changes in these assumptions may have a material impact on the plan's obligations and costs.

The components of net periodic benefit cost for the three months ended March 31, 2024, which is included within selling, general and administrative expenses in the accompanying condensed consolidated statements of operations and comprehensive loss, are as follows:

Service cost	$ 24,650
Interest cost	7,558
Expected return on plan assets	(23,495)
Amortization of net (gain)	(15,446)
Total	$ (6,733)

During the three months ended March 31, 2024, the Company made pension contributions of approximately $21,400.

Note 15 — Subsequent Events

Veru Forbearance Agreement

On April 24, 2024, the Company entered into a forbearance agreement with Veru (the "Forbearance Agreement"). Pursuant to the Forbearance Agreement, Veru will forbear from exercising its rights and remedies under the $5.0 million note payable that had a maturity date of April 19, 2024 (the "April Veru Note") (see Notes 5 and 7), until March 31, 2025 (the "Forbearance Period"). Interest will accrue on any unpaid principal balance of the April Veru Note at a rate of 10% per annum, commencing on April 20, 2024 through the date that the outstanding principal balance under the April Veru Note is paid in full. Any such accrued interest will become immediately due and payable upon the earlier of (i) certain events of default under the April Veru Note or the $5.0 million note payable that matures on September 30, 2024 (the "September Veru Note"), (ii) a payment default under the September Veru Note and (iii) the final payment of any principal amount payable under the September Veru Note. No interest will accrue under the September Veru Note during the Forbearance Period unless an Event of Default (as defined in the Forbearance Agreement) occurs, in which case interest will accrue from and after the date on which such default occurs.

In consideration for Veru's entrance into the Forbearance Agreement, the Company agreed to pay Veru:

- $50,000 of the principal due under the April Veru Note, which was paid on April 25, 2024, and up to $10,000 of out-of-pocket expenses incurred by Veru in connection with the Forbearance Agreement;
- 15% of (i) the monthly cash receipts of Proteomedix for the licensing or sale of any products or services, (ii) monthly cash receipts of the Company or any of its subsidiaries for the sales of Proclarix anywhere in the world, and (iii) monthly cash receipts of the Company or any of its subsidiaries for milestone payments or royalties from Labcorp; and
- 10% of the net proceeds from any financing or certain asset sale, transfer or licensing transactions that are consummated prior to March 31, 2025.

The Company also agreed to a general release of claims against Veru and its representatives arising out of or relating to any act or omission thereof prior to April 24, 2024.

Related Party Debenture

On April 24, 2024, the maturity date of the Debenture (see Note 7) was extended to October 31, 2024 through the execution of an extension agreement between the Company and the investor. No other terms of the Debenture were modified in connection with the extension agreement.

Stock Option Modification

On April 16, 2024, the board of directors of Proteomedix approved a two-year extension of 12,257 stock options that were set to expire in April 2024. The extended expiration date for these options is April 18, 2026.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this Report and with the audited financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the SEC, on April 11, 2024. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors. See "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a commercial stage biotechnology company focused on the research, development, and commercialization of innovative solutions for men's health and oncology. Through our recent acquisition of Proteomedix, which closed on December 15, 2023, we own Proclarix, an in vitro diagnostic test for prostate cancer originally developed by Proteomedix and approved for sale in the European Union under the In Vitro Diagnostic Regulation ("IVDR"), which we anticipate will be marketed in the U.S. as a lab developed test through our license agreement with LabCorp.

We also own ENTADFI, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of BPH, a disorder of the prostate. However, in light of (i) the time and resources needed to continue pursuing commercialization of ENTADFI, and (ii) the Company's cash runway and indebtedness, the Company has now determined to pause its commercialization of ENTADFI, as it explores strategic alternatives to monetize ENTADFI, such as a potential sale of the ENTADFI assets. To that end, the Company has engaged an investment advisor to assist with a potential sale or other transaction of the ENTADFI assets. As part of a cost reduction plan approved by the Board and in connection with our pause in commercializing ENTADFI, we terminated three employees involved with the ENTADFI program, effective April 30, 2024, with such individuals to continue assisting the Company on an as-needed, consulting basis. The Company continues to search for a new Chief Executive Officer.

We are currently focusing our efforts on commercializing Proclarix.

Proclarix is an easy-to-use next generation protein-based blood test that can be done with the same sample as a patient's regular Prostate-Specific Antigen ("PSA") test. The PSA test is a well-established prostate specific marker that measures the concentration of PSA molecules in a blood sample. A high level of PSA can be a sign of prostate cancer. However, PSA levels can also be elevated for many other reasons including infections, prostate stimulation, vigorous exercise or even certain medications. PSA results can be confusing for many patients and even physicians. It is estimated over 50% of biopsies with elevated PSA are negative or clinically insignificant resulting in an overdiagnosis and overtreatment that impacts the physician's routine, our healthcare system, and the quality of patients' lives. Proclarix helps doctors and patients with unclear PSA test results through the use of our proprietary Proclarix Risk Score which delivers clear and immediate diagnostic support for further treatment decisions. No additional intervention is required, and results are available quickly. Local diagnostic laboratories can integrate this multiparametric test into their current workflow because Proclarix assays use the enzyme-linked immunosorbent assay (ELISA) standard, which most diagnostic laboratories are already equipped to process.

ENTADFI allows men to receive treatment for their symptoms of BPH without the negative sexual side effects typically seen in patients on finasteride alone. Following a recent business strategy shift towards the field of men's health and oncology and halting of preclinical vaccine programs, we are building additional assets in therapeutics, diagnostics, and clinician services for men's health and oncology.

Since our inception in October 2018 until April 2023, when we acquired ENTADFI, we devoted substantially all of our resources to performing research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and now deprioritized vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities.

Prior to the acquisition of ENTADFI, we managed one distinct business segment, which was research and development. Beginning in the second quarter of 2023, as a result of the acquisition of ENTADFI, for which we were working towards commercial launch, we operated in two business segments: research and development and commercial. During the third quarter of 2023, we halted our vaccine discovery and development programs, and accordingly, we now operate in one segment: commercial. Our recent acquisition of Proteomedix during the fourth quarter of 2023 and its related diagnostic product Proclarix was determined to be within our commercial segment. The research and development segment was our historical business, and was dedicated to the research and development of various vaccines to prevent infectious diseases. The commercial segment was new in the second quarter of 2023 and is dedicated to the commercialization of our products approved for sale, currently, Proclarix in Europe.

Given Proclarix is CE-marked for sale in the European Union, we expect to generate revenue from sales of Proclarix by 2025. Although we anticipate these sales to offset some expenses relating to commercial scale up and development, we expect our expenses will increase substantially in connection with our ongoing activities, as we:

- commercialize Proclarix;
- hire additional personnel;
- operate as a public company, and;
- obtain, maintain, expand and protect our intellectual property portfolio.

We rely and will continue to rely on third parties for the manufacturing of Proclarix. We have no internal manufacturing capabilities, and we will continue to rely on third parties, of which the main suppliers are single-source suppliers, for commercial products.

We do not have any products approved for sale, aside from Proclarix, from which we have generated only minimal amounts of development revenue since its acquisition, and ENTADFI, from which we have not generated any revenue from product sales, and for which we have determined to pause commercialization activities and as we explore strategic alternatives to monetize ENTADFI, such as a potential sale of the ENTADFI assets. To date, we have financed our operations primarily with proceeds from our sale of preferred securities to seed investors, the initial public offering, the private placements completed during 2022, the proceeds received from a warrant exercise in August 2023, and the proceeds received from the issuance of debt in January 2024. We will continue to require significant additional capital to commercialize Proclarix, and to fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and to rely on third-party resources for marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches, to support our operations.

Since December 31, 2023, some key developments affecting our business include the following:

Altos Amendment

On January 23, 2024, the Company issued a non-convertible debenture (the "Altos Debenture") in the principal sum of $5.0 million, in connection with a Subscription Agreement, to Altos Ventures, a stockholder of the Company and related party ("Altos"). The Altos Debenture has an interest rate of 4.0% per annum, and the principal and accrued interest was to be payable in full upon the earlier of (i) the closing under the Subscription Agreement and (ii) June 30, 2024. Additionally, the $5.0 million subscription amount under the Subscription Agreement shall be increased by the amount of interest payable under the Altos Debenture. On April 24, 2024, the Altos Debenture was amended to extend the maturity date to the earlier of (i) the closing under the Subscription Agreement and (ii) October 31, 2024 (the "Altos Amendment").

Forbearance Agreement

On April 24, 2024, the Company entered into a forbearance agreement with Veru (the "Forbearance Agreement"). Pursuant to the Forbearance Agreement, Veru will forbear from exercising its rights and remedies under the April Veru Note until March 31, 2025 (the "Forbearance Period"). Interest will accrue on any unpaid principal balance of the April Veru Note at a rate of 10% per annum, commencing on April 20, 2024 through the date that the outstanding principal balance under the April Veru Note is paid in full. Any such accrued interest will become immediately due and payable upon the earlier of (i) certain events of default under the April Veru Note or September Veru Note, (ii) a payment default under the September Veru Note and (iii) the final payment of any principal amount payable under the September Veru Note. No interest will accrue under the September Veru Note during the Forbearance Period unless an Event of Default (as defined in the Forbearance Agreement) occurs, in which case interest will accrue from and after the date on which such default occurs.

In consideration for Veru's entrance into the Forbearance Agreement, the Company agreed to pay Veru:

- $50,000 of the principal due under the April Veru Note and up to $10,000 of out-of-pocket expenses incurred by Very in connection with the Forbearance Agreement;

- 15% of (i) the monthly cash receipts of Proteomedix for the licensing or sale of any products or services, (ii) monthly cash receipts of the Company or any of its subsidiaries for the sales of Proclarix anywhere in the world, and (iii) monthly cash receipts of the Company or any of its subsidiaries for milestone payments or royalties from Labcorp; and

- 10% of the net proceeds from any financing or certain asset sale, transfer or licensing transactions that are consummated prior to March 31, 2025.

The Company also agreed to a general release of claims against Veru and its representatives. arising out of or relating to any act or omission thereof prior to April 24, 2024.

We have incurred net losses since inception and expect to continue to incur net losses in the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending in large part on the timing of our preclinical studies, clinical trials and manufacturing activities, our expenditures on other research and development activities and commercialization activities. As of March 31, 2024, the Company had a working capital deficit of approximately $15.1 million and an accumulated deficit of approximately $63.2 million. In addition, as of May 15, 2024, the Company's cash balance was approximately $1.9 million. The Company believes that its current cash balance is only sufficient to fund its operations into the third quarter of 2024, and as such, we will need to raise additional capital prior to this to sustain operations. In addition, if Stockholder Approval for certain transactions involving the Company's Series B Preferred Stock is not obtained by January 1, 2025, the Company may be obligated to cash settle the Series B Preferred Stock. Based on the closing price of $0.156 for the Company's stock as of May 17, 2024, the Series B Preferred Stock would be redeemable for approximately $42.1 million.

Until we generate revenue sufficient to support self-sustaining cash flows, if ever, we will need to raise additional capital to fund our continued operations, including our product development and commercialization activities related to our current and future products. There can be no assurance that additional capital will be available to us on acceptable terms, or at all, or that we will ever generate revenue sufficient to provide self-sustaining cash flows. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements of Onconetix, as of and for the three months ended March 31, 2024, included elsewhere in this Report do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

Because of the numerous risks and uncertainties associated with our business, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Additionally, even if we are able to generate revenue from Proclarix or our other assets, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Certain Significant Relationships

We have entered into license and other arrangements with various third parties as summarized below. For further details regarding these and other agreements, see Notes 6 and 9 to each of our audited financial statements included in the Form 10-K and unaudited financial statements included elsewhere in this Report.

Laboratory Corporation of America

On March 23, 2023, Proteomedix entered into a license agreement Laboratory Corporation of America ("Labcorp") pursuant to which Labcorp has the exclusive right to develop and commercialize Proclarix, and other products developed by Labcorp using Proteomedix's intellectual property covered by the license, in the United States ("Licensed Products"). In consideration for granting Labcorp an exclusive license, Proteomedix received an initial license fee in the mid-six figures upon signing of the contract. Additionally, Proteomedix is entitled to royalty payments of between 5% and 10% on the net sales recognized by Labcorp of any Licensed Products plus milestone payments as follows:

- After the first sale of Proclarix as a laboratory developed test, Labcorp will pay an amount in the mid-six figures,
- after Labcorp achieves a certain amount in the low seven figures in net sales of Licensed Products, Labcorp will pay Proteomedix an amount in the low seven figures,
- after a certain amount in the mid-seven figures in net sales of Licensed Products, Labcorp will pay Proteomedix an amount in the low seven figures.

The total available milestone payments available under the terms of this contract is $2.5 million of which $0.5 million has been paid to Proteomedix.

Labcorp is wholly responsible for the cost, if any, of research, development and commercialization of Licensed Products in the United States but has the right to offset a portion of those costs against future royalty and milestone payments. Additionally, Labcorp may deduct royalties or other payments made to third parties related to the manufacture or sale of Licensed Products up to a maximum amount of any royalty payments due to Proteomedix.

The license agreement and related royalty payment provisions expire during 2038, which approximates the expiration of the last patent covered by the license agreement. Labcorp has the right to terminate the license agreement for any reason by providing 90 days written notice to Proteomedix. Either party may terminate the license agreement due to a material breach of the terms of the license agreement with 30 days' notice, provided such breach is not cured within the foregoing 30 day period. Finally, Proteomedix may terminate the license agreement with 60 days' notice in the event Labcorp fails to make any undisputed payment due, provided that Labcorp does not remit the payment within the foregoing 60 day period.

Services Agreement

On July 21, 2023, the Company, entered into a Licensing and Services Master Agreement ("Master Services Agreement") and a related statement of work with a vendor, pursuant to which the vendor was to provide to the Company commercialization services for the Company's products, including recruiting, managing, supervising and evaluating sales personnel and providing sales-related services for such products, for fees totaling up to $29.1 million over the term of the statement of work. The statement of work had a term through September 6, 2026, unless earlier terminated in accordance with the Master Services Agreement and the statement of work. On July 29, 2023, a second statement of work was entered into with the same vendor for certain subscription services providing prescription market data access to the Company. The fees under the second statement of work totaled approximately $800,000, and the term was through July 14, 2025. On October 12, 2023, the Company terminated the Master Services Agreement and the statements of work. The Company recorded approximately $3.1 million in expense related to this contract during the year ended December 31, 2023, which is included in selling, general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss. The Company had approximately $1.5 million and $1.8 million recorded in related accounts payable as of March 31, 2024 and December 31, 2023, respectively, which includes amounts due for early termination of the contract. See Note 6 to our consolidated financial statements included elsewhere in this Report.

Components of Results of Operations

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of commercialization activities, payroll, and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, information technology costs, costs incurred with respect to acquisitions and potential acquisitions, and other general operating expenses.

We anticipate that our selling, general and administrative expenses will continue to increase when compared to historical levels as a result of efforts to commercialize Proclarix, costs associated with integration of Proteomedix's operations, as well as expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the applicable stock exchange and the SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our product candidates. These expenses historically have included fees paid to third parties to conduct certain research and development activities on our behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll, and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for our research and product development employees. We expense both internal and external research and development expenses as they are incurred.

We do not allocate our costs by product candidate, as a significant amount of research and development expenses include internal costs, such as payroll and other personnel expenses, laboratory supplies, and external costs, such as fees paid to third parties to conduct research and development activities on our behalf, that are not tracked by product candidate.

We expect our research and development expenses to increase if research and development activities are resumed. Predicting the timing or cost to complete our clinical programs for future product candidates, or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control, such as regulatory approvals. Furthermore, we are unable to predict when or if our future product candidates will receive regulatory approval with any certainty.

Other Income (Expense)

Other income (expense) is comprised of interest expense on notes payable, the change in fair value of financial instruments that are recorded as liabilities, which includes the related party subscription agreement liability and the contingent warrant liability, and other financing-related costs.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our statements of operations for the periods indicated:

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023	$ Change	% Change
Revenue	$ 700,433	$ -	$ 700,433	100%
Cost of revenue	511,433	-	511,433	100%
Gross profit	189,000	-	189,000	100%
Operating expenses				
Selling, general and administrative	$ 3,736,450	$ 1,766,022	1,970,428	111.6%
Research and development	48,964	1,082,237	(1,033,273)	(95.5)%
Impairment of goodwill	5,192,000	-	5,192,000	100.0%
Impairment of ENTADFI assets	2,293,576	-	2,293,576	100.0%
Total operating expenses	11,270,990	2,848,259	8,442,731	295.7%
Loss from operations	(11,081,990)	(2,848,259)	(8,233,731)	(289.1)%
Other income (expense)				
Interest expense – related party	(225,063)	-	(225,063)	(100)%
Interest expense	(187,993)	-	(187,993)	(100)%
Change in fair value of subscription agreement liability – related party	226,400	-	226,400	100%
Change in fair value of contingent warrant liability	-	1,615	(1,615)	(100)%
Other income	28,507	-	28,507	100%
Total other income (expense)	(158,149)	1,615	(159,764)	(9,893)%
Loss before income taxes	(11,240,139)	(2,846,644)	(8,393,495)	(294.9)%
Income tax benefit	121,567	-	121,567	100%
Net loss	$ (11,118,572)	$ (2,846,644)	(8,271,928)	(290.6)%

Revenue, Cost of Revenue, and Gross Margin

For the three months ended March 31, 2024, the Company had approximately $0.7 million of revenue, which was attributable to sales and development services generated by Proteomedix. Cost of revenue of approximately $0.5 million is attributable to costs incurred on Proteomedix revenue including amortization of the product rights intangible asset of approximately $0.2 million. The Company did not have any revenue during the three months ended March 31, 2023.

Selling, General and Administrative Expenses

For the three months ended March 31, 2024, selling, general and administrative expenses increased by approximately $2.0 million compared to the same period in 2023. The increase was mainly due to an increase in professional fees of $1.0 million, which is comprised primarily of audit, accounting, and legal services, an increase in certain regulatory-related expenses of $0.1 million, commercialization activities for ENTADFI of $0.1 million, and $0.1 million incurred for the loss on related party receivable. In addition, the Company incurred approximately $1.0 million related to Proteomedix, which consists primarily of Proteomedix's selling, general and administrative expenses. These increases were offset by a decrease in various business activities, such as travel related expenses, and rent expense, totaling $0.3 million.

Research and Development Expenses

For the three months ended March 31, 2024, research and development expenses decreased by approximately $1.0 million compared to the same period in 2023. The decrease was primarily due to the Company's decision to halt its vaccine programs and focus on commercialization activities, which occurred during the third quarter of 2023. This change in business strategy led to a pause in the Company's clinical and other research activities, and a resulting decrease of approximately $1.1 million due to decreased costs for related outside services and reduced compensation expense. This was slightly offset by an increase related to Proteomedix's research and development activities of approximately $0.1 million.

Impairments

During the three months ended March 31, 2024, the Company recorded an impairment loss of approximately $5.2 million related to goodwill recorded in connection with the PMX acquisition and an impairment loss of approximately $2.3 million on the assets acquired as part of the ENTADFI asset acquisition. No such impairments were recorded in the same period in 2023.

Other Income (Expense)

Other expense incurred during the three months ended March 31, 2024 increased by approximately $0.2 million compared to the same period in 2023. The increase relates to approximately $0.4 million of interest expense incurred on notes payable issued in April 2023 related to the acquisition of ENTADFI and the related party debenture issued in January 2024, offset by the change in fair value of the related party subscription agreement liability of approximately $0.2 million.

Income Tax Benefit

The Company recorded an income tax benefit of approximately $0.1 million during the three months ended March 31, 2024, related to foreign deferred income taxes in connection with Proteomedix. There was no income tax benefit or expense recorded during the same period in 2023.

Liquidity and Capital Resources

The Company's operating activities to date have been devoted to seeking licenses, engaging in research and development activities, potential asset and business acquisitions, and expenditures associated with the commercial launch of ENTADFI and the commercialization of Proclarix.

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of March 31, 2024, the Company had cash of approximately $4.5 million, a working capital deficit of approximately $15.1 million and an accumulated deficit of approximately $67.9 million. In addition, as of May 15, 2024, the Company's cash balance was approximately $1.9 million. The Company believes that its current cash balance is only sufficient to fund its operations into the third quarter of 2024 and this raises substantial doubt about the Company's ability to continue as a going concern within one year from the date of the issuance of these consolidated financial statements, and indicates that the Company is unable to meet its contractual commitments and obligations as they come due in the ordinary course of business. The Company will require significant additional capital in the short-term to fund its continuing operations, satisfy existing and future obligations and liabilities, including the remaining payments due for the acquisition of the ENTADFI assets, payment due on the Debenture, in addition to funds needed to support the Company's working capital needs and business activities. These business activities include the commercialization of Proclarix, and the development and commercialization of the Company's future product candidates. In addition, as discussed more fully in Note 5, if stockholder approval is not obtained by January 1, 2025 with respect to the Series B Convertible Redeemable Preferred Stock issued in connection with the acquisition of Proteomedix, these shares become redeemable for cash at the option of the holders, and the Company currently does not have sufficient cash to redeem such shares. Based on the closing price of $0.156 for the Company's stock as of May 17, 2024, the Series B Convertible Redeemable Preferred Stock would be redeemable for approximately $42.1 million.

Management's plans for funding the Company's operations include generating product revenue from sales of Proclarix, which may still be subject to further successful commercialization activities within certain jurisdictions. In addition, as discussed above, the Company has paused commercialization activities for ENTADFI and it is exploring strategic alternatives for its monetization, such as a potential sale of the ENTADFI assets for which the Company has engaged a financial advisor to assist with. Management's plans also include attempting to secure additional required funding through equity or debt financings if available. However, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all. This creates significant uncertainty that the Company will have the funds available to be able to sustain its operations and expand commercialization of Proclarix. If the Company is unable to secure additional capital, it may be required to curtail any future clinical trials, development and/or commercialization of future product candidates, and it may take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations.

Because of historical and expected operating losses and net operating cash flow deficits, there is substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the condensed consolidated financial statements, which is not alleviated by management's plans. The condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. These condensed consolidated financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty.

Future Funding Requirements

Our primary uses of cash to date have been to fund our operations, which consist primarily of research and development expenditures related to our programs, costs related to acquisitions and potential acquisitions, commercializing ENTADFI and other selling, general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to commercialize Proclarix, and expand our corporate infrastructure, including the costs associated with being a public company.

We will require significant amounts of additional capital in the short-term, to continue to fund our continuing operations, satisfy existing and future obligations and liabilities, including the remaining payments due under the Veru APA and other contracts entered into in support of the Company's commercialization plans, in addition to funds needed to support our working capital needs and business activities, including the commercialization of Proclarix, and the development and commercialization of our future product candidates. Until we can generate a sufficient amount of revenue from sales of Proclarix, we expect to finance our future cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. The future sale of equity or convertible debt securities may result in dilution to our stockholders, and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financing may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of our business activities.

Our future capital requirements will depend on many factors, including:

- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties, and distribution, for Proclarix, and other products for which we may receive marketing approval;
- the cost of redeeming our Series B Convertible Redeemable Preferred Stock, if stockholder approval is not obtained by January 1, 2025;
- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical and non-clinical studies and clinical trials;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the revenue, if any, received from commercial sales of Proclarix or ENTADFI (if we sell the ENTADFI assets or decide to resume its commercialization), or other products for which we may have received or will receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights; and
- the costs of operating as a public company.

A change in the outcome of any of these or other variables could significantly change the costs and timing associated with our business activities. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such change.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Net cash used in operating activities	$ (5,232,063)	$ (4,411,631)
Net cash used in investing activities	(4,578)	(36,271)
Net cash provided by (used in) financing activities	5,205,093	(48,954)
Effect of exchange rate changes on cash	(58,917)	-
Net decrease in cash	$ (90,465)	$ (4,496,856)

Cash Flows from Operating Activities

Net cash used in operating activities for the three months ended March 31, 2024 was approximately $5.2 million, which primarily resulted from a net loss of $11.1 million, a decrease in the fair value of the subscription agreement liability of $0.2 million, a deferred tax benefit of $0.1 million, and a net change in our operating assets and liabilities of $1.9 million. This was offset by an impairment loss of $5.2 million related to goodwill recorded in connection with the acquisition of Proteomedix, an impairment loss of $2.3 million related to the ENTADFI assets, noncash interest expense of $0.4 million, and depreciation and amortization expense of $0.2 million.

Net cash used in operating activities for the three months ended March 31, 2023 was $4.4 million, which primarily resulted from a net loss of $2.8 million and a net change in our operating assets and liabilities of $1.8 million, which was partially offset by noncash stock-based compensation of approximately $0.2 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the three months ended March 31, 2024 of approximately $5,000 resulted from purchases of property and equipment.

Net cash used in investing activities for the three months ended March 31, 2023 was approximately $36,000, which resulted from purchases of property and equipment and the net change in the receivable from related parties.

Cash Flows from Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2024 was approximately $5.2 million, and resulted primarily from the issuance of an aggregate of $5.7 million in notes payable, consisting of a $5.0 million debenture and $0.7 million for the financing for certain director and officer liability insurance policy premiums, offset by the payment of $0.4 million in financing costs and $0.1 million in payment on one of the notes payable.

Net cash used in financing activities for the three months ended March 31, 2023 was $49,000, and resulted from $33,000 in purchases of treasury shares and $16,000 of payment in deferred offering costs.

Legal Contingencies

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Recent Accounting Pronouncements Not Yet Adopted

See Note 3 to our condensed consolidated financial statements included elsewhere in this Report for more information.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

As of March 31, 2024, there have been no material changes to our critical accounting policies and estimates from those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates," included in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on April 11, 2024.

JOBS Act

Section 107 of the Jumpstart Our Business Startups Act ("JOBS") Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period.

For as long as we remain an "emerging growth company" under the JOBS Act, we will, among other things:

- be exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act, which requires that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- be permitted to omit the detailed compensation discussion and analysis from proxy statements and reports filed under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), and instead provide a reduced level of disclosure concerning executive compensation; and
- be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We currently intend to take advantage of some or all of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company," including the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Among other things, this means that our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an emerging growth company, which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an emerging growth company, we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. As a result, investor confidence in our company and the market price of our common stock may be materially and adversely affected.

Related Party Transactions

Consulting Agreement

On February 6, 2024, the Company appointed Thomas Meier, PhD, as a member of the Company's board of directors. Dr. Meier provides consulting services to Proteomedix, through a consulting agreement that was effective January 4, 2024.

Debenture

On January 23, 2024, the Company issued a non-convertible debenture (the "Debenture") in the principal sum of $5.0 million, in connection with a Subscription Agreement, to Altos Ventures, a stockholder of the Company. The Debenture has an interest rate of 4.0% per annum, and the principal and accrued interest are payable in full upon the earlier of (i) the closing under the Subscription Agreement and (ii) June 30, 2024. Additionally, the $5.0 million subscription amount under the Subscription Agreement shall be increased by the amount of interest payable under the Debenture. On April 24, 2024, the maturity date of the Debenture was extended to October 31, 2024 through the execution of an extension agreement between the Company and the investor. No other terms of the Debenture were modified in connection with the extension agreement.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the appropriate time periods, and that such information is accumulated and communicated to the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer has evaluated the effectiveness of our disclosure controls and procedures. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of March 31, 2024, as a result of the material weaknesses described below.

Material Weaknesses in Internal Control Over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

During 2023, after a review completed by the Audit Committee, it was determined that our former CEO and an accounting employee charged certain personal expenses on their corporate credit cards that were not recorded as related party receivables. These unauthorized charges, in addition to personal charges that were identified as such in previous reporting periods, may have constituted personal loans that are not permissible under Section 402 of the Sarbanes-Oxley Act of 2002. We determined that this credit card misuse arose from the following control deficiencies, which we have determined to be material weaknesses as of March 31, 2024:

- We did not maintain an effective control environment as there was an inadequate segregation of duties with respect to certain cash disbursements. The processing and the approval for payment of credit card transactions and certain bank wires were being handled by the CEO and an accounting employee, and the accounting employee was responsible for the reconciliation of credit card statements and bank statements. This allowed these individuals to submit unauthorized payments to unauthorized third parties.

- We do not have an effective risk assessment process and effective monitoring of compliance with established accounting policies and procedures, and do not demonstrate a sufficient level of precision in the application of our controls, including the maintenance of board committee minutes and unanimous written consents.

- Our controls over the approval and reporting of expenses paid with the Company's credit cards and certain bank wires were not designed and maintained to achieve the Company's objectives.

- We have insufficient accounting resources to maintain adequate segregation of duties, maintain adequate controls over the approval and posting of journal entries, and to provide optimal levels of oversight in order to process financial information in a timely manner, analyze and account for complex, non-routine transactions, and prepare financial statements.

- We do not yet have adequate internal controls in place for the timely identification, approval or reporting of related party transactions.

- The Company did not design, implement and maintain effective controls to ensure information technology ("IT") policies and procedures set the tone at the top, to mitigate the risks to the achievement of IT objectives and ITGCs in the change management, logical security and computer operations domains. Specifically, the design and implementation of user authentication, user access privileges, data backup and data recovery controls as well as the monitoring controls of excessive user access and elevated privileged access to financial applications and data were not appropriately designed and maintained. In addition, these inadequate ITGC controls combined with the use of personal devices to conduct business, can lead to an IT control environment vulnerable to breaches and social engineering persuasion.

The above material weaknesses did not result in a material misstatement of our previously issued financial statements but could have resulted in material misstatements of our account balances or disclosures of our annual or interim financial statements that would not be prevented or detected. We have developed a remediation plan for these material weaknesses which is described below in *Remediation of Material Weaknesses*.

Remediation of Material Weaknesses

We are committed to maintaining a strong internal control environment and implementing measures designed to help ensure that the material weaknesses are remediated as soon as possible. We believe we have made progress towards remediation and continue to implement our remediation plan for the material weaknesses, which includes steps to increase dedicated qualified personnel including financial consultants, improve reporting processes, and design and implement new controls. Further, following the credit card misuse discussed above, management has designed and begun to implement the following remediation plan:

- Terminated the accounting employee involved in the misuse and reassigned such employee's roles and responsibilities regarding impacted control activities.
- Implemented a travel, entertainment, and gift policy, which our Board approved on August 31, 2023.
- Implement a formal information security policy.
- Review and update, as necessary, the design and operation of our process level and transaction level controls for cash disbursements, credit card transactions, and journal entries. Implement enhanced approval policies.

We will consider the material weaknesses remediated after the applicable controls operate for a sufficient period of time, and management has concluded, through testing, that the controls are operating effectively.

The process of designing and implementing an effective accounting and financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain an accounting and financial reporting system that is adequate to satisfy our reporting obligations. As we continue to evaluate and take actions to improve our internal control over financial reporting, we may determine to take additional actions to address control deficiencies or determine to modify certain of the remediation measures described above. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses.

Inherent Limitation on the Effectiveness of Internal Control Processes

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Control over Financial Reporting

During the fiscal quarter ended March 31, 2024, there were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings, nor, to our knowledge, is any material legal proceeding threatened against us or any of our officers or directors in their corporate capacity.

Item 1A. Risk Factors

In addition to the following risk factors, you should carefully consider the risk factors included in our Annual Report on Form 10-K, filed with the SEC on April 11, 2024. Any of these factors could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations.

Risks Related to our Financial Position and Need for Capital

We have incurred significant net losses since inception, have only generated minimal revenue, and anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve profitability. Our stock is a highly speculative investment.

We are a commercial-stage biotechnology company that was incorporated in October 2018. Our net loss was $11.1 million for the three months ended March 31, 2024. As of March 31, 2024, we had an accumulated deficit of $67.9 million. We also generated negative operating cash flows of $5.2 million for the three months ended March 31, 2024.

We expect to continue to spend significant resources to commercialize our product. We expect to incur substantial and increasing operating losses over the next several years. As a result, our accumulated deficit will also increase significantly. Additionally, there can be no assurance that our current products or those that may be under development by us in the future will be commercially viable. If we are unable to achieve profitability or raise sufficient working capital, we may be unable to continue our operations.

There is substantial doubt about our ability to continue as a "going concern," and we will require substantial additional funding to finance our long-term operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate some or all of our products and operations.

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of March 31, 2024, the Company had cash of approximately $4.5 million, a working capital deficit of approximately $15.1 million and an accumulated deficit of approximately $67.9 million. In addition, as of May 15, 2024, the Company's cash balance was approximately $1.9 million.

On January 23, 2024, the Company issued the Debenture in exchange for $4.6 million in net cash proceeds. The Debenture, as amended on April 24, 2024, is repayable in full upon the earlier of (i) the closing under the Subscription Agreement and (ii) October 31, 2024.

We estimate, as of the date of this Report, that our current cash balance is only sufficient to fund our operations into the third quarter of 2024. We believe that we will need to raise substantial additional capital to fund our continuing operations, satisfy existing and future obligations and liabilities, and otherwise support the Company's working capital needs and business activities, including making the remaining payments to Veru and the commercialization of Proclarix. In addition, if Stockholder Approval is not obtained by January 1, 2025, the Company may be obligated to cash settle the Series B Preferred Stock. The Company does not currently have sufficient cash to redeem the shares of Series B Preferred Stock. Based on the closing price of $0.156 for the Company's stock as of May 17, 2024, the Series B Preferred Stock would be redeemable for approximately $42.1 million. Management's plans include generating product revenue from sales of Proclarix, which may still be subject to further successful commercialization activities within certain jurisdictions. In addition, the Company has paused commercialization activities for ENTADFI and it is exploring strategic alternatives for its monetization, such as a potential sale of the ENTADFI assets. Management's plans also include attempting to secure additional required funding through equity or debt financings if available. However, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all. If the Company is unable to secure additional capital, it may be required to delay or curtail any future commercialization of products, and it may take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of time within one year from the issuance of the condensed consolidated financial statements. Our future capital requirements will depend on many factors, including:

- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for Proclarix, and ENTADFI (if we decide to resume its commercialization), and other products for which we have received or will receive marketing approval;
- the cost of redeeming our Series B Convertible Redeemable Preferred Stock, if stockholder approval is not obtained by January 1, 2025;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire, and retain skilled personnel;
- the revenue, if any, received from commercial sales of Proclarix and ENTADFI (if we decide to resume its commercialization), or other products for which we may receive marketing approval;
- the costs to establish, maintain, expand, enforce, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending, and enforcing our patents or other intellectual property rights; and
- the costs of operating as a public company.

Our ability to raise additional funds will depend on financial, economic, and other factors, many of which are beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be forced to delay, reduce or terminate our business activities.

We owe a significant amount of money to Veru, which funds we do not have. Veru may take action against us to enforce its rights to payment in the future, which could have a material adverse effect on us and our operations.

Due to recent financial constraints, the Company may be unable to timely pay amounts due to Veru, from whom we purchased ENTADFI in April 2023. We may not have sufficient funds to pay amounts due to Veru in the near term, if at all, including but not limited to $10 million, $5 million of which was due on April 19, 2024 and is subject to certain forbearance terms, and $5 million is due on September 30, 2024. On April 24, 2024, Veru agreed to forbear its rights and remedies until March 31, 2025 with respect to, among other things, our inability to pay amounts due as of April 19, 2024. However, Veru may take future action against us, including filing legal proceedings against us seeking amounts due and interest accrued or attempting to terminate its relationship with us. If Veru were to take legal action against us, we may be forced to scale back our business plan and/or seek bankruptcy protection. We may be subject to litigation and damages for our failure to pay amounts due to Veru, and may be forced to pay interest and penalties, which funds we do not currently have. We are currently considering strategic options for ENTADFI, including a potential sale, and plan to seek funding to support our operations, and to pay amounts due to Veru, through a combination of equity offerings, debt financing or other capital sources, including potential collaborations, licenses, sales, and other similar arrangements, which may not be available on favorable terms, if at all. The sale of additional equity or debt securities, if accomplished, may result in dilution to our stockholders. Furthermore, any revenue or financing proceeds that we are required to pay to Veru will detract from our ability to use such funds to support our operations.

Our current liabilities are significant, and if those to whom we owe accounts payable, such as Veru, IQVIA or other creditors or vendors, were to demand payment, we would be unable to pay.

As of March 31, 2024, we had total current liabilities of approximately $21.4 million, including accounts payable of approximately $4.3 million, accrued expenses of approximately $1.9 million, and approximately $15.2 million (net of discounts) related to notes payable, primarily due to Veru and the debenture due to the PMX Investor. As of the same date, we had cash of only $4.5 million. We are currently considering strategic options for ENTADFI, including a potential sale, and plan to seek funding to support our operations. However, the level of our current liabilities may make it more difficult for us to obtain adequate financing on favorable terms, if at all. If those to whom these payments are due were to demand immediate payment, as they are entitled to do, and we are not able to make the required payments, we would be subject to liability if our creditors chose to enforce their rights, which could result in our bankruptcy and insolvency. Under such a scenario, our assets would be distributed to our creditors, leaving nothing to be distributed to our stockholders.

Risks Related to the Commercialization of our Products

Company shareholders may not realize a benefit from the ENTADFI or Proteomedix acquisitions commensurate with the ownership dilution they have experienced in connection with the transactions.

If the Company is unable to realize the full strategic and financial benefits previously anticipated from the recent ENTADFI and Proteomedix acquisitions, our shareholders may experience a dilution of their ownership interests in our Company without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the Company is able to realize only part of the strategic and financial benefits previously anticipated from the transactions.

We may fail or elect not to commercialize our products.

We may not successfully commercialize our products. We or our collaboration partners in any potential commercial marketing efforts of our product may not be successful in achieving widespread patient or physician awareness or acceptance of this product. Also, we may be subject to pricing pressures from competitive products or from governmental or commercial payors or regulatory bodies that could make it difficult or impossible for us to commercialize our products. Any failure to commercialize our products could have a material adverse effect on our future revenue and our business.

In light of (i) the time and resources needed to continue pursuing commercialization of ENTADFI, and (ii) the Company's cash runway and indebtedness, the Company has determined to pause its commercialization of ENTADFI, as it considers strategic alternatives, including a potential sale of the ENTADFI assets. To that end, the Company has engaged an investment advisor to assist with a potential sale or other transaction of the ENTADFI assets. The Company continues to consider various measures, including strategic alternatives, to rationalize its operations and optimize its existing Proclarix diagnostic program.

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

ENTADFI is subject to competition from other BPH drugs and larger, well-established companies with substantially greater resources than us.

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

Zydus Life Sciences recently received FDA approval for a combined finasteride-tadalafil (5 mg/5 mg) capsule, pursuant to the FDA's Competitive Generic Therapy Program, which was designed to enhance patient access to affordable medications by encouraging the development and commercialization of generic drugs in clinical areas with limited generic options for patients. Pursuant to the program, Zydus has a 180-day period to be the sole supplier of the generic version of the drug in the market and during this period, other generic manufacturers cannot enter the market with their versions of the same drug, provided that Zydus commences marketing the drug by 75 days from approval. As a result, there is a risk that the Company will face additional challenges in resuming commercializing ENTADFI, if it chooses to do so.

Other parties have developed and marketed drugs for BPH that have been accepted by the healthcare provider, patient, and payor communities. Many of these other products have also reached the point where they are now generic drugs, which means that they are sold at a very low price, a price which ENTADFI may not be able to meet which could limit the reach of ENTADFI into the healthcare provider, patient, and payor communities, including government payors.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

There are no transactions that have not been previously included in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

There were no share repurchases for the three months ended March 31, 2024.

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The following documents are filed as exhibits to this Report.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation filed with Delaware Secretary of State on February 23, 2022.(1)
3.2	Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation(2)
3.3	Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation.(3)
3.4	Fourth Amended and Restated Bylaws of the Company.(3)
10.1	Release, dated January 10, 2024, between the Company and Dr. Neil Campbell.(4)
10.2	Separation Agreement, dated January 17, 2024, between the Company and Erin Henderson.(5)
10.3	Consulting Agreement, dated January 17, 2024, between the Company and The Aetos Group.(5)
10.4	Debenture, dated January 23, 2024.(6)
10.5	Consulting Agreement, dated January 4, 2024, between Proteomedix and Thomas Meier.(7)
10.6	Forbearance Agreement, dated April 24, 2024, between the Company and Veru(8)
10.7	Amendment to Non-Convertible Debenture, dated April 24, 2024, between the Company and Altos(8)
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Principal Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

(1) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on February 24, 2022.
(2) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on April 24, 2023.
(3) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on December 21, 2023.
(4) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on January 12, 2024.
(5) Incorporated by reference the Company's Current Report on Form 8-K, filed with the SEC on January 19, 2024.
(6) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on January 29, 2024.
(7) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on February 12, 2024.
(8) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 26, 2024.

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.

Onconetix, Inc.

Date: May 20, 2024

/s/ Ralph Schiess
Ralph Schiess
Interim Chief Executive Officer
(principal executive officer)

Date: May 20, 2024

By: /s/ Bruce Harmon
Bruce Harmon
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 31.1

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

I, Ralph Schiess, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 20, 2024

By: /s/ Ralph Schiess
Ralph Schiess
Interim Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Bruce Harmon, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 20, 2024

By: /s/ Bruce Harmon
Bruce Harmon
Chief Financial Officer
(*Principal Financial Officer)*

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Onconetix, Inc. (the "Company") for the quarterly period ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ralph Schiess, Interim Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

Date: May 20, 2024

By: /s/ Ralph Schiess
Ralph Schiess
Interim Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Onconetix, Inc. (the "Company") for the quarterly period ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Bruce Harmon, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

Date: May 20, 2024

By: /s/ Bruce Harmon
Bruce Harmon
Chief Financial Officer
(Principal Financial Officer)