

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 2
TO
FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Onconetix, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

83-2262816
(I.R.S. Employer
Identification No.)

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Cincinnati, Ohio 45202
Telephone: (513) 620-4101
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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 | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| | | Emerging growth company | <input checked="" type="checkbox"/> |

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 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholder named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

PROSPECTUS

SUBJECT TO COMPLETION

DATED DECEMBER 10, 2024

6,250,000 Shares of Common Stock

This prospectus relates to the offer and sale from time to time by Keystone Capital Partners, LLC (“Keystone” or the “Selling Stockholder”) of up to 6,250,000 shares of common stock of Onconetix, Inc. (“we,” “us,” “our,” the “Company,” or “Onconetix”), par value \$0.00001 per share (the “Common Stock”), that have been or may be issued by us to Keystone pursuant to that certain Common Stock ELOC Purchase Agreement, dated as of October 2, 2024, by and between us and Keystone (the “ELOC Purchase Agreement”), establishing an equity line of credit (“ELOC”). Such shares of our Common Stock include up to 6,250,000 shares of Common Stock (assuming the shares to be issued are sold at a price of \$4.00 per share) that we may elect, in our sole discretion, to issue and sell to Keystone, from time to time from and after the commencement date under the ELOC Purchase Agreement, and subject to applicable stock exchange rules.

The actual number of shares of our Common Stock issuable will vary depending on the then-current market price of shares of our Common Stock sold to the Selling Stockholder under the ELOC Purchase Agreement, but will not exceed the number set forth in the preceding sentences unless we file an additional registration statement under the Securities Act of 1933, as amended (the “Securities Act”), with the U.S. Securities and Exchange Commission (SEC). See “*The Keystone Equity Financing*” for a description of the ELOC Purchase Agreement and “*Selling Stockholder*” for additional information regarding Keystone.

We are registering the shares on behalf of the Selling Stockholder, to be offered and sold by it from time to time. We are not selling any securities under this prospectus, and will not receive any proceeds from the sale of Common Stock by the Selling Stockholder pursuant to this prospectus. We may receive up to \$25.0 million in aggregate gross proceeds from Keystone under the ELOC Purchase Agreement in connection with sales of the shares of our Common Stock pursuant to the ELOC Purchase Agreement at varying purchase prices after the date of this prospectus. However, the actual proceeds from Keystone may be less than this amount depending on the number of shares of our Common Stock sold and the price at which the shares of our Common Stock are sold. The purchase price per share that Keystone will pay for shares of Common Stock purchased from us under the ELOC Purchase Agreement will fluctuate based on the market price of our shares at the time we elect to sell shares to Keystone and, further, to the extent that the Company sells shares of Common Stock under the ELOC Purchase Agreement, substantial amounts of shares could be issued and resold, which would cause dilution and may impact the Company’s stock price.

Our Common Stock is listed on The Nasdaq Capital Market under the symbol “ONCO.” The last reported sale price of our Common Stock on The Nasdaq Capital Market on December 9, 2024 was \$0.7101 per share. We recommend that you obtain current market quotations for our Common Stock prior to making an investment decision.

The Selling Stockholder is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act. The Selling Stockholder may offer all or part of the shares for resale from time to time through public or private transactions, at either prevailing market prices or at privately negotiated prices. Our registration of the shares of Common Stock covered by this prospectus does not mean that the Selling Stockholder will offer or sell any of the shares. With regard only to the shares the Selling Stockholder sells for its own behalf, the Selling Stockholder may be deemed an “underwriter” within the meaning of the Securities Act of 1933, as amended (the “Securities Act”). The Company has paid all of the registration expenses incurred in connection with the registration of the shares. We will not pay any of the selling commissions, brokerage fees and related expenses.

We will pay the expenses incurred in registering the shares, including legal and accounting fees. See “*Plan of Distribution*” on page 28 of this prospectus.

Investing in our Common Stock involves certain risks. See “*Risk Factors*” on page 8 of this prospectus, included in any accompanying prospectus supplement and in the documents incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to purchase these securities.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. We urge you to read the entire prospectus, any amendments or supplements, any free writing prospectuses, and any documents incorporated by reference carefully before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2024

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission (the “SEC”) for the delayed or continuous offering and sale of securities pursuant to Rule 415 under the Securities Act. This prospectus generally describes Onconetix, Inc. and our Common Stock. The Selling Stockholder may use this registration statement to sell up to an aggregate of up to 6,250,000 shares of our Common Stock from time to time through any means described in the section entitled “*Plan of Distribution*.” Our registration of the securities covered by this prospectus does not mean that either we or the Selling Stockholder will issue, offer or sell, as applicable, any of the securities registered hereunder. Under this registration statement, the Selling Stockholder may, from time to time, sell the securities offered by it described in this prospectus.

We will not receive any proceeds from the sale of Common Stock by the Selling Stockholder pursuant to this prospectus. However, we will pay the expenses, other than underwriting discounts and commissions, associated with the sale of shares pursuant to this prospectus. We may receive up to \$25.0 million in aggregate gross proceeds from Keystone under the ELOC Purchase Agreement in connection with sales of the shares of our Common Stock pursuant to the ELOC Purchase Agreement after the date of this prospectus. However, the actual proceeds from Keystone may be less than this amount depending on the number of shares of our Common Stock sold and the price at which the shares of our Common Stock are sold.

We and the Selling Stockholder, as applicable, may deliver a prospectus supplement with this prospectus, to the extent appropriate, to update the information contained in this prospectus. The prospectus supplement may also add, update or change information included in this prospectus. You should read both this prospectus and any applicable prospectus supplement, together with additional information described below under the captions “*Where You Can Find More Information*” and “*Incorporation of Certain Information by Reference*.”

No offer of these securities will be made in any jurisdiction where the offer is not permitted.

You should rely only on the information contained in or incorporated by reference in this prospectus, any accompanying prospectus supplement or in any related free writing prospectus filed by us with the SEC. We have not authorized anyone to provide you with different information. This prospectus and any accompanying prospectus supplement do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the securities described in this prospectus or such accompanying prospectus supplement or an offer to sell or the solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should assume that the information appearing in this prospectus, any prospectus supplement, the documents incorporated by reference and any related free writing prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

Unless the context otherwise indicates, references in this prospectus to “we,” “our” and “us” refer, collectively, to Onconetix, Inc., a Delaware corporation.

Unless otherwise indicated, all share amounts and share prices disclosed herein are presented on a post-split basis, giving effect to the one-for-forty (1:40) reverse stock split (the “Reverse Stock Split”) of all of the outstanding shares of the Company’s issued and outstanding Common Stock on September 24, 2024. Any financial statements incorporated by reference into this prospectus that were filed prior to the Reverse Stock Split present the outstanding shares on a pre-split basis. Financial statements filed after September 24, 2024 retroactively present the shares on a post-split basis.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains “forward-looking statements” within the meaning of the federal securities laws, and that involve significant risks and uncertainties. Words such as “may,” “should,” “could,” “would,” “predicts,” “potential,” “continue,” “expects,” “anticipates,” “future,” “intends,” “plans,” “believes,” “estimates,” and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or management’s good faith belief as of that time with respect to future events and are subject to significant risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Forward-looking statements are subject to a number of risks, uncertainties and assumptions in other documents we file from time to time with the SEC, specifically our most recent Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K.

Important factors that could cause such differences include, but are not limited to:

- our projected 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;
- our ability to commercialize or monetize Proclarix and integrate the assets and commercial operations acquired in the share exchange with Proteomedix AG (“Proteomedix”);
- our reliance on third parties, including Labcorp, to develop, market, distribute and sell our products;
- the successful development of our commercialization capabilities, including sales and marketing capabilities.
- our ability to obtain and 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 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 the Company or Proteomedix, which could have an adverse effect on their respective businesses and financial results.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “*Risk Factors*.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus forms a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

PROSPECTUS SUMMARY

The SEC allows us to “incorporate by reference” certain information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will update automatically, supplement and/or supersede the information disclosed in this prospectus. Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other document that also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You should read the following summary together with the more detailed information regarding our company, our Common Stock and our financial statements and notes to those statements included in this prospectus.

Our Company

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 determined to pause its commercialization of ENTADFI during the first quarter of 2024, as it explores strategic alternatives to monetize ENTADFI, such as a potential sale of the ENTADFI assets. To that end, the Company has been working with an investment advisor to assist with a potential sale or other transaction of the ENTADFI assets during the second and third quarters of 2024. There is currently no plan to resume commercialization of ENTADFI, and as such, if we are not able to consummate a sale or other transaction of the ENTADFI assets, we may abandon the assets and destroy our inventory of the product. In addition, as part of cost reduction efforts and in connection with our initial 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. Based on the circumstances surrounding ENTADFI, at June 30, 2024, the ENTADFI assets were fully impaired. Refer to Notes 4 and 5 in the accompanying condensed consolidated financial statements incorporated by reference in this prospectus for further discussion. The Company continues to search for a permanent Chief Executive Officer and Chief Financial 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. Approximately 10% of all men have elevated PSA levels, commonly referred to as the diagnostic “grey zone”, of which only 20 – 40% present clinically with cancer. Proclarix is intended for use in diagnosing these patients where it is difficult to decide if a biopsy is necessary to verify a potential clinically significant cancer diagnosis. 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.

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 halted vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities.

During the third quarter of 2023, we halted our vaccine discovery and development programs, and accordingly, we now operate in one segment: commercial. The commercial segment was new in the second quarter of 2023 and is currently dedicated to the development and commercialization of Proclarix.

Given Proclarix is CE-marked for sale in the European Union, we expect to generate revenue from sales of Proclarix by 2026. 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 in the European Union, and ENTADFI, from which we have not generated any revenue from product sales, and for which we have now abandoned commercialization activities for. We are exploring strategic alternatives to monetize ENTADFI, such as a potential sale of the ENTADFI assets. However, if we are not able to consummate a sale or other transaction of the ENTADFI assets, we may abandon the assets and destroy our inventory of the product. 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, the proceeds received from the issuance of debt in January 2024, the proceeds received from a warrant exercise in July 2024, and proceeds received from the private placement in October 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 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.

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 September 30, 2024, the Company had a working capital deficit of approximately \$16.3 million and an accumulated deficit of approximately \$86.0 million. In addition, as of December 5, 2024, the Company's cash balance was approximately \$0.4 million, which is held by the Company's foreign subsidiary. The Company believes that its current cash balance is not sufficient to fund its operations through the end of December 2024, until it can utilize the ELOC, which it entered into in on October 2, 2024, and as such, we will need to raise additional capital prior to this to sustain operations. However, based on the terms of the ELOC and the current maximum availability, management has determined that the funds readily available under the ELOC will not be sufficient to sustain operations for the next 12 months.

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 condensed consolidated financial statements incorporated by reference in this prospectus 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, 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.

Recent Developments

PIPE Financing and ELOC

On October 2, 2024, the Company entered into, and sold, to six institutional investors (collectively, the “PIPE Investors”), pursuant to a securities purchase agreement an aggregate of 3,499 shares of Series C convertible preferred stock, par value \$0.00001 per share (“Series C Preferred Stock”), which includes an issuance of 840 shares of Series C Preferred Stock to the lead investor in consideration for the PIPE Investors’ irrevocable commitment to purchase shares of the Series C Preferred Stock, and warrants to purchase 591,856 shares of Common Stock, (together, the “PIPE Securities”) for aggregate cash proceeds to the Company of \$2.0 million and net proceeds of \$1.9 million. The exercise price of the warrants is \$4.38, and the warrants are exercisable six months after the issuance date and expire on the third anniversary of the initial exercisability date.

On October 2, 2024, the Company entered into a Common Stock ELOC Purchase Agreement relating to a Committed Equity Facility with Keystone, whereby the Company may offer and sell, from time to time at its sole discretion, and whereby Keystone has committed to purchase, up to \$25.0 million of the Company’s newly issued Common Stock, subject to certain limitations. Concurrently with entering into the ELOC Purchase Agreement, the Company also entered into a registration rights agreement with Keystone, pursuant to which it agreed to provide Keystone with certain registration rights related to the shares issued under the ELOC Purchase Agreement (the “ELOC Registration Rights Agreement”). For more information, see “*ELOC Financing*.”

Reverse Stock Split

On September 23, 2024, the Company filed an amendment (the “Amendment”) to the Company’s Amended and Restated Certificate of Incorporation to effect a Reverse Stock Split of all of the outstanding shares of its issued and outstanding Common Stock at a ratio of one-for-forty (1:40). The Reverse Stock Split became effective in accordance with the terms of the Amendment at 12:01 a.m. Eastern Time on September 24, 2024 (the “Effective Time”). The Company’s Common Stock continued to be traded on The Nasdaq Capital Market under the symbol ONCO and began trading on a split-adjusted basis when the market opened on Tuesday, September 24, 2024, under a new CUSIP number, 68237Q104.

At the Effective Time, every 40 shares of the Company’s issued and outstanding Common Stock were converted automatically into one issued and outstanding share of Common Stock, with no corresponding reduction in the number of authorized shares of Common Stock, and without any change in the par value per share.

Conversion of Series A Preferred Stock

On September 24, 2024, the Company issued an aggregate of 142,749 post-Reverse Stock Split shares of Common Stock to Veru Inc. (“Veru”), following Veru’s election to convert all of the 3,000 shares of Series A preferred stock (“Series A Preferred Stock”) of the Company issued to it on September 29, 2023. The Series A Preferred Stock was originally issued to Veru pursuant to an Amendment to Asset Purchase Agreement, dated September 29, 2023, between the Company and Veru.

Conversion of Series B Preferred Stock

On September 24, 2024, the Company issued an aggregate of 6,741,820 post-Reverse Stock Split shares of Common Stock to certain stockholders of the Company (the “PMX Converted Shares”) who were formerly holders of outstanding capital stock or convertible securities (the “Sellers”) of Proteomedix AG (“Proteomedix”), pursuant to the automatic conversion of all the 2,696,729 shares of Series B preferred stock (“Series B Preferred Stock”) of the Company, which Series B Preferred Stock was originally issued to the Sellers on December 15, 2023. The Series B Preferred Stock was originally issued to the Sellers pursuant to a Share Exchange Agreement, dated December 15, 2023, between the Company, Proteomedix and the Sellers (the “Share Exchange Agreement”), and were subject to automatic conversion following (i) the Company’s receipt of stockholder approval for the issuance of the PMX Converted Shares and (ii) the effectiveness of the Reverse Stock Split, which provided for a sufficient number of authorized shares to issue the PMX Converted Shares, as contemplated by the Share Exchange Agreement.

Altos Units

On September 24, 2024, pursuant to the Subscription Agreement, dated December 18, 2023, between the Company and Altos Venture AG (“Altos” and such agreement, the “Subscription Agreement”), the Company issued an aggregate of 513,424 units (the “Units”) to Altos, each Unit comprised of (i) one share of Common Stock and (ii) one pre-funded warrant (collectively, the “Altos Warrants”) to purchase 0.3 shares of Common Stock at an exercise price of \$0.04 per share. The Altos Warrants were immediately exercisable at any time on or after the date of issuance and had a term of exercise of five (5) years from the date of issuance. Additional shares are issuable to Altos to the extent Altos continues to hold Common Stock included in the Units and if the VWAP during the 270 days following closing is less than \$10.00, as set forth in the Subscription Agreement.

On September 24, 2024, Altos exercised all of the Altos Warrants, and the Company issued to Altos an additional 154,027 shares of Common Stock upon such exercise.

Veru Agreement

Previously, on April 19, 2023, the Company entered into an asset purchase agreement with Veru (the “Veru APA”). Pursuant to the terms of the Veru APA, the Company agreed to pay to Veru aggregate consideration of \$20.0 million, consisting of: (i) \$6.0 million paid upon the closing of the transaction; (ii) \$4.0 million in the form of a non-interest bearing note payable due on September 30, 2023; and (iii) \$10.0 million in the form of two equal (i.e. each for \$5.0 million) non-interest bearing notes payable, which were to be due on April 19, 2024 (the “April Veru Note”) and September 30, 2024 (the “September Veru Note”), respectively. On September 29, 2023, the parties amended (the “Veru Amendment”) the Veru APA. Pursuant to the Veru Amendment, the \$4.0 million note payable originally due on September 30, 2023, was deemed paid and fully satisfied upon (1) the payment to Veru of \$1 million in immediately available funds on September 29, 2023, and (2) the issuance to Veru by October 3, 2023, of 3,000 shares of Series A Preferred Stock of the Company.

On April 24, 2024, the Company entered into a Forbearance Agreement with Veru (the “Original Forbearance Agreement”), pursuant to which Veru agreed, among other things, to forbear from exercising its rights and remedies under the April Veru Note until March 31, 2025 (the “April 2024 Forbearance Period”).

On September 19, 2024, the Company entered into an Amended and Restated Forbearance Agreement with Veru (the “A&R Forbearance Agreement”) which amends and restates the Original Forbearance Agreement in its entirety. Pursuant to the A&R Forbearance Agreement, Veru will forbear from exercising its rights under both the April Veru Note and the September Veru Note, subject to the terms and conditions set forth below.

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

Pursuant to the A&R Forbearance Agreement, the Company agreed to make the following required payments (the “Required Payments”) during the April 2024 Forbearance Period first to accrued and unpaid interest under the April Veru Note and then any remainder to the outstanding principal amount of the April Veru Note:

- Interest at the rate of 10% per annum shall accrue on any unpaid principal balance of the April Veru commencing on April 20, 2024 through the date that the outstanding principal balance under the April Veru Note is paid in full;

- monthly payments equal to 25% (increased from 15% in the Original Forbearance Agreement) 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 cash receipts of the Company or its subsidiaries from certain sale or licensing revenues or payments (the Ordinary Cash Revenue”), which increased amount shall begin on October 20, 2024 for cash receipts in September 2024;
- payment of 20% (increased from 10% in the Original Forbearance Agreement) of the net proceeds from certain financing or other transactions outside the ordinary course of business completed by the Company or any of its subsidiaries during the April 2024 Forbearance Period, which increased amount will begin for any net proceeds received after September 19, 2024;
- 15% of the Ordinary Cash Revenue generated in August 2024 shall be due to Veru on September 26, 2024 (the “September Veru Payment”); and
- The remaining balance of the April Veru Note will be due at the end of the April 2024 Forbearance Period.

The Company and Veru also agreed to the following amendments to the September Veru Note in the A&R Forbearance Agreement:

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

On September 26, 2024, Veru and the Company entered into a waiver agreement, pursuant to which Veru postponed the Company’s obligation to make the September Veru Payment until the earlier of (i) the date upon which the Company consummates a financing transaction in which it raises gross proceeds of greater or equal to \$1,000,000 and (ii) October 4, 2024. The Company paid the September Veru Payment on October 10, 2024.

On November 26, 2024, the Company and Veru entered into a waiver and amendment to the A&R Forbearance Agreement (the “Amendment”), pursuant to which Veru agreed to waive the due date for payment of applicable Cash Receipt Payments (as such term is defined in the A&R Forbearance Agreement) generated in October 2024 until the Company receives funds of at least \$97,000 pursuant to its equity line of credit facility with Keystone Capital Partners LLC. In exchange, the Company agreed to increase its payments to be made to Veru out of future financing and strategic transactions through June 30, 2025, from 20% to 25% of net proceeds generated from such transactions.

Warrant Inducement

On July 11, 2024, the Company, entered into common stock preferred investment options exercise inducement offer letters (the “Inducement Letter”) with certain holders of existing preferred investment options to purchase shares of the Company’s common stock at the original exercise prices of \$101.84 and \$43.60 per share, issued on August 11, 2022 and August 2, 2023, respectively, pursuant to which the holders agreed to exercise for cash such existing preferred investment options to purchase an aggregate of 186,465 of the Company’s common stock, at a reduced exercise price of \$6.00 per share, in consideration for the Company’s agreement to issue new preferred investment options (the “PIOs”) to purchase up to an aggregate of 559,397 shares of the Company’s common stock.

The transaction closed on July 12, 2024 and the Company received aggregate net proceeds of approximately \$0.9 million from the exercise of the existing preferred investment options by the holders and the sale of the Inducement PIOs, after deducting placement agent fees and other offering expenses payable by the Company.

The Company engaged H.C. Wainwright & Co., LLC (“Wainwright”) to act as its exclusive placement agent in connection with the Warrant Inducement and paid Wainwright a cash fee equal to 7.5% of the gross proceeds received from the exercise of the existing preferred investment options as well as a management fee equal to 1.0% of the gross proceeds from the exercise of the existing preferred investment options, plus the reimbursement of up to \$85,000 in certain expenses. The Company also agreed to (i) issue to Wainwright or its designees an aggregate of 13,054 preferred investment options, and (ii) upon any exercise for cash of the Inducement PIOs, 7.5% of the aggregate exercise price and such number of warrant to purchase shares of common stock equal to 7.0% of the aggregate number of such shares of common stock underlying the Inducement PIOs that have been exercised, which warrants will have substantially the same terms as the Placement Agent Inducement PIOs.

The Inducement PIOs have an initial exercise price of \$6.00 per share, subject to adjustment; one-third of such preferred investment options will expire five years from the date of stockholder approval (September 5, 2024), and the remaining two-thirds will expire twenty-four months from such date. The Placement Agent Inducement PIOs have an initial exercise price of \$7.50 per share, subject to adjustment, and will expire five years from the issuance date.

In addition, per the terms of the Inducement Letter, the Company agreed not to issue any shares of common stock or common stock equivalents or to file any other registration statement with the SEC (in each case, subject to certain exceptions) until the later of (i) the filing of a definitive proxy statement on Schedule 14A for the purpose of obtaining the requisite stockholder approval and (ii) 30 days after the closing date. The Company also agreed not to effect or agree to effect any variable rate transaction (as defined in the Inducement Letter) until six months after the closing date (subject to certain exceptions).

ABOUT THIS OFFERING

| | |
|---|---|
| Common Stock outstanding prior to this offering | 8,294,734 shares |
| Shares of Common Stock offered by the Selling Stockholder | Up to 6,250,000 shares of Common Stock (assuming the shares to be issued are sold at a price of \$4.00 per share) |
| Common Stock to be outstanding after this offering | 14,544,734 shares (assuming the issuance of all shares of Common Stock issuable under the ELOC Purchase Agreement) |
| Use of proceeds | <p>We are not selling any securities under this prospectus, and will not receive any proceeds from the sale of Common Stock by the Selling Stockholder pursuant to this prospectus. We may receive up to \$25.0 million in aggregate gross proceeds from Keystone under the ELOC Purchase Agreement in connection with sales of the shares of our Common Stock pursuant to the ELOC Purchase Agreement after the date of this prospectus. However, the actual proceeds from Keystone may be less than this amount depending on the number of shares of our Common Stock sold and the price at which the shares of our Common Stock are sold.</p> <p>Pursuant to the ELOC Purchase Agreement, 30% of the gross proceeds to the Company from any sale of Common Stock thereunder must be applied towards the redemption of the Company's Series C Preferred Stock.</p> <p>Pursuant to the Amended and Restated Forbearance Agreement, dated September 19, 2024, between the Company and Veru, as further amended on November 26, 2024, we are required to pay to Veru 25% of the net proceeds received from any sale of Common Stock under the ELOC Purchase Agreement to pay down our obligations to Veru.</p> |
| Terms of this offering | The Selling Stockholder, including its transferees, donees, pledgees, assignees, and successors-in-interest, may sell, transfer, or otherwise dispose of any or all of the shares of Common Stock offered by this prospectus from time to time on The Nasdaq Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. The shares of Common Stock may be sold at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market price or at negotiated prices. |
| Nasdaq symbol | Our Common Stock is listed on The Nasdaq Capital Market under the symbol "ONCO." |
| Risk Factors | Investing in our securities involves significant risks. Before making a decision whether to invest in our securities, please read the information contained in or incorporated by reference under the heading " <i>Risk Factors</i> " in this prospectus, the documents we have incorporated by reference herein and under similar headings in other documents filed after the date hereof and incorporated by reference into this prospectus. See " <i>Incorporation of Certain Information by Reference</i> " and " <i>Where You Can Find More Information</i> ." |

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described in this prospectus, in our most recent Annual Report on Form 10-K, as supplemented and updated by subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K that we have filed or will file with the SEC, and in other documents which are incorporated by reference into this prospectus, before making an investment decision pursuant to this.

Our business, financial condition and results of operations could be materially and adversely affected by any or all of these risks or by additional risks and uncertainties not presently known to us or that we currently deem immaterial that may adversely affect us in the future.

Risks Related to This Offering

It is not possible to predict the actual number of shares of our Common Stock, if any, we will sell under the ELOC Purchase Agreement, or the actual gross proceeds resulting from those sales or the dilution to you from those sales. Further, we may not have access to the full amount available under the ELOC Purchase Agreement.

Pursuant to the ELOC Purchase Agreement, Keystone shall purchase from us up to the lesser of (i) \$25.0 million in shares of our Common Stock and (ii) 1,658,525 shares, representing 19.99% of the total number of shares of Common Stock outstanding immediately prior to the execution of the ELOC Purchase Agreement (the "Exchange Cap"), upon the terms and subject to the conditions and limitations set forth in the ELOC Purchase Agreement (the "Keystone Commitment Amount"); provided, however, that such limitations will not apply if we obtain stockholder approval to issue additional shares of Common Stock. On October 11, 2024 the Company obtained stockholder approval to issue shares to Keystone in excess of the Exchange Cap. Accordingly, we have reserved 6,250,000 shares for issuance under the ELOC Purchase Agreement and resale pursuant to this prospectus. The shares of our Common Stock that may be issued under the ELOC Purchase Agreement may be sold by us to Keystone at our discretion from time to time from the Commencement Date (as defined below) until the earliest to occur of (i) the 36-month anniversary of the effective date of the registration statement of which this prospectus forms a part, (ii) the date on which Keystone has purchased the Keystone Commitment Amount pursuant to the ELOC Purchase Agreement, (iii) the date on which our Common Stock fails to be listed or quoted on Nasdaq or any successor Eligible Market (as defined in the ELOC Purchase Agreement), and (iv) the date on which, pursuant to or within the meaning of any bankruptcy law, a custodian is appointed for us or for all or substantially all of our property, or we make a general assignment for the benefit of our creditors.

We generally have the right to control the timing and amount of any sales of our Common Stock to Keystone under the ELOC Purchase Agreement. Sales of our Common Stock, if any, to Keystone under the ELOC Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Keystone all, some or none of the Common Stock that may be available for us to sell to Keystone pursuant to the ELOC Purchase Agreement. Accordingly, we cannot guarantee that we will be able to sell all of the Keystone Commitment Amount or how much in proceeds we may obtain under the ELOC Purchase Agreement. If we cannot sell securities under the Keystone Equity Financing, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could have a material adverse effect on our liquidity and cash position.

Because the purchase price per share of Common Stock to be paid by Keystone for the Common Stock that we may elect to sell to Keystone under the ELOC Purchase Agreement, if any, will fluctuate based on the market prices of our Common Stock at the time we make such election, it is not possible for us to predict, as of the date of this prospectus and prior to any such sales, the number of shares of Common Stock that we will sell to Keystone under the ELOC Purchase Agreement, the purchase price per share that Keystone will pay for shares of Common Stock purchased from us under the ELOC Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Keystone under the ELOC Purchase Agreement.

We are registering 6,250,000 shares of our Common Stock under this prospectus. As of December 5, 2024, there were 8,294,734 shares of Common Stock outstanding. If all of the 6,250,000 shares of our Common Stock offered for resale by the Selling Stockholder under this prospectus were issued and outstanding as of December 5, 2024, such shares would represent approximately 43.0% of total number of shares of our Common Stock outstanding.

The actual number of shares of our Common Stock Issuable will vary depending on the then current market price of shares of our Common Stock sold to the Selling Stockholder in this offering and the number of shares of our Common Stock we ultimately elect to sell to the Selling Stockholder under the ELOC Purchase Agreement. If it becomes necessary for us to issue and sell to Keystone under the ELOC Purchase Agreement more than the 6,250,000 shares of our Common Stock (assuming the shares are sold at a price of \$4.00 per share) being registered for resale under this prospectus in order to receive aggregate gross proceeds equal to \$25.0 million under the ELOC Purchase Agreement, we must file with the SEC one or more additional registration statements to register under the Securities Act the resale by Keystone of any such additional shares of our Common Stock we wish to sell from time to time under the ELOC Purchase Agreement, which the SEC must declare effective, in each case before we may elect to sell any additional shares of our Common Stock under the ELOC Purchase Agreement. Keystone is not obligated to buy any Common Stock under the ELOC Purchase Agreement if such shares, when aggregated with all other Common Stock then beneficially owned by Keystone and its affiliates (as calculated pursuant to Section 13(d) of the Securities Exchange Act, and Rule 13d-3 promulgated thereunder), would result in Keystone beneficially owning Common Stock in excess of 4.99% of the then-outstanding shares of Common Stock. Our inability to access a portion or the full amount available under the ELOC Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business or results of operation.

Keystone will pay less than the then-prevailing market price for our Common Stock, which could cause the price of our Common Stock to decline.

The purchase price of our Common Stock to be sold to Keystone under the ELOC Purchase Agreement is derived from the market price of our Common Stock on Nasdaq. Shares to be sold to Keystone pursuant to the ELOC Purchase Agreement will be purchased at a discounted price.

For example, we may effect sales to Keystone pursuant to a Fixed Purchase Notice (as defined below) at a purchase price equal to the lesser of 90% of (i) the daily VWAP (as defined below) of the Common Stock for the five trading days immediately preceding the applicable Fixed Purchase Date (as defined below) and (ii) the closing price of a share of Common Stock on the applicable Fixed Purchase Date during the full trading day on such applicable Purchase Date. See “*Keystone Committed Equity Financing*” for more information.

As a result of this pricing structure, Keystone may sell the shares they receive immediately after receipt of such shares, which could cause the price of our Common Stock to decrease.

Investors who buy shares of Common Stock from Keystone at different times will likely pay different prices.

Pursuant to the ELOC Purchase Agreement, we have discretion, to vary the timing, price and number of shares of Common Stock we sell to Keystone. If and when we elect to sell shares of Common Stock to Keystone pursuant to the ELOC Purchase Agreement, after Keystone has acquired such shares, Keystone may resell all, some or none of such shares at any time or from time to time in its sole discretion and at different prices. As a result, investors who purchase shares from Keystone in this offering at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Keystone in this offering as a result of future sales made by us to Keystone at prices lower than the prices such investors paid for their shares in this offering. In addition, if we sell a substantial number of shares to Keystone under the ELOC Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangements with Keystone may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

Future resales and/or issuances of shares of Common Stock, including pursuant to this prospectus, or the perception that such sales may occur, may cause the market price of our shares to drop significantly.

The shares of our Common Stock that may be issued under the ELOC Purchase Agreement may be sold by us to Keystone at our discretion from time to time from the date of effectiveness of effectiveness of the registration statement of which this prospectus forms a part until the earliest to occur of (i) the 36-month anniversary of the effective date of the registration statement of which this prospectus forms a part, (ii) the date on which Keystone has purchased the Aggregate Limit pursuant to the ELOC Purchase Agreement, (iii) the date on which our Common Stock fails to be listed or quoted on Nasdaq or any successor Eligible Market (as defined in the ELOC Purchase Agreement), and (iv) the date on which, pursuant to or within the meaning of any bankruptcy law, a custodian is appointed for us or for all or substantially all of our property, or we make a general assignment for the benefit of our creditors.

The purchase price for shares of our Common Stock that we may sell to Keystone under the ELOC Purchase Agreement will fluctuate based on the trading price of shares of our Common Stock. Depending on market liquidity at the time, sales of shares of our Common Stock may cause the trading price of shares of our Common Stock to decrease. We generally have the right to control the timing and amount of any future sales of shares of our Common Stock to Keystone. Additional sales of shares of our Common Stock, if any, to Keystone will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Keystone all, some or none of the additional shares of our Common Stock that may be available for us to sell pursuant to the ELOC Purchase Agreement. If and when we do sell shares of our Common Stock to Keystone, after Keystone has acquired shares of our Common Stock, Keystone may resell all, some or none of such shares of our Common Stock at any time or from time to time in its discretion and at different prices. Therefore, sales to Keystone by us could result in substantial dilution to the interests of other holders of shares of our Common Stock. In addition, if we sell a substantial number of shares of our Common Stock to Keystone under the ELOC Purchase Agreement, or if investors expect that we will do so, the shares held by Keystone will represent a significant portion of our public float and may result in substantial decreases to the price of our Common Stock. The actual sales of shares of our Common Stock or the mere existence of our arrangement with Keystone may also make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

The market price of shares of our Common Stock could drop significantly if Keystone sells shares of Common Stock or is perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of shares of our Common Stock or other securities.

We may use proceeds from sales of our Common Stock made pursuant to the ELOC Purchase Agreement in ways with which you may not agree or in ways which may not yield a significant return.

We will have broad discretion over the use of proceeds from sales of our Common Stock made pursuant to the ELOC Purchase Agreement, including for any of the purposes described in the section entitled “*Use of Proceeds*,” and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds, their ultimate use may vary substantially from their currently intended use. While we expect to use the net proceeds from this offering as set forth in “*Use of Proceeds*,” we are not obligated to do so. The failure by us to apply these funds effectively could harm our business, and the net proceeds may be used for corporate purposes that do not increase our operating results or enhance the value of our Common Stock.

Other Risks

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 September 30, 2024, the Company had cash of approximately \$0.3 million, a working capital deficit of approximately \$16.3 million and an accumulated deficit of approximately \$86.0 million. In addition, as of December 5, 2024, the Company’s cash balance was approximately \$0.4 million, which is held by the Company’s foreign subsidiary, and the Company has approximately \$9.8 million of debt due within the next 12 months.

We estimate, as of the date of this prospectus, that our current cash balance is not sufficient to fund our operations through the end of December, until we can utilize the ELOC. 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. Management’s plans for funding the Company’s operations include generating product revenue from sales of Proclarix, which is still subject to further successful development and commercialization activities within certain jurisdictions. Management also intends to secure additional required funding through equity or debt financings if available, and to utilize the ELOC on an as-needed basis to assist with the paydown of the debentures and to fund current operating needs, subject to certain restrictions and beneficial ownership constraints. However, based on the terms of the ELOC and the current maximum availability, management has determined that the funds readily available under the ELOC will not be sufficient to sustain operations for the next 12 months. In addition, there are currently no other 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 whether the Company will have the funds available to be able to sustain its long-term 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, or, if it is required to, file for bankruptcy.

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 development and commercialization activities, including product manufacturing, marketing, sales, royalties, and distribution, for Proclarix and other products for which we have received or will receive marketing approval;
- 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 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 of which was due on September 30, 2024 and is subject to certain forbearance terms. 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 on April 19, 2024. Additionally, on September 19, 2024 and November 26, 2024, Veru agreed to forbear its rights and remedies until June 30, 2025 with respect to, among other things, our inability to certain pay amounts due on September 30, 2024 and November 20, 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 or abandonment, 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 September 30, 2024, we had total current liabilities of approximately \$17.4 million, including accounts payable of approximately \$4.1 million, accrued expenses of approximately \$1.3 million, the related party subscription liability of \$1.8 million, and approximately \$9.8 million (net of discounts) related to notes payable, primarily due to Veru. As of the same date, we had cash of only \$0.3 million. We are currently considering strategic options for ENTADFI, including a potential sale or abandonment, 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.

We are dependent on third parties, including Labcorp, to develop, market, distribute and sell our products.

Our ability to receive revenues is dependent upon the sales and marketing efforts of co-marketing partners and third-party distributors. In particular, the development and commercialization of Proclarix in the United States is being pursued by Labcorp, pursuant to an exclusive license agreement that grants Labcorp 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 for identification, screening, staging, predisposition, diagnosis, prognosis, monitoring, prevention or treatment selection with respect to prostate cancer. However, we do not have control over Labcorp's development and commercialization of Proclarix, and there can be no guarantee that Labcorp will continue to advance development and commercialization efforts, or that Labcorp will successfully commercialize Proclarix in the United States.

Labcorp may terminate or seek to renegotiate the terms of this agreement, which could adversely affect our business operations and financial condition. If Labcorp terminates the agreement or demands terms that are less favorable to us, we may experience disruptions in our product development and commercialization efforts, potentially leading to a loss of revenue and market share.

Additionally, if Labcorp is unable to commercialize Proclarix in the United States, and we fail to reach an agreement with any other commercialization partner, or upon reaching such an agreement that partner fails to sell a large volume of our products, it may have a negative impact on our business, financial condition, and results of operations.

PIPE FINANCING

On October 2, 2024, the Company entered into, and sold to the PIPE Investors, pursuant to the Securities Purchase Agreement an aggregate of 3,499 shares of Series C Preferred Stock, which includes an issuance of 830 shares of Series C Preferred Stock to the lead investor as consideration for the PIPE Investors' irrevocable commitment to purchase shares of the Series C Preferred Stock, and 591,856 PIPE Warrants, for aggregate cash proceeds to the Company of \$2.0 million. Concurrently with entering into the Securities Purchase Agreement, the Company also entered into a registration rights agreement with the PIPE Investors, pursuant to which it has agreed to provide the PIPE Investors with certain registration rights related to the shares of Common Stock underlying the PIPE Securities.

The material terms of the Series C Preferred Stock and the PIPE Warrants are set forth below.

Series C Preferred Stock

Certificate of Designations

General. Pursuant to the Certificate of Designations, the Company has authorized the issuance of up to 10,000 shares of Series C Preferred Stock, each having a stated value of \$1,000 per share (the "Stated Value"). The Company has issued 3,499 shares of the Company Series C Preferred Stock to the PIPE Investors.

Ranking. Except (i) for the Series A Preferred Stock of the Company (of which there are no shares currently outstanding), which shall be Parity Stock, and (ii) to the extent that the Required Holders (as defined in the Securities Purchase Agreement) expressly consent to the creation of Parity Stock or Senior Preferred Stock, all shares of capital stock of the Company will be junior in rank to all Preferred Shares with respect to the preferences as to dividends, distributions and payments upon the liquidation, dissolution and winding up of the Company.

Dividends. The holders of Series C Preferred Stock are entitled to dividends, on an as-if converted basis, equal to and in the same form as dividends actually paid on shares of Common Stock, when and if actually paid. In addition, from and after the occurrence and during the continuance of any Triggering Event, dividends ("Default Dividends") will accrue on the Stated Value of each Preferred Share at a rate of fifteen percent (15.0%) (the "Default Rate") per annum. Default Dividends are payable by way of inclusion of Default Dividends in the Conversion Amount (as defined below) on each Conversion Date, upon any redemption or upon any required payment upon any Bankruptcy Triggering Event. In the event that such Triggering Event is subsequently cured (and no other Triggering Event then exists), the accrual of Default Dividends will cease to be effective as of the calendar day immediately following the date of such cure; provided that Default Dividends as calculated and unpaid during the continuance of such Triggering Event will continue to apply to the extent relating to the days after the occurrence of such Triggering Event through and including the date of such cure of such Triggering Event.

Conversion Rights:

Conversion at Option of Holder. Each holder is entitled to convert any portion of the outstanding Preferred Shares held by such holder into validly issued, fully paid and non-assessable Conversion Shares at the Conversion Rate. Except as otherwise provided in the Certificate of Designations, the number of Conversion Shares issuable upon conversion of any Preferred Share will be determined by dividing (x) the Conversion Amount of such Preferred Share by (y) the Conversion Price (the "Conversion Rate"). As used herein, the term "Conversion Amount" means, with respect to each Preferred Share, as of the applicable date of determination, the sum of (1) the Stated Value thereof plus (2) any Default Dividends thereon as of such date of determination plus (3) any other amounts owed to such PIPE Investor pursuant to the terms of the Certificate of Designations or any other Transaction Document; and the term "Conversion Price" means, with respect to each Preferred Share, as of any Conversion Date or other date of determination, \$4.5056, subject to adjustment as provided in the Certificate of Designations.

Conversion at the Option of the Holder Upon the Occurrence of a Triggering Event. After the Stockholder Approval Date (as defined in the Securities Purchase Agreement), if a Triggering Event occurs and is continuing, at any time after the earlier of a holder's receipt of a Triggering Event Notice and such holder becoming aware of such Triggering Event (such earlier date, the "Alternate Conversion Right Commencement Date") and ending on the twentieth (20th) Trading Day after the later of (x) the date such Triggering Event is cured and (y) such holder's receipt of a Triggering Event Notice (such ending date, the "Alternate Conversion Right Expiration Date", and each such period, an "Alternate Conversion Right Period"), such holder may, at such holder's option, by delivery of a Conversion Notice to the Company (the date of any such Conversion Notice, each an "Alternate Conversion Date"), convert all, or any number of Preferred Shares held by such holder into shares of Common Stock at the Alternate Conversion Price (each, an "Alternate Conversion").

As used herein:

“Alternate Conversion Price” means, with respect to any Alternate Conversion that price which will be the lowest of (i) the applicable Conversion Price as in effect on the applicable Conversion Date of the applicable Alternate Conversion, and (ii) the greater of (x) the Floor Price and (y) 80% of the lowest VWAP of the Common Stock during the five (5) consecutive Trading Day period ending and including the Trading Day immediately preceding the delivery or deemed delivery of the applicable Conversion Notice (such period, the “Alternate Conversion Measuring Period”). All such determinations to be appropriately adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction that proportionately decreases or increases the Common Stock during such Alternate Conversion Measuring Period.

“Alternate Conversion Floor Amount” means an amount equal to the product obtained by multiplying (A) the higher of (i) the highest price that the Common Stock trades at on the Trading Day immediately preceding the relevant Alternate Conversion Date and (ii) the applicable Alternate Conversion Price and (B) the difference obtained by subtracting (i) the number of shares of Common Stock delivered (or to be delivered) to such holder on the applicable Share Delivery Deadline with respect to such Alternate Conversion from (ii) the quotient obtained by dividing (x) the applicable Conversion Amount that such holder has elected to be the subject of the applicable Alternate Conversion, by (y) the applicable Alternate Conversion Price, without giving effect to the Floor Price.

“Floor Price” means \$1.00 (as adjusted for stock splits, stock dividends, stock combinations, recapitalizations and similar events), or, subject to the rules and regulations of the Principal Market, such lower price as the Company and the Required Holders may agree, from time to time.

“Triggering Event Notice” means written notice from the Company delivered to each holder within two Business Days after the occurrence of a Triggering Event) that includes (i) a reasonable description of the applicable Triggering Event, (ii) a certification as to whether, in the reasonable opinion of the Company, such Triggering Event is capable of being cured and, if applicable, a reasonable description of any existing plans of the Company to cure such Triggering Event and (iii) a certification as to the date the Triggering Event occurred and, if cured on or prior to the date of such Triggering Event Notice, the applicable Alternate Conversion Right Expiration Date.

“Triggering Event” includes, but is not limited to, the following, subject to certain cure periods as set forth in the Certificate of Designations:

(i) the failure to file a registration statement for the resale of the shares of Common Stock underlying the Preferred Shares and the PIPE Warrants, or the failure of the applicable Registration Statement to be declared effective by the SEC, ten (10) days after the applicable deadline;

(ii) the failure to maintain the effectiveness of a registration statement pursuant to the terms of the Registration Rights Agreement;

(iii) the suspension from trading or the failure of the Common Stock to be trading or listed (as applicable) on an Eligible Market for a period of five (5) consecutive Trading Days;

(iv) failure to cure a Conversion Failure or a Delivery Failure (as defined in the PIPE Warrants) by delivery of the required number of shares of Common Stock within the requisite time frame;

(v) failure to maintain authorized, but unissued shares equal to 150% of the shares underlying the Preferred Shares and the PIPE Warrants;

(vi) the occurrence of any default under, redemption of or acceleration prior to maturity of at least an aggregate of \$500,000 of Indebtedness of the Company or any of its Subsidiaries, or a final judgment or judgments for the payment of money aggregating in excess of \$500,000 are rendered against the Company and/or any of its Subsidiaries;

(vii) the institution, commencement, court order or decree by or against the Company or any Subsidiary of certain bankruptcy, insolvency, reorganization or liquidation proceedings or other proceedings for the relief of debtors (the “Bankruptcy Triggering Events”);

(viii) the Company and/or any Subsidiary, individually or in the aggregate, either (i) fails to pay, when due, or within any applicable grace period, any payment with respect to any Indebtedness in excess of \$500,000 due to any third party (other than, with respect to unsecured Indebtedness only, payments contested by the Company and/or such Subsidiary (as the case may be) in good faith by proper proceedings and with respect to which adequate reserves have been set aside for the payment thereof in accordance with Generally Accepted Accounting Principles (GAAP)) or is otherwise in breach or violation of any agreement for monies owed or owing in an amount in excess of \$500,000, which breach or violation permits the other party thereto to declare a default or otherwise accelerate amounts due thereunder, or (ii) suffer to exist any other circumstance or event that would, with or without the passage of time or the giving of notice, result in a default or event of default under any agreement binding the Company or any Subsidiary, which default or event of default would or is likely to have a material adverse effect on the business, assets, operations (including results thereof), liabilities, properties, condition (including financial condition) or prospects of the Company or any of its Subsidiaries, individually or in the aggregate;

(ix) the Company or any Subsidiary breaches any representation or warranty in any material respect (other than representations or warranties subject to Material Adverse Effect or materiality, which may not be breached in any respect) or any covenant or other term or condition of any Transaction Document;

(x) a false or inaccurate certification (including a false or inaccurate deemed certification) by the Company that either (A) the Equity Conditions are satisfied, (B) there has been no Equity Conditions Failure, or (C) as to whether any Triggering Event has occurred;

(xi) any breach or failure in any respect by the Company or any Subsidiary to comply with any provision of the covenants included in the Certificate of Designations;

(xii) any Preferred Shares remain outstanding on or after April 2, 2026;

(xiii) any Change of Control occurs without the prior written consent of the Required Holders, which consent will not be unreasonably withheld, conditioned or delayed;

(xiv) any Material Adverse Effect occurs; or

(xv) any provision of any Transaction Document will at any time for any reason (other than pursuant to the express terms thereof) cease to be valid and binding on or enforceable against the Company, or the validity or enforceability thereof is contested.

Conversion Price Adjustments. If on the ninetieth (90th) calendar day and one hundred eightieth (180) calendar day (each an “Adjustment Date”) following the occurrence of the later of (x) the date that Company stockholders approve the transaction and all securities issuable to the PIPE Investors in connection therewith, as required by Nasdaq (“Stockholder Approval”) and (y) the earlier of (a) the effective date of the registration statement to be filed pursuant to the Registration Rights Agreement and (b) the date that the Series C Preferred Stock is eligible to be resold without restriction under Rule 144 of the Securities Act, as amended (the “Securities Act”), the Conversion Price then in effect is greater than the Market Price then in effect (the “Adjustment Price”), the Conversion Price will automatically lower to the Adjustment Price. As used herein, “Market Price” means, with respect to any Adjustment Date, the greater of (x) the Floor Price and (y) the lowest closing price of the Common Stock on the Principal Market on any Trading Day during the five (5) Trading Day period ended on, and including, the Trading Day ended immediately prior to such applicable Adjustment Date (each, a “Market Price Measuring Period”). All such determinations to be appropriately adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction that proportionately decreases or increases the Common Stock during such applicable Market Price Measuring Period. Only downward adjustments will be made.

Share Combination Event Adjustment. In addition to the adjustments set forth above, if at any time and from time to time on or after Stockholder Approval, there occurs any share split, share dividend, share combination recapitalization or other similar transaction involving the Common Stock (each, a “Share Combination Event”, and such date thereof, the “Share Combination Event Date”) and the lowest VWAP during the ten consecutive (10) Trading Day period ending and including the fifth (5) Trading Day immediately preceding the Share Combination Event Date (the “Event Market Price”) (provided if the Share Combination Event is effective after close of trading on the primary Trading Market, then commencing on the next Trading Day which period will be the “Share Combination Adjustment Period”) is less than the Conversion Price then in effect, then at the close of trading on the primary Trading Market on the last day of the Share Combination Adjustment Period, the Conversion Price then in effect on such fifth (5th) Trading Day will be reduced (but in no event increased) to the Event Market Price, but not less than the Floor Price. Notwithstanding the foregoing, if one or more Share Combination Events occur prior to Stockholder Approval being obtained and a reduction of the Conversion Price did not occur, once Stockholder Approval is obtained, the Conversion Price will automatically be reduced to equal the lowest Event Market Price with respect to any Share Combination Event that occurred prior to Stockholder Approval being obtained, but not less than the Floor Price.

Adjustments for Dilutive Issuances or Variable Price Securities. If and whenever the Company grants, issues or sells (or enters into any agreement to grant, issue or sell), or pursuant to the provisions of the Certificate of Designations is deemed to have done any of the foregoing, but excluding any Excluded Securities granted, issued or sold or deemed to have been granted, issued or sold, any shares of Common Stock for a consideration price per share (the “New Issuance Price”) less than a price equal to the Conversion Price in effect immediately prior to such granting, issuance or sale (such Conversion Price then in effect is referred to herein as the “Applicable Price”) (the foregoing a “Dilutive Issuance”), then, immediately after such Dilutive Issuance, the Conversion Price then in effect will be reduced to an amount equal to the New Issuance Price.

Additionally, if the Company grants, issues or sells (or enters into any agreement to grant, issue or sell) securities that are issuable pursuant to such agreement or convertible into or exchangeable or exercisable for shares of Common Stock at a price which varies or may vary with the market price of the shares of Common Stock, including by way of one or more reset(s) to a fixed price, (each of the formulations for such variable price being herein referred to as, the “Variable Price”), the holder shall have the right, but not the obligation, in its sole discretion to substitute the Variable Price for the Conversion Price.

Voluntary Adjustment Right. Subject to the rules and regulations of the Principal Market, the Company has the right, at any time, with the written consent of the Required Holders, to lower the fixed conversion price to any amount and for any period of time deemed appropriate by the Company board of directors.

Change of Control Exchange. Upon a change of control of the Company, each holder may require the Company to exchange the holder’s shares of Series C Preferred Stock for consideration equal to the change of Control Election Price, to be satisfied at the Company’s election in either (x) cash or (y) rights convertible into such securities or other assets to which such holder would have been entitled with respect to such shares of Common Stock had such shares of Common Stock been held by such holder upon consummation of such corporate event.

Fundamental Transactions. The Certificate of Designations prohibits the Company from entering specified fundamental transactions (including, without limitation, mergers, business combinations and similar transactions) unless the Company (or the Company’s successor) assumes in writing all of the Company’s obligations under the of Common Stock, except as provided in the transaction documents in the PIPE Financing.

Redemption Rights:

Optional Redemption by the Company. At any time, the Company has the right to redeem in cash all, but not less than all, of the Preferred Shares then outstanding at a price (the “Company Optional Redemption Price”) equal to 125% of the greater of (i) the Conversion Amount being redeemed and (ii) the product of (1) the Conversion Rate with respect to the Conversion Amount being redeemed multiplied by (2) the greatest closing sale price of the Company’s Common Stock on any Trading Day during the period commencing on the date immediately preceding the date the Company notifies the holders of its election to redeem and the date the Company makes the entire payment required.

Mandatory Redemption by the Company Upon a Bankruptcy Triggering Event. Upon the occurrence and continuation of a Bankruptcy Triggering Event, the Company will immediately redeem, in cash, each of the Preferred Shares then outstanding at a redemption price equal to the greater of (i) the product of (A) the Conversion Amount to be redeemed multiplied by (B) 125% and (ii) the product of (X) the Conversion Rate with respect to the Conversion Amount in effect immediately following the date of initial public announcement (or public filing of bankruptcy documents, as applicable) of such Bankruptcy Triggering Event multiplied by (Y) the product of (1) 125% multiplied by (2) the greatest closing sale price of the Common Stock on any Trading Day during the period commencing on the date immediately preceding such Bankruptcy Triggering Event and ending on the date the Company pays the entire payment required, provided that a Holder may, in its sole discretion, waive such right to receive payment upon a Bankruptcy Triggering Event, in whole or in part, and any such waiver will not affect any other rights of such Holder or any other Holder hereunder, including any other rights in respect of such Bankruptcy Triggering Event or any right to conversion (or Alternate Conversion), as applicable.

Voting Rights. The holders of the Series C Preferred Stock have no voting power and no right to vote on any matter at any time, either as a separate series or class or together with any other series or class of share of capital stock, and are not entitled to call a meeting of such holders for any purpose nor are they entitled to participate in any meeting of the holders of Common Stock, except as provided in the Certificate of Designations (or as otherwise required by applicable law).

Covenants. The Certificate of Designations contains a variety of obligations on the Company's part not to engage in specified activities, which are typical for transactions of this type. In particular, the Company will not, and will cause the Company's subsidiaries to not, redeem, repurchase or declare any dividend or distribution on any of its capital stock (other than as required under the Certificate of Designations). In addition, the Company will not issue any preferred stock or issue any other securities that would cause a breach or default under the of Certificate of Designations or PIPE Warrants.

Ownership Limitation. In no event may any Preferred Shares be converted (or PIPE Warrants be exercised) and shares of Common Stock be issued to any holder if after giving effect to the issuance of shares of Common Stock upon such conversion of the Preferred Shares (or exercise of the PIPE Warrants), the holder (together with its affiliates, if any) would beneficially own more than 4.99% of the outstanding shares of Common Stock, which we refer to herein as the "*PIPE Blocker*". The PIPE Blocker may be raised or lowered to any other percentage not in excess of 9.99% at the option of the applicable holder of the Preferred Shares (or PIPE Warrants), except that any raise will only be effective upon 61-days' prior notice to the Company.

Exchange Right. If the Company or any of its Subsidiaries consummates any Subsequent Placement (other than with respect to Excluded Securities (as defined in the Securities Purchase Agreement)), and a holder elects in writing to the Company to participate in such Subsequent Placement, each such holder may, at the option of such holder as elected in writing to the Company, exchange all, or any part, of the Preferred Shares of such holder into the securities in such Subsequent Placement (with the aggregate amount of such securities to be issued in such exchange equal to such aggregate amount of such securities with a purchase price valued at 120% of the Conversion Amount of the Preferred Shares delivered by such holder in exchange therefor); provided that any such exchange will be subject to all applicable Nasdaq restrictions.

Reservation Requirements. So long as any Series C Preferred Stock remains outstanding, the Company will at all times reserve at least 150% of the number of shares of Common Stock as will from time to time be necessary to effect the conversion of all Preferred Shares then outstanding.

Conditions Precedent to Closing: As set forth in the Securities Purchase Agreement, the obligations of each party to consummate the PIPE Financing are conditioned upon, among other things, customary closing conditions and the consummation of the transactions contemplated by the Committed Equity Line of Credit ("*ELOC*"), described below under the caption "*Common Stock Purchase Agreement*".

PIPE Warrants

Exercise Price. The exercise price of the PIPE Warrants is \$4.38, the Nasdaq Minimum Price (as defined below.) The exercise price is subject to adjustment for stock splits, combinations and similar events, and, in the event of stock dividends and splits, the number of shares of Common Stock issuable upon the exercise of the Warrant also will be adjusted so that the aggregate exercise price will be the same immediately before and immediately after any such adjustment.

Exercise Price Adjustments. If on an Adjustment Date, the exercise price then in effect is greater than the Market Price then in effect (the “Warrant Adjustment Price”), the exercise price will automatically lower to the Warrant Adjustment Price. As used herein, “Market Price” means, with respect to any Adjustment Date, the greater of (x) the Floor Price and (y) the lowest closing price of the Common Stock on the Principal Market on any Trading Day during the five (5) Trading Day period ended on, and including, the Trading Day ended immediately prior to such applicable Adjustment Date (each, a “Market Price Measuring Period”). All such determinations to be appropriately adjusted for any stock dividend, stock split, stock combination, reclassification or similar transaction that proportionately decreases or increases the Common Stock during such applicable Market Price Measuring Period. Only downward adjustments will be made.

Adjustments for Dilutive Issuances or Variable Price Securities. If and whenever the Company grants, issues or sells (or enters into any agreement to grant, issue or sell), or pursuant to the provisions of the Warrant is deemed to have done any of the foregoing, but excluding any Excluded Securities granted, issued or sold or deemed to have been granted, issued or sold any shares of Common Stock for a consideration price per share (the “Warrant New Issuance Price”) less than a price equal to the exercise price in effect immediately prior to such granting, issuance or sale (the foregoing a “Warrant Dilutive Issuance”), then, immediately after such Warrant Dilutive Issuance, the exercise price then in effect will be reduced to an amount equal to the Warrant New Issuance Price.

Additionally, if the Company grants, issues or sells (or enters into any agreement to grant, issue or sell) securities at a Variable Price, the warrant holder shall have the right, but not the obligation, in its sole discretion to exercise the PIPE Warrants at the Variable Price.

Exercise Period. The PIPE Warrants are exercisable beginning six months after the issuance date (the “Initial Exercisability Date”) and expiring on the third anniversary of the Initial Exercisability Date. The PIPE Warrants require “buy-in” payments to be made by us for failure to deliver any shares of Common Stock issuable upon exercise.

Cashless Exercise. If at the time of exercise of the PIPE Warrants, there is no effective registration statement registering the shares of the Company Common Stock underlying the PIPE Warrants, such PIPE Warrants may be exercised on a cashless basis pursuant to their terms.

Purchase Rights; Participation Rights. If the Company issues options, convertible securities, warrants, shares, or similar securities to holders of the Company shares of the Company Common Stock, each Warrant holder has the right to acquire the same as if the holder had exercised its Warrant. The holders of the PIPE Warrants are entitled to receive any dividends paid or distributions made to the holders of the Company’s shares of Common Stock on an “as if converted” basis.

Fundamental Transactions. The PIPE Warrants prohibit the Company from entering into specified fundamental transactions unless the successor entity assumes all of the Company obligations under the PIPE Warrants under a written agreement before the transaction is completed. Upon specified corporate events, a Warrant holder will thereafter have the right to receive upon an exercise such shares, securities, cash, assets or any other property whatsoever which the holder would have been entitled to receive upon the happening of the applicable corporate event had the Warrant been exercised immediately prior to the applicable corporate event. When there is a transaction involving specified changes of control, a Warrant holder will have the right to force the Company to repurchase the holder’s Warrant for a purchase price in cash equal to the Black Scholes value, as calculated under the PIPE Warrants, of the then unexercised portion of the Warrant.

ELOC FINANCING

On October 2, 2024, the Company entered into a Common Stock ELOC Purchase Agreement relating to a Committed Equity Facility with Keystone, whereby the Company may offer and sell, from time to time at its sole discretion, and whereby Keystone has committed to purchase, up to \$25.0 million of the Company's newly issued Common Stock, subject to the limitations described below. Concurrently with entering into the ELOC Purchase Agreement, the Company also entered into a registration rights agreement with Keystone, pursuant to which it agreed to provide Keystone with certain registration rights related to the shares issued under the ELOC Purchase Agreement.

The Company may, from time to time and at its sole discretion, direct Keystone to purchase shares of Common Stock upon the satisfaction of certain conditions set forth in the Common Stock Purchase Agreement at a purchase price per share based on the market price of Common Stock at the time of sale as computed under the ELOC Purchase Agreement. There is no upper limit on the price per share that Keystone could be obligated to pay for Common Stock under the ELOC Purchase Agreement. The Company will control the timing and amount of any sales of Common Stock to Keystone, and Keystone has no right to require the Company to sell any shares to it under the ELOC Purchase Agreement.

The Company does not have a right to commence any sales of Common Stock to the Purchaser under the ELOC Purchase Agreement until the time when all of the conditions to the Company's right to commence sales of Common Stock to the Purchaser set forth in the ELOC Purchase Agreement have been satisfied, including that a registration statement covering the resale of such shares is declared effective by the SEC and the final form of prospectus is filed with the SEC (the "Commencement Date"). Over the 36-month period from and after the Commencement Date, the Company will control the timing and amount of any sales of Common Stock to the Purchaser. Actual sales of shares of Common Stock to the Purchaser under the ELOC Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the Common Stock and determinations by us as to the appropriate sources of funding and the Company's operations.

Although the Purchase Agreement provides that we may sell up to an aggregate of \$25.0 million of our shares of our Common Stock to Keystone, only 6,250,000 shares of our Common Stock (assuming the shares are sold at a price of \$4.00 per share) are being registered for resale under the registration statement that includes this prospectus. If it becomes necessary for us to issue and sell to Keystone under the Purchase Agreement more shares than are being registered for resale under this prospectus in order to receive aggregate gross proceeds equal to \$25.0 million under the Purchase Agreement, we must first file with the SEC one or more additional registration statements to register under the Securities Act the resale by Keystone of any such additional shares of our Common Stock we wish to sell from time to time under the Purchase Agreement, which the SEC must declare effective, in each case, before we may elect to sell any additional shares of our Common Stock to Keystone under the Purchase Agreement.

In no event will the Company issue to the Purchaser under the ELOC Purchase Agreement more than 1,658,525 shares of Common Stock, representing 19.99% of the total number of shares of Common Stock outstanding immediately prior to the execution of the Common Stock Purchase Agreement, unless (i) the Company obtains the approval of the issuance of such shares by its stockholders in accordance with the applicable stock exchange rules or (ii) sales of Common Stock are made at a price equal to or in excess of the lower of (A) the closing price immediately preceding the delivery of the applicable notice to the Purchaser and (B) the average of the closing prices of the Common Stock for the five business days immediately preceding the delivery of such notice, such that the sales of such Common Stock to the Purchaser would not count toward the Exchange Cap because they are "at market" under applicable stock exchange rules. On October 11, 2024 the Company obtained stockholder approval to issue shares to Keystone in excess of the Exchange Cap.

In all cases, the Company may not issue or sell any shares of Common Stock to Keystone under the Common Stock Purchase Agreement which, when aggregated with all other shares of Common Stock then beneficially owned by Keystone and its affiliates (as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 promulgated thereunder), would result in Keystone beneficially owning more than 4.99% of the outstanding shares of Common Stock (the "ELOC Blocker").

At any time from and after the Commencement Date, on any business day on which the closing sale price of the Common Stock is equal to or greater than \$0.05 (the "Purchase Date"), the Company may direct the Purchaser to purchase a specified number of shares of Common Stock (a "Fixed Purchase") not to exceed 100,000 shares at a purchase price equal to the lesser of 90% of (i) the daily volume weighted average price (the "VWAP") of the Common Stock for the five trading days immediately preceding the applicable Purchase Date for such Fixed Purchase and (ii) the lowest sale price of a share of Common Stock on the applicable Purchase Date for such Fixed Purchase during the full trading day on such applicable Purchase Date. In any case, the Purchaser's commitment in any single Fixed Purchase may not exceed \$10,000.

In addition, at any time from and after the Commencement Date, on any business day on which the closing sale price of the Common Stock is equal to or greater than \$0.05 and such business day is also the Purchase Date for a Fixed Purchase of an amount of shares of Common Stock not less than the applicable Fixed Purchase Maximum Amount (as defined in the Common Stock Purchase Agreement) (the "VWAP Purchase Date"), the Company may also direct the Purchaser to purchase, on the immediately following business day, an additional number of shares of Common Stock in an amount up to the Maximum VWAP Purchase Amount (as defined in the Common Stock Purchase Agreement) (a "VWAP Purchase") at a purchase price equal to the lesser of 90% of (i) the closing sale price of the Common Stock on the applicable VWAP Purchase Date and (ii) the VWAP during the period on the applicable VWAP Purchase Date beginning at the opening of trading and ending at the VWAP Purchase Termination Time (as defined in the Purchase Agreement). At any time from and after the Commencement Date, on any business day that is also the VWAP Purchase Date for a VWAP Purchase, the Company may also direct the Purchaser to purchase, on such same business day, an additional number of shares of Common Stock in an amount up to the Maximum Additional VWAP Purchase Amount (as defined in the ELOC Purchase Agreement) (an "Additional VWAP Purchase") at a purchase price equal to the lesser of 90% of (i) the closing sale price of the Common Stock on the applicable Additional VWAP Purchase Date and (ii) the VWAP during the Additional VWAP Purchase Period (as defined in the Common Stock Purchase Agreement).

The net proceeds under the Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its Common Stock to Keystone. Pursuant to the ELOC Purchase Agreement, up to 30% of the proceeds from each Fixed Purchase and VWAP Purchase Notice must be used to redeem shares of Series C Preferred Stock.

The ELOC Purchase Agreement contains customary representations, warranties and agreements of the Company and Keystone, limitations and conditions regarding sales of Common Stock, indemnification rights and other obligations of the parties.

There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the ELOC Purchase Agreement other than a prohibition (with certain limited exceptions) on entering into a dilutive securities transaction during certain periods when the Company is selling Common Stock to Keystone under the Purchase Agreement. Keystone has agreed that, during the term of the Purchase Agreement, it will not engage in or effect, directly or indirectly, any short sales involving the Company's securities or any hedging transaction that transfers the economic risk of ownership of the Common Stock.

The Purchase Agreement will automatically terminate on the earliest to occur of (i) the expiration of the ELOC Registration Statement, (ii) the date on which Keystone will have purchased from the Company under the ELOC Purchase Agreement an aggregate limit of shares of Common Stock as defined therein, (iii) the date on which the Common Stock will have failed to be listed or quoted on Nasdaq or another U.S. national securities exchange identified as an "eligible market" in the ELOC Purchase Agreement, (iv) the 30th trading day after the date on which a voluntary or involuntary bankruptcy proceeding involving the Company has been commenced that is not discharged or dismissed prior to such trading day, and (v) the date on which a bankruptcy custodian is appointed for all or substantially all of the Company's property or the Company makes a general assignment for the benefit of creditors. The Company has the right to terminate the ELOC Purchase Agreement at any time after the Commencement Date (as defined in the ELOC Purchase Agreement), at no cost or penalty, upon one trading day's prior written notice to Keystone. Keystone has the right to terminate the Purchase Agreement upon ten trading days' prior written notice to the Company if certain specified events occur. The Company and Keystone may also agree to terminate the ELOC Purchase Agreement by mutual written consent. Neither the Company nor Keystone may assign or transfer the Company's respective rights and obligations under the ELOC Purchase Agreement.

Concurrent with the execution of the ELOC Purchase Agreement, the Company entered into a registration rights agreement with Keystone (the "ELOC Registration Rights Agreement"), pursuant to which the Company agreed to file a registration statement covering the issuance and sale of the maximum number of shares issuable under the ELOC Purchase Agreement as may be permitted under applicable rules. The Company agreed to use its commercially reasonable efforts to cause the registration statement to be filed within 45 days after the closing of the ELOC Purchase Agreement and to have such registration statement effective within 120 days of such closing (or 90 days of such closing if the Company is notified by the Securities and Exchange Commission that such registration statement will not be reviewed or subject to further review).

Effect of Sales of our Common Stock under the ELOC Purchase Agreements on our Stockholders

The Common Stock being registered for resale in this offering may be issued and sold by us to the Selling Stockholder from time to time at our discretion, during the terms described above. The resale by the Selling Stockholder of a significant quantity of shares registered for resale in this offering at any given time, or the perception that these sales may occur, could cause the market price of our Common Stock to decline and to be highly volatile. Sales of our Common Stock, if any, to Keystone under the ELOC Purchase Agreement will be determined by us in our sole discretion, subject to the satisfaction of certain conditions in the ELOC Purchase Agreement, and will depend upon market conditions and other factors. We may ultimately decide to sell to Keystone all, some or none of the Common Stock that may be available for us to sell to Keystone pursuant to the ELOC Purchase Agreement. If we elect to sell Common Stock to Keystone pursuant to the ELOC Purchase Agreement, after Keystone has acquired such shares, Keystone may resell all, some or none of such Common Stock at any time or from time to time in its discretion and at different prices. As a result, investors who purchase Common Stock from Keystone in this offering at different times will likely pay different prices for those shares of Common Stock, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. See “*Risk Factors—Risks Related to the Committed Equity Financings—Investors who buy shares of Common Stock from Keystone at different times will likely pay different prices.*”

Investors may experience a decline in the value of the Common Stock they purchase from Keystone in this offering as a result of future sales made by us to Keystone at prices lower than the prices such investors paid for their shares in this offering. In addition, if we sell a substantial number of shares of Common Stock to Keystone under the Keystone ELOC Purchase Agreement, or if investors expect that we will do so, the actual sales of Common Stock or the mere existence of our arrangement with Keystone may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

Because the purchase price per share to be paid by Keystone for the Common Stock that we may elect to sell to Keystone under the ELOC Purchase Agreement, if any, will fluctuate based on the market prices of our Common Stock at the time we make such election, as of the date of this prospectus, it is not possible for us to predict the number of shares of Common Stock that we will sell to Keystone under the ELOC Purchase Agreement, the actual purchase price per share to be paid by Keystone for those shares of Common Stock, or the actual gross proceeds to be raised by us from those sales, if any. As of December 5, 2024, there were 8,294,734 shares of Common Stock outstanding. If all of the 6,250,000 shares of our Common Stock offered for resale by the Selling Stockholders under this prospectus were issued and outstanding as of December 5, 2024, such shares would represent approximately 42.97% of total number of shares of our Common Stock outstanding. The actual number of shares of our Common Stock issuable will vary depending on the then current market price of shares of our Common Stock sold to the Selling Stockholder in this offering.

The number of shares of Common Stock ultimately offered for sale by the Selling Stockholder for resale under this prospectus is dependent upon the number of shares of Common Stock, if any, we ultimately sell to Keystone under the ELOC Purchase Agreement. Further, if and when we elect to sell shares of Common Stock to Keystone pursuant to the ELOC Purchase Agreement, after Keystone has acquired such shares, Keystone may resell all, some or none of such shares of Common Stock at any time or from time to time in its discretion and at different prices.

The issuance of our shares of Common Stock to the Selling Stockholder pursuant to the ELOC Purchase Agreement will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted. Although the number of shares of Common Stock that our existing stockholders own will not decrease, the shares of Common Stock owned by our existing stockholders will represent a smaller percentage of our total outstanding shares of Common Stock after any such issuance.

Although the ELOC Purchase Agreement provides that we may sell up to an aggregate of \$25.0 million of shares of our Common Stock to Keystone, only 6,250,000 shares (assuming the shares are sold at a price of \$4.00 per share) are being registered for resale under the registration statement that includes this prospectus. If it becomes necessary for us to issue and sell more shares than are being registered for resale under this prospectus in order to receive aggregate gross proceeds equal to \$25.0 million under the ELOC Purchase Agreement, we must first file with the SEC one or more additional registration statements to register under the Securities Act the resale by Keystone of any such additional shares of our Common Stock we wish to sell from time to time under the ELOC Purchase Agreement, which the SEC must declare effective, in each case, before we may elect to sell any additional shares of our Common Stock to Keystone under the ELOC Purchase Agreement.

The following table sets forth the number of shares of Common Stock to be issued to Keystone under the ELOC Purchase Agreement registered hereunder at varying purchase prices:

| Assumed Average Purchase Price Per Share | Number of Registered Shares to be Issued if Full Purchase⁽¹⁾ | Percentage of Outstanding Shares After Giving Effect to the Issuance to Keystone⁽²⁾ | Gross Proceeds from the Sale of Shares to Keystone Under the Purchase Agreement |
|---|--|---|--|
| \$ 0.63(3) | 39,682,540 | 82.7% | \$ 25,000,000 |
| \$ 2.00 | 12,500,000 | 60.1% | \$ 25,000,000 |
| \$ 4.00 | 6,250,000 | 43.0% | \$ 25,000,000 |
| \$ 7.50 | 3,333,333 | 28.7% | \$ 25,000,000 |
| \$ 10.00 | 2,500,000 | 23.2% | \$ 25,000,000 |

Notes to table:

- (1) The purchase prices assume a discount to the market prices of our shares, in accordance with the ELOC Purchase Agreement.
- (2) The denominator is based on 8,294,734 shares outstanding as of December 5, 2024, adjusted to include the number of shares set forth in the adjacent column that we would have sold to Keystone, assuming the average purchase price in the first column. The numerator is based on the number of shares issuable pursuant to future sales under the ELOC Purchase Agreement (that are the subject of this offering) at the corresponding assumed average purchase price set forth in the first column.
- (3) The closing sale price of our Common Stock on December 6, 2024.

USE OF PROCEEDS

We will not receive any proceeds from the sale of Common Stock by the Selling Stockholder pursuant to this prospectus. We may receive up to \$25.0 million in aggregate gross proceeds from Keystone under the ELOC Purchase Agreement in connection with sales of the shares of our Common Stock pursuant to the ELOC Purchase Agreement after the date of this prospectus. However, the actual proceeds from Keystone may be less than this amount depending on the number of shares of our Common Stock sold and the price at which the shares of our Common Stock are sold.

Pursuant to the ELOC Purchase Agreement, 30% of the gross proceeds to the Company from any sale of Common Stock thereunder must be applied towards the redemption of the Company's Series C Preferred Stock.

Pursuant to the Amended and Restated Forbearance Agreement, dated September 19, 2024, as amended on November 26, 2024, between the Company and Veru, we are required to pay to Veru 25% of the net proceeds received from any sale of Common Stock under the ELOC Purchase Agreement during the to pay down our obligations to Veru.

Any proceeds we receive from the sale of Common Stock under the ELOC Purchase Agreement, net of our obligations to Keystone and Veru, will be used for general corporate and working capital or for other purposes that the Board, in its good faith, deems to be in the best interest of the Company. No assurances can be given that we will receive any proceeds from sale of Common Stock under the ELOC Purchase Agreement.

DETERMINATION OF OFFERING PRICE

The Selling Stockholder will offer Common Stock at the prevailing market prices or a privately negotiated price as it may determine from time to time.

The offering price of our Common Stock to be sold by the Selling Stockholder does not necessarily bear any relationship to our book value, assets, past operating results, financial condition, or any other established criteria of value. The facts considered in determining the offering price were our financial condition and prospects, our limited operating history and the general condition of the securities market.

In addition, there is no assurance that our Common Stock will trade at market prices in excess of the offering price as prices for our Common Stock in any public market will be determined in the marketplace and may be influenced by many factors, including the depth and liquidity.

DESCRIPTION OF CAPITAL STOCK

General

Our Amended and Restated Certificate of Incorporation authorizes the issuance of up to 250,000,000 shares of Common Stock, \$0.00001 par value per share, and 10,000,000 shares of preferred stock, \$0.00001 par value per share. As of the date of this prospectus, we have 8,294,734 shares of Common Stock outstanding, and 3,499 shares of Series C Preferred Stock issued and outstanding. Our shares of Common Stock are held of record by approximately 37 stockholders.

Common Stock

Our Common Stock is listed on the Nasdaq Capital Market under the symbol “ONCO.”

Under the terms of our Amended and Restated Certificate of Incorporation, holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. The holders of outstanding shares of Common Stock are entitled to receive dividends out of assets or funds legally available for the payment of dividends of such times and in such amounts as our Board from time to time may determine. Our Common Stock is not entitled to pre-emptive rights and is not subject to conversion or redemption. Upon liquidation, dissolution or winding up of our company, the assets legally available for distribution to stockholders are distributable ratably among the holders of our Common Stock after payment of liquidation preferences, if any, on any outstanding payment of other claims of creditors. The rights, preferences and privileges of holders of Common Stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock and Warrants

Under the terms of our Amended and Restated Certificate of Incorporation, our Board is authorized, without further action by the stockholders, to establish one or more class or series, and fix the relative rights and preferences of the company’s undesignated capital stock.

For the material terms of the Series C Preferred Stock and the PIPE Warrants, see “*PIPE Financing*.”

Anti-Takeover Effects of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Some provisions of Delaware law, our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the Board.

Choice of Forum

Our Amended and Restated Certificate of Incorporation provides that, unless we consent in writing to an alternative forum, to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and certain other actions may be brought only in the Court of Chancery in the State of Delaware, except any action (A) as to which the Court of Chancery in the State of Delaware determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), (B) which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery or (C) for which the Court of Chancery does not have subject matter jurisdiction. If an action is brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel. Although we believe this provision benefits us by providing increased consistency in the application of law in the types of lawsuits to which it applies, a court may determine that this provision is unenforceable, and to the extent it is enforceable, the provision may have the effect of discouraging lawsuits against our directors and officers.

Our Amended and Restated Certificate of Incorporation provides that the exclusive forum provision will be applicable to the fullest extent permitted by applicable law, subject to certain exceptions. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, our Amended and Restated Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the rules and regulations promulgated thereunder. We note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Continental Stock Transfer & Trust Company. The Transfer Agent's address is 1 State Street, 30th Floor, New York, New York 10004.

Listing

Our Common Stock is traded on The Nasdaq Capital Market under the trading symbol "ONCO."

Elimination of Monetary Liability for Officers and Directors

Our Amended and Restated Certificate of Incorporation incorporates certain provisions permitted under the Delaware General Corporation Law ("DGCL") relating to the liability of directors. The provisions eliminate a director's liability for monetary damages for a breach of fiduciary duty, including gross negligence, except in circumstances involving certain wrongful acts, such as the breach of director's duty of loyalty or acts or omissions, which involve intentional misconduct or a knowing violation of law. These provisions do not eliminate a director's duty of care. Moreover, these provisions do not apply to claims against a director for certain violations of law, including knowing violations of federal securities law. Our Amended and Restated Certificate of Incorporation also contains provisions to indemnify the directors, officers, employees or other agents to the fullest extent permitted by the DGCL. We believe that these provisions will assist us in attracting and retaining qualified individual to serve as directors.

Indemnification of Officers and Directors

Our Amended and Restated Certificate of Incorporation also contains provisions to indemnify the directors, officers, employees or other agents to the fullest extent permitted by the DGCL. These provisions may have the practical effect in certain cases of eliminating the ability of stockholders to collect monetary damages from directors. We are also a party to indemnification agreements with each of our directors. We believe that these provisions will assist us in attracting or retaining qualified individuals to serve as our directors.

SELLING STOCKHOLDER

The shares of Common Stock being offered by the Selling Stockholder are those previously issued to the Selling Stockholder, and those issuable to the Selling Stockholder under the ELOC Purchase Agreement. We are registering the shares of Common Stock in order to permit the Selling Stockholder to offer the shares for resale from time to time.

The table below lists the Selling Stockholder and other information regarding the beneficial ownership of the shares of Common Stock by the Selling Stockholder. The second column lists the number of shares of Common Stock beneficially owned by each Selling Stockholder.

The third column lists the shares of Common Stock being offered by this prospectus by the Selling Stockholder.

The fourth column assumes the sale of all of the shares offered by the Selling Stockholder pursuant to this prospectus.

Under the terms of the ELOC Purchase Agreement, the Company may not issue shares to the Selling Stockholder under the ELOC Purchase Agreement to the extent that such issuance would cause the Selling Stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% of our then outstanding Common Stock following such issuance, excluding for purposes of such determination shares of Common Stock issuable under the ELOC Purchase Agreement which have not been issued. The number of shares in the second and fourth columns do not reflect this limitation.

The Selling Stockholder may sell all, some or none of its shares in this offering. See “*Plan of Distribution*.”

| Name of Selling Shareholder | Number of shares of Common Stock Beneficially Owned Prior to Offering | Percentage of shares of Common Stock Beneficially Owned Prior to Offering⁽¹⁾ | Maximum Number of shares of Common Stock to be Sold Pursuant to this Prospectus | Number of shares of Common Stock Beneficially Owned After Offering | Percentage of shares of Common Stock Beneficially Owned After Offering⁽¹⁾ |
|------------------------------------|--|--|--|---|---|
| Keystone Capital Partners, LLC | 435,646 ⁽²⁾ | 4.99% | 6,250,000 | 435,646 | 2.91% |

(1) Based on 8,294,734 shares outstanding as of December 5, 2024.

(2) Represents shares of Common Stock underlying Series C Preferred Stock held by this Selling Stockholder, after giving effect to the Maximum Percentage (as defined in the Series C Preferred Stock Certificate of Designations). Keystone Capital Partners LLC is managed by RANZ Group LLC. Frederic Zaino, the Managing Member of RANZ Group LLC, may be deemed to have investment discretion and voting power over the shares held by Keystone Capital Partners LLC. RANZ Group LLC and Mr. Zaino each disclaim any beneficial ownership of these shares. The address of the selling stockholder is 139 Fulton Street, Suite 412, New York, NY 10038.

PLAN OF DISTRIBUTION

The Selling Stockholder of the securities and any of its pledgees, assignees and successors-in-interest may, from time to time, sell any or all of its securities covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholder to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholder may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholder (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with Financial Industry Regulatory Authority ("FINRA") Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

Keystone Capital Partners, LLC is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

Keystone Capital Partners, LLC has represented to us that at no time prior to the date of the ELOC Purchase Agreement has such Selling Stockholder or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. Keystone Capital Partners, LLC has agreed that during the term of the ELOC Purchase Agreement, neither Keystone Capital Partners, LLC nor any of its agents, representatives or affiliates will enter into or effect, directly or indirectly, any of the foregoing transactions.

The Selling Stockholder and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholder against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We have advised the Selling Stockholder that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the Selling Stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

EXPERTS

The consolidated balance sheet of Onconetix, Inc. and Subsidiary as of December 31, 2023, and the related consolidated statements of operations and comprehensive loss, convertible redeemable preferred stock and stockholders' equity (deficit), and cash flows for the year then ended, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report, which report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern. Such financial statements have been incorporated herein by reference in this prospectus in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

The consolidated financial statements of Onconetix, Inc., formerly known as Blue Water Vaccines Inc., as of and for the year ended December 31, 2022, appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, have been audited by CBIZ CPAs P.C. (formerly Mayer Hoffman McCann, P.C.), independent registered public accounting firm, as set forth in their report, and have been incorporated herein by reference in this prospectus in reliance upon such report given on the authority of such firm as experts in accounting and auditing, in giving said reports.

The financial statements of Proteomedix AG as of December 31, 2022, and 2021 and for each of the two years in the period ended December 31, 2022, which have been incorporated by reference in this prospectus and the registration statement of which it forms a part, have been so included in reliance on the report of BDO AG, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. The report on the financial statements contains an explanatory paragraph regarding Proteomedix AG's ability to continue as a going concern. Such financial statements and audit report are incorporated by reference to the Company's Current Report on Form 8-K/A, as filed with the SEC on February 27, 2024.

LEGAL MATTERS

Ellenoff Grossman & Schole LLP, New York, New York, will pass upon the validity of the securities offered hereby.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act and, in accordance therewith, file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at www.sec.gov. Copies of certain information filed by us with the SEC are also available on our website at www.onconetix.com. Our website is not a part of this prospectus and is not incorporated by reference in this prospectus.

This prospectus is part of a registration statement we filed with the SEC. This prospectus omits some information contained in the registration statement in accordance with SEC rules and regulations. You should review the information and exhibits in the registration statement for further information about us and our consolidated subsidiaries and the securities we are offering. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference in this prospectus is considered to be part of this prospectus. Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated, and those future filings may modify or supersede some of the information included or incorporated in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents listed below (File No. 000-52994) and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (in each case, other than those documents or the portions of those documents not deemed to be filed) between the date of the initial registration statement and the effectiveness of the registration statement and following the effectiveness of the registration statement until the offering of the securities under the registration statement is terminated or completed:

- (i) our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2023, as filed with the SEC on April 11, 2024
- (ii) our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2024, as filed with the SEC on [May 20, 2024](#), for the quarter ended June 30, 2024, as filed with the SEC on [August 29, 2024](#) and for the quarter ended September 30, 2024, as filed with the SEC on [December 10, 2024](#);
- (iii) Current Reports on Form 8-K filed on each of [January 12, 2024](#), [January 19, 2024](#), [January 29, 2024](#), [February 12, 2024](#), [February 13, 2024](#), [February 27, 2024](#), [April 8, 2024](#), [April 26, 2024](#), [May 13, 2024](#), [June 13, 2024](#), [June 14, 2024](#), [July 11, 2024](#), [July 15, 2024](#), [August 7, 2024](#), [September 3, 2024](#), [September 5, 2024](#), [September 11, 2024](#), [September 20, 2024](#), [September 24, 2024](#), [October 3, 2024](#), [October 9, 2024](#), [October 21, 2024](#) and [December 3, 2024](#);
- (iv) our Definitive Proxy Statement, as filed with the SEC on [August 1, 2024](#), and the [supplemental proxy materials](#) filed with the SEC on September 3, 2024;
- (v) our Definitive Information Statement, as filed with the SEC on [October 31, 2024](#); and
- (vi) the description of our securities registered under Section 12 of the Exchange Act as filed as [Exhibit 4.2](#) on our Annual Report on [Form 10-K](#) for the year ended December 31, 2023, as filed with the SEC on April 11, 2024.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address or telephone number:

Onconetix, Inc.
201 E. Fifth Street, Suite 1900
Cincinnati, Ohio 45202
(513) 620-4101

You may also access the documents incorporated by reference in this prospectus through our website at www.onconetix.com. Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part. The information contained on our website is not part of this prospectus.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

Set forth below are estimates (except in the case of SEC registration fees) of the amount of fees and expenses to be incurred in connection with the issuance and distribution of the offered securities, other than underwriting discounts and commissions.

| | |
|----------------------|---------------------|
| SEC registration fee | \$ 2,885 |
| Accounting services | 37,500 |
| Legal fees | 37,500* |
| Miscellaneous | 5,000* |
| Total | <u>\$ 82,884.98</u> |

* Estimated

Item 14. Indemnification of Directors and Officers.

Section 145 of the DGCL inter alia, empowers a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. Similar indemnity is authorized for such persons against expenses (including attorneys' fees) actually and reasonably incurred in connection with the defense or settlement of any such threatened, pending or completed action or suit if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and provided further that (unless a court of competent jurisdiction otherwise provides) such person shall not have been adjudged liable to the corporation. Any such indemnification may be made only as authorized in each specific case upon a determination by the stockholders or disinterested directors or by independent legal counsel in a written opinion that indemnification is proper because the indemnitee has met the applicable standard of conduct.

Section 145 further authorizes a corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against any liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not the corporation would otherwise have the power to indemnify him under Section 145. We maintain policies insuring our officers and directors against certain liabilities for actions taken in such capacities, including liabilities under the Securities Act.

Section 102(b)(7) of the DGCL permits a corporation to include in its certificate of incorporation a provision eliminating or limiting the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL (relating to unlawful payment of dividends and unlawful stock purchase or redemption) or (iv) for any transaction from which the director derived an improper personal benefit.

Article 6 of the bylaws of the Company contains provisions which are designed to provide mandatory indemnification of directors and officers of the Company to the full extent permitted by law, as now in effect or later amended. The bylaws further provide that, if and to the extent required by the DGCL, an advance payment of expenses to a director or officer of the Company that is entitled to indemnification will only be made upon delivery to the Company of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification.

Item 16. Exhibits and Financial Statement Schedules.

| Exhibit No. | Description | Incorporated by Reference | | |
|-------------|--|---------------------------|---------|--------------------|
| | | Form | Exhibit | Filing Date |
| 3.1 | Amended and Restated Certificate of Incorporation filed with Delaware Secretary of State on February 23, 2022. | 8-K | 3.1 | February 24, 2022 |
| 3.2 | Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation | 8-K | 3.1 | April 24, 2023 |
| 3.3 | Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation. | 8-K | 3.1 | December 21, 2023 |
| 3.4 | Fourth Amended and Restated Bylaws of the Company. | 8-K | 3.2 | December 21, 2023 |
| 3.5 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation, as amended, of Onconetix, Inc., dated September 24, 2024. | 8-K | 3.1 | September 20, 2024 |
| 3.6 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation, as amended, of Onconetix, Inc., dated September 24, 2024. | 8-K | 3.1 | September 24, 2024 |
| 4.1 | Specimen Common Stock Certificate. | S-1 | 4.1 | October 8, 2021 |
| 4.2 | Description of Registered Securities. | 10-K | 4.2 | April 11, 2024 |
| 4.3 | Form of Inducement PIO. | 8-K | 4.1 | July 11, 2024 |
| 4.4 | Form of Warrant. | 8-K | 4.1 | October 3, 2024 |
| 4.5 | Certification of Designation of Series C Preferred Stock. | 8-K | 3.1 | October 3, 2024 |
| 5.1** | Opinion of Ellenoff Grossman & Schole LLP as to the legality of the securities being registered. | | | |
| 10.1 | 2019 Equity Incentive Plan. | S-1 | 10.1 | October 8, 2021 |
| 10.2 | 2022 Equity Incentive Plan. | S-1/A | 10.2 | November 29, 2021 |
| 10.3 | 2019 Equity Incentive Plan Form of Stock Option Grant Agreement. | S-1 | 10.3 | October 8, 2021 |
| 10.4 | 2022 Equity Incentive Plan Form of Incentive Stock Option Agreement (Employee). | S-1/A | 10.4 | January 6, 2022 |
| 10.5 | 2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Consultant). | S-1/A | 10.5 | January 6, 2022 |
| 10.6 | 2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Non-Employee Director). | S-1/A | 10.6 | January 6, 2022 |
| 10.7 | 2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Employee). | S-1/A | 10.7 | January 6, 2022 |
| 10.8 | Lease Agreement, dated as of April 29, 2021, between the Registrant and Regus Management Group, LLC. | S-1 | 10.11 | October 8, 2021 |
| 10.9 | Form of Employment Agreement with Ralph Schiess. | 10-K | 10.21 | April 11, 2024 |
| 10.10 | Amendment to Employment Agreement, dated October 15, 2020, by and between Proteomedix and Ralph Schiess. | 10-K | 10.22 | April 11, 2024 |
| 10.11 | Amendment to Employment Agreement by and between Proteomedix and Ralph Schiess. | 10-K | 10.23 | April 11, 2024 |
| 10.12 | Form of Employment Agreement with Christian Brühlmann. | 10-K | 10.24 | April 11, 2024 |
| 10.13 | Amendment to Employment Agreement, dated October 16, 2020, by and between Proteomedix and Christian Brühlmann. | 10-K | 10.25 | April 11, 2024 |
| 10.14 | Amendment to Employment Agreement by and between Proteomedix and Christian Brühlmann. | 10-K | 10.26 | April 11, 2024 |
| 10.15 | General Release of Claims, dated October 5, 2023, by and between Jon Garfield and the Company. | 8-K | 99.1 | October 10, 2023 |
| 10.16 | Release, dated January 10, 2024, by and between the Company and Dr. Neil Campbell. | 8-K | 99.1 | January 12, 2024 |
| 10.17 | Form of Indemnification Agreement for Directors and Officers. | 8-K | 10.3 | October 10, 2023 |

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|---------|---|------|-------|-------------------|
| 10.18 | <u>At-the-Market Offering Agreement, dated March 29, 2023, between the Company and H.C. Wainwright & Co., LLC.</u> | 8-K | 1.1 | March 29, 2023 |
| 10.19† | <u>Asset Purchase Agreement, dated April 19, 2023, between the Company and Veru Inc.</u> | 8-K | 10.1 | April 20, 2023 |
| 10.20 | <u>Amendment to Asset Purchase Agreement, dated September 29, 2023, between the Company and Veru Inc.</u> | 8-K | 10.1 | October 3, 2023 |
| 10.21 | <u>Form of Non-Competition and Non-Solicitation Agreement, dated April 19, 2023.</u> | 8-K | 10.2 | April 20, 2023 |
| 10.22 | <u>Asset Purchase Agreement, dated June 13, 2023, by and among WraSer, Xspire, and the Company.</u> | 8-K | 10.1 | June 14, 2023 |
| 10.23 | <u>Management Services Agreement, dated June 13, 2023, by and among WraSer, Xspire and the Company.</u> | 8-K | 10.2 | June 14, 2023 |
| 10.24 | <u>Form of Amendment, dated October 5, 2023, to Asset Purchase Agreement, dated June 13, 2023, by and among WraSer, Xspire, Legacy-Xspire Holdings, LLC, and the Company.</u> | 10-Q | 10.14 | October 20, 2023 |
| 10.25#† | <u>Exclusive Distribution Agreement, dated September 20, 2023, between the Company and Cardinal Health 105, LLC.</u> | 10-Q | 10.6 | November 17, 2023 |
| 10.26 | <u>Form of Lock-Up Agreement, dated December 15, 2023, by and among the Company and certain stockholders of Proteomedix.</u> | 8-K | 10.1 | December 21, 2023 |
| 10.27 | <u>Form of Non-Competition and Non-Solicitation Agreement, dated December 15, 2023, by and among the Company and certain stockholders of Proteomedix.</u> | 8-K | 10.2 | December 21, 2023 |
| 10.28 | <u>Form of Stockholder Support Agreement, dated December 15, 2023, by and among the Company, Proteomedix, and certain stockholders of Proteomedix.</u> | 8-K | 10.3 | December 21, 2023 |
| 10.29 | <u>Form of Subscription Agreement, dated December 15, 2023, by and among the Company, Proteomedix, and the PMX Investor.</u> | 8-K | 10.4 | December 21, 2023 |
| 10.30 | <u>Separation Agreement, dated January 17, 2024, between the Company and Erin Henderson.</u> | 8-K | 10.1 | January 19, 2024 |
| 10.31 | <u>Consulting Agreement, dated January 17, 2024, between the Company and The Aetos Group.</u> | 8-K | 10.2 | January 19, 2024 |
| 10.32 | <u>Debenture, dated January 23, 2024 issued to the PMX Investor</u> | 8-K | 10.1 | January 29, 2024 |
| 10.33 | <u>Consulting Agreement, dated January 4, 2024, by and between the Company and Thomas Meier.</u> | 8-K | 10.1 | February 12, 2024 |

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|--------|---|-------|-------|--------------------|
| 10.34 | License Agreement, dated March 27, 2023, between Proteomedix and Laboratory Corporation of America Holdings. | 10-K | 10.55 | April 11, 2024 |
| 10.35 | Forbearance Agreement, dated April 24, 2024, by and between the Company and Veru Inc. | 8-K | 10.1 | April 26, 2024 |
| 10.36 | Master Research Services Agreement, dated October 1, 2022, by and between Proteomedix AG and Immunovia, AB | S-1/A | 10.60 | June 25, 2024 |
| 10.37 | Collaboration Agreement, dated July 19, 2021, by and between Proteomedix AG and New Horizon Health Limited | S-1/A | 10.61 | June 25, 2024 |
| 10.38 | Amendment No. 1, dated June 26, 2023, to Collaboration Agreement, dated July 19, 2021, by and between Proteomedix AG and New Horizon Health Limited | S-1/A | 10.62 | June 25, 2024 |
| 10.39 | Release Agreement, dated June 10, 2024, between the Company and Bruce Harmon. | 8-K | 99.1 | June 13, 2024 |
| 10.40 | Consulting Agreement, dated June 10, 2024, between the Company and Karina Fedasz. | 8-K/A | 10.1 | June 14, 2024 |
| 10.41 | Form of Inducement Letter | 8-K | 10.1 | July 11, 2024 |
| 10.42 | Amended and Restated Forbearance Agreement between the Company and Veru, dated September 19, 2024 | 8-K | 10.1 | September 20, 2024 |
| 10.43 | Form of Securities Purchase Agreement dated October 2, 2024 relating to the sale of the Series C Preferred Stock and Warrants | 8-K | 10.1 | October 3, 2024 |
| 10.44 | Form of Registration Rights Agreement dated as of October 2, 2024 relating to the resale of the shares of Common Stock underlying the Series C Preferred Stock and Warrants | 8-K | 10.2 | October 3, 2024 |
| 10.45 | Form of ELOC Purchase Agreement dated October 2, 2024 | 8-K | 10.3 | October 3, 2024 |
| 10.46 | Form of ELOC Registration Rights Agreement dated October 2, 2024 | 8-K | 10.4 | October 3, 2024 |
| 10.47 | Waiver and Amendment No. 1 to Forbearance Agreement, dated November 26, 2024, between the Company and Veru | 8-K | 10.1 | December 3, 2024 |
| 16 | Letter from EisnerAmper LLP, dated October 21, 2024. | 8-K | 6.1 | October 21, 2024 |
| 21 | List of Subsidiaries. | 10-K | 21 | April 11, 2024 |
| 23.1* | Consent of CBIZ CPAs P.C. | | | |
| 23.2* | Consent of EisnerAmper LLP. | | | |
| 23.3* | Consent of BDO AG. | | | |
| 23.4** | Consent of Ellenoff Grossman & Schole (included as part of Exhibit 5.1 hereto). | | | |
| 24** | Power of Attorney. | | | |
| 107* | Filing Fee Table. | | | |

* Filed herewith.

** Previously filed.

† Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Company agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

Certain portions of this exhibit (indicated by “[*]” have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K as we have determined they (1) are not material and (2) are the type that the Company treats as private or confidential. The Registrant hereby agrees to furnish a copy of any omitted portion to the SEC upon request.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (1) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (2) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (3) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
 - (i) If the registrant is relying on Rule 430B:
 - (A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
 - (B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or
 - (ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cincinnati, Ohio, on December 10, 2024.

ONCONETIX, INC.

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

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|------------------------------|---|-------------------|
| * <u>Ralph Schiess</u> | Interim Chief Executive Officer (Principal Executive Officer) | December 10, 2024 |
| * <u>Karina M. Fedasz</u> | Interim Chief Financial Officer (Principal Financial and Accounting Officer) | December 10, 2024 |
| * <u>James Sapirstein</u> | Chairman of the Board and Director | December 10, 2024 |
| * <u>Thomas Meier</u> | Director | December 10, 2024 |
| * <u>Timothy Ramdeen</u> | Director | December 10, 2024 |
| * <u>Ajit Singh</u> | Director | December 10, 2024 |
| * <u>Simon Tarsh</u> | Director | December 10, 2024 |

Pursuant to Power of Attorney

By: /s/ Karina M. Fedasz
Karina M. Fedasz
Attorney-in-Fact

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Amendment No. 2 to the Registration Statement on Form S-1 and related prospectus of our report dated March 8, 2023, with respect to the consolidated financial statements of Onconetix, Inc. (formerly known as Blue Water Vaccines Inc.) (the “Company”) as of and for the year ended December 31, 2022, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, and to the reference to us under the heading “Experts” in the prospectus which is part of this Registration Statement.

/s/ CBIZ CPAs P.C.¹

Los Angeles, California
December 10, 2024

¹ In certain jurisdictions, CBIZ CPAs P.C. operates under its previous name, Mayer Hoffman McCann P.C.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Amendment No. 2 to the Registration Statement of Onconetix, Inc. on Form S-1 (No. 333-282958) to be filed on or about December 9, 2024 of our report dated April 11, 2024, on our audit of the financial statements as of December 31, 2023 and for the year then ended, which report was included in the Annual Report on Form 10-K filed April 11, 2024. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern. We also consent to the reference to our firm under the caption "Experts" in this Registration Statement.

/s/ EISNERAMPER LLP

EISNERAMPER LLP
Iselin, New Jersey
December 9, 2024

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Prospectus constituting a part of Onconetix Inc.'s Registration Statement of our report dated February 14, 2024, relating to the financial statements of Proteomedix AG (the Company), appearing in Onconetix Inc's Current Report on Form 8-K/A filed February 27, 2024. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/ Christoph Tschumi

Christoph Tschumi

/s/ Marc Furlato

Marc Furlato

BDO AG
Zurich, Switzerland

December 10, 2024

BDO Ltd, a limited company under Swiss law, incorporated in Zurich, forms part of the international BDO Network of independent member firms.

Calculation of Filing Fee Table

Form S-1
(Form Type)Onconetix, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

| | Security Type | Security Class Title | Fee Calculation or Carry Forward Rule | Amount Registered ⁽¹⁾ | Proposed Maximum Offering Price Per Share | Maximum Aggregate Offering Price | Fee Rate | Amount of Registration Fee | Carry Forward Form Type | Carry Forward File Number | Carry Forward Initial effective date | Filing Fee Previously Paid In Connection with Unsold Securities to be Carried Forward |
|------------------------------------|-----------------------------------|----------------------|---------------------------------------|----------------------------------|---|----------------------------------|------------|----------------------------|-------------------------|---------------------------|--------------------------------------|---|
| Newly Registered Securities | | | | | | | | | | | | |
| Fees to Be Paid | Equity | Common Stock | 457(c) | 6,250,000 ⁽²⁾ | \$ 0.63 ⁽³⁾ | \$3,937,500 | 0.00015310 | \$ 602.84 ⁽⁴⁾ | | | | |
| Fees Previously Paid | - | - | - | - | - | - | - | - | - | - | - | - |
| Carry Forward Securities | | | | | | | | | | | | |
| Carry Forward Securities | - | - | - | - | - | - | - | - | - | - | - | - |
| | Total Offering Amounts | | | | | | | \$ 602.84 | | | | |
| | Total Fees Previously Paid | | | | | | | 602.84 | | | | |
| | Total Fee Offsets | | | | | | | - | | | | |
| | Net Fee Due | | | | | | | <u>\$ 0.00</u> | | | | |

(1) Pursuant to Rule 416(a) of the Securities Act of 1933, as amended (the "Securities Act"), there are also being registered an indeterminable number of additional securities as may be issued to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2) Represents up to 25,000,000 shares of common stock, par value \$0.00001 per share (the "Common Stock") of Onconetix, Inc., a Delaware corporation (the "Company"), that the Company may elect, in its sole discretion, to issue and sell to Keystone Capital Partners, LLC ("Keystone") pursuant to that certain Common Stock ELOC Purchase Agreement, dated as of October 2, 2024, by and between the Company and Keystone, assuming the shares to be issued are sold at a price of \$4.00 per share.

(3) Estimated solely for the purpose of calculating the registration fee, based on the average of the high and low prices of the Common Stock on The Nasdaq Stock Market LLC on December 6, 2024 (\$0.63 per share), in accordance with Rule 457(c) of the Securities Act.

(4) Calculated pursuant to Rule 457 of the Securities Act by multiplying the proposed maximum aggregate offering price of securities to be registered by 0.00015310.