As filed with the Securities and Exchange Commission on February 1, 2024

Registration No. 333-_____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-8

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Onconetix, Inc.

(Exact name of registrant as specified in charter)

Delaware	**81-2262816**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
201 E. Fifth Street, Suite 1900 Cincinnati, OH	**45202**
(Address of Principal Executive Offices)	(Zip Code)

Onconetix, Inc. 2019 Equity Incentive Plan
Onconetix, Inc. 2022 Equity Incentive Plan

(Full Title of the Plan)

Dr. Ralph Schiess
Interim Chief Executive Officer
Onconetix, Inc.
201 E. Fifth Street, Suite 1900
Cincinnati, OH 45202

(Name and Address of Agent For Service)

(513) 620-4101

Telephone Number, Including Area Code of Agent For Service.

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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. (Check one):

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

Explanatory Note

Onconetix, Inc. (the "Registrant" or the "Company") is filing this registration statement on Form S-8 under the Company's 2019 Equity Incentive Plan (the "2019 Plan") and the 2022 Equity Incentive Plan (the "2022 Plan") to (i) register 550,000 shares of our common stock, par value $0.00001 per share (the "Common Stock"), to be issued pursuant to the 2022 Plan, as described in more detail herein, (ii) register for resale pursuant to a reoffer prospectus 885,796 shares of Common Stock issued to our executive officers and directors or to be issued to such officers and directors upon exercise of outstanding options or vesting of outstanding restricted stock units as described below, and (iii) serve as a post-effective amendment, pursuant to Rule 429 under the Securities Act of 1933, as amended (the "Securities Act"), to our Registration Statement on Form S-8 (File No. 333-265843) filed with the Securities and Exchange Commission ("SEC") on June 27, 2022 as amended by the Registration Statement on Form S-8 (File No. 333-268357) filed with the SEC on November 14, 2022 (the "Prior Registration Statement").

Pursuant to General Instruction E to Form S-8, the contents of the Prior Registration Statement is incorporated herein by reference, except to the extent supplemented, amended or superseded by the information set forth in this registration statement on Form S-8.

This Registration Statement includes, pursuant to General Instruction E to Form S-8, a re-offer prospectus in Part I (the "Reoffer Prospectus"). The Reoffer Prospectus may be utilized for reofferings and resales by certain executive officers and directors listed in the Reoffer Prospectus who may be deemed "affiliates" of the Company on a continuous or a delayed basis in the future of up to 885,796 Common Shares issued or to be issued under the 2019 and the 2022 Plan. These shares constitute "control securities" or "restricted securities" which have been issued prior to or issuable after the filing of this Registration Statement. The Reoffer Prospectus does not contain all of the information included in the Registration Statement, certain items of which are contained in schedules and exhibits to the Registration Statement, as permitted by the rules and regulations of the SEC. Statements contained in the Reoffer Prospectus as to the contents of any agreement, instrument or other document referred to are not necessarily complete. With respect to each such agreement, instrument or other document filed as an exhibit to the Registration Statement, we refer you to the exhibit for a more complete description of the matter involved, and each such statement shall be deemed qualified in its entirety by this reference.

As specified in General Instruction C of Form S-8, until such time as we meet the registrant requirements for use of Form S-3, the number of shares of Common Stock to be offered by means of the Reoffer Prospectus, by each of the selling security holders, and any other person with whom he or she is acting in concert for the purpose of selling our shares of Common Stock, may not exceed, during any three month period, the amount specified in Rule 144(e) of the Securities Act.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

Item 1. Plan Information.*

Item 2. Registrant Information and Employee Plan Annual Information.*

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* Pursuant to the Note to Part I on Form S-8, the documents containing the information specified in Part I of this Registration Statement will be sent or given to plan participants as specified by Rule 428(b)(1) of the Securities Act of 1934, as amended (the "Securities Act"). Such documents are not required to be filed, and are not filed, with the United States Securities and Exchange Commission either as part of this Registration Statement or as prospectuses or prospectus supplements pursuant to Rule 424 of the Securities Act. These documents and the documents incorporated by reference in this Registration Statement pursuant to Item 3 of Part II of this Form S-8, taken together, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act.

REOFFER PROSPECTUS

Onconetix, Inc.

Up to 885,796 shares of Common Stock under the 2019 Equity Incentive Plan and 2022 Equity Incentive Plan

This prospectus relates to the resale of up to 885,796 shares (the "Shares") of common stock, par value $0.00001 per share (the "Common Stock"), of Onconetix, Inc., a Delaware corporation (the "Company", "us", "our" or "we"), which may be offered and sold from time to time by certain stockholders of the Company (the "Selling Stockholders") who have acquired or will acquire such Shares in connection with the exercise of stock options granted, and with stock or other awards made, and with the purchase of stock under, the 2019 Plan or the 2022 Plan. The 2019 Plan and the 2022 Plan are intended to provide incentives which will attract, retain, and motivate highly competent persons such as officers, employees, directors, and consultants to our Company by providing them opportunities to acquire shares of our Common Stock. Additionally, the 2019 Plan and the 2022 Plan are intended to assist in further aligning the interests of our officers, employees, directors and consultants to those of the Company's other stockholders.

The persons who are issued such Shares may include our directors, officers, employees and consultants, certain of whom may be considered our "affiliates". Such persons may, but are not required to, sell the Shares they acquire pursuant to this prospectus. If any additional awards are issued to or Shares are purchased by affiliates under the 2019 Plan or the 2022 Plan, we will file with the Securities and Exchange Commission (the "Commission") an update to this prospectus naming such person as a selling shareholder and indicating the number of shares such person is offering pursuant to the prospectus. See "Selling Stockholders" on page 40 of this prospectus. Our Common Stock is listed on The Nasdaq Capital Market under the symbol "ONCO." On January 30, 2024, the closing price of the Common Stock on The Nasdaq Capital Market was $0.207 per share.

Our shares of common stock have experienced extreme volatility in market prices and trading volume since listing. From February 18, 2022 (the date our shares were initially listed on Nasdaq) to the date hereof, the market price of our common stock has fluctuated from an intra-day low on Nasdaq of $0.146 on January 24, 2024 to an intra-day high of $90.90 per share on February 22, 2022. By comparison, our initial public offering, which closed on February 23, 2022, was conducted at $9.00 per share. During this time, we have made various announcements regarding certain research developments, agreements, acquisitions, a shift in business strategy to focus on oncology, changes in management and other matters. Notwithstanding the foregoing, since our initial public offering on February 18, 2022, there were no material recent publicly disclosed changes in the financial condition or results of operations of the Company, such as our earnings or revenue, that are consistent with or related to the changes in our stock price. The trading price of our common stock has been, and may continue to be, subject to wide price fluctuations in response to various factors, many of which are beyond our control, including those described under the heading "Risk Factors" beginning on page 33 of this prospectus.

We will not receive any of the proceeds from sales of the Shares by any of the Selling Stockholders. The Shares may be offered from time to time by any or all of the Selling Stockholders through ordinary brokerage transactions, in negotiated transactions or in other transactions, at such prices as such Selling Stockholder may determine, which may relate to market prices prevailing at the time of sale or be a negotiated price. See "Plan of Distribution." Sales may be made through brokers or to dealers, who are expected to receive customary commissions or discounts. We are paying all expenses of registration incurred in connection with this offering but the Selling Stockholders will pay all brokerage commissions and other selling expenses.

The Selling Stockholders and participating brokers and dealers may be deemed to be "underwriters" within the meaning of the Securities Act, in which event any profit on the sale of shares of those Selling Stockholders and any commissions or discounts received by those brokers or dealers may be deemed to be underwriting compensation under the Securities Act.

SEE "RISK FACTORS" BEGINNING ON PAGE 33 OF THIS PROSPECTUS FOR A DISCUSSION OF CERTAIN RISKS AND OTHER FACTORS THAT YOU SHOULD CONSIDER BEFORE PURCHASING OUR COMMON STOCK.

Neither the Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 1, 2024.

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You should rely only on the information contained in or incorporated by reference into this prospectus or any prospectus supplement. We have not authorized any person to give any information or to make any representations other than those contained or incorporated by reference in this prospectus, and, if given or made, you must not rely upon such information or representations as having been authorized. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any securities other than our shares of Common Stock described in this prospectus or an offer to sell or the solicitation to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should not assume that the information we have included in this prospectus is accurate as of any date other than the date of this prospectus or that any information we have incorporated by reference is accurate as of any date other than the date of the document incorporated by reference regardless of the time of delivery of this prospectus or of any securities registered hereunder.

WHERE YOU CAN FIND MORE INFORMATION

The Company is subject to the information requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and, in accordance therewith, files reports, proxy statements and other information with the Commission. We are required to file electronic versions of those materials with the Commission through the Commission's EDGAR system. The Commission maintains an Internet site at http://www.sec.gov, which contains reports, proxy and information statements and other information regarding registrants that file electronically with the Commission. You can read and copy the reports, proxy statements and other information filed by the Company with the Commission at such Internet site.

This prospectus constitutes part of a Registration Statement on Form S-8 filed on the date hereof (herein, together with all amendments and exhibits, referred to as the "Registration Statement") by the Company with the Commission under the Securities Act. This prospectus does not contain all of the information set forth in the Registration Statement, certain parts of which we have omitted, in accordance with the rules and regulations of the Commission. You should refer to the full Registration Statement for further information with respect to the Company and our Common Stock.

Statements contained herein concerning the provisions of any contract, agreement or other document are not necessarily complete, and in each instance reference is made to the copy of such contract, agreement or other document filed as an exhibit to the Registration Statement or otherwise filed with the Commission. Each such statement is qualified in its entirety by such reference. Copies of the Registration Statement together with exhibits may be inspected at the offices of the Commission as indicated above without charge and copies thereof may be obtained therefrom upon payment of a prescribed fee.

No person is authorized to give any information or to make any representations, other than those contained in this prospectus, in connection with the offering described herein, and, if given or made, such information or representations must not be relied upon as having been authorized by the Company or any Selling Stockholder. This prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, nor shall there be any sale of these securities by any person in any jurisdiction in which it is unlawful for such person to make such offer, solicitation or sale. Neither the delivery of this prospectus nor any sale made hereunder shall under any circumstances create an implication that the information contained herein is correct as of any time subsequent to the date hereto.

PROSPECTUS SUMMARY

The Commission allows us to "incorporate by reference" certain information that we file with the Commission, 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 Commission 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 incorporated herein by reference.

Our Company

We are a commercial stage biotechnology company focused on the research, development, and commercialization of innovative solutions for oncology. We own ENTADFI, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia ("BPH"), a disorder of the prostate, and Proclarix, a European CE IVD approval for prostate diagnostics and a lab developed test currently in the U.S., originally developed by Proteomedix.

ENTADFI allows men to receive treatment for their symptoms of BPH without the negative sexual side effects typically seen in patients on finasteride alone. Following a recent business strategy shift towards the field of oncology and deprioritization of preclinical vaccine programs, we are building additional assets in therapeutics, diagnostics, and clinician services for oncology. ENTADFI will become the inaugural therapeutic drug in the Company's expanding portfolio of oncology therapeutics once launched.

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

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

Recent key developments affecting our business include:

- ***Announced Shift in Business Strategy to Focus on the Field of Oncology:*** On October 30, 2023, in a letter to shareholders, former President and CEO, Dr. Neil Campbell, announced that the Company intends to shift its focus toward building a foundation of therapeutic, diagnostic, and service products in the field of oncology. The Company's previous activities in acquiring assets from WraSer and Xspire Pharma, including certain commercial relationships intended for the marketing and sale of these assets, were reassessed and it was decided that they would not align with the new shift towards oncology. Additionally, the Company conducted a strategic and tactical assessment of its preclinical vaccine programs and, considering the immense amount of time and resources needed to pursue these programs as well as evolving market dynamics, these programs have been deprioritized. The Company believes that the strategic shift in business strategy towards the field of oncology, as well as pursuing the launch of ENTADFI in 2024, will enhance shareholder value and enable the Company to provide leading-edge therapeutics, diagnostics, and services to clinicians, patients, and caregivers.

- ***Acquired a Commercial Stage Oncology Company:*** On December 15, 2023, the Company closed its acquisition of Proteomedix AG, a private, commercial-stage diagnostics oncology company ("Proteomedix"), and introduced Onconetix, Inc. as a new name for the combined Company. The closing of the acquisition of Proteomedix for all stock consideration (the "Closing") provides Proteomedix shareholders with an initial 19.9% ownership stake of Onconetix, and Series B preferred stock convertible into 269,672,900 additional common shares of Onconetix subject to Onconetix shareholder approval of the same.

- ***Signed Various Agreements to Support the Commercial Launch of ENTADFI:*** Throughout the third quarter of 2023, the Company signed several agreements and established key relationships to support the commercial launch of ENTADFI. These agreements include the following:

- ***Marketing and Advertising Support:*** In July 2023, the Company signed a Master Services Agreement with bfw Advertising Inc. ("bfw") to generate marketing and advertising material for Onconetix's commercial stage drug portfolio. Bfw will work with Onconetix's commercial team to increase awareness for its commercial products through patient-facing materials, website updates, social ads, targeted provider engagement, as well as materials to support Onconetix's sales team, among other services.

- ***Healthcare Payer Coverage Support:*** In July 2023, Onconetix signed an agreement with Advantage Point Solutions, LLC ("APS") to support Onconetix's market access strategy for its commercial pharmaceutical portfolio. APS will support market access for ENTADFI, including assistance in formulary negotiations with key healthcare payers and pharmacy benefit managers in the commercial and government sectors. With its robust network of relationships, APS helps commercial stage pharmaceutical companies build long-term relationships with payers with the goal of maximizing access and reimbursement for approved pharmaceutical products. APS also has decades of experience advising companies on product launches across a broad spectrum of therapeutic areas.

- ***Telemedicine Channel:*** In July 2023, Onconetix signed an agreement with UpScriptHealth to generate a robust, online telemedicine platform to distribute ENTADFI. Through this platform, UpScriptHealth will help support patients with benign prostatic hyperplasia throughout the prescription and coverage process, as well as provide eligible patients access to ENTADFI mailed directly to their homes.

- ***Entered into Distribution Agreement***: On September 21, 2023, the Company entered into an Exclusive Distribution Agreement to engage Cardinal Health 105, LLC as its exclusive third-party logistics distribution agent for sales of all of the Company's commercial assets.

- ***Granted Pharmaceutical Wholesaler License in Ohio and Tennessee:*** The Ohio State Board of Pharmacy and the Tennessee State Board of Pharmacy, in July 2023 and September 2023, respectively, granted Onconetix a license to operate as a pharmaceutical wholesaler. These licenses allow Onconetix to conduct business in the States of Ohio and Tennessee.

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

We are currently focusing our efforts on (i) building out our commercial capabilities to launch ENTADFI in the marketplace and (ii) commercializing Proclarix.

Given ENTADFI and Proclarix are currently FDA-approved, we expect to generate revenue from sales of ENTADFI and Proclarix in the near term. 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 and/or launch ENTADFI and Proclarix, and other commercial-stage products,
- 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 ENTADFI and 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.

As we have a product in commercial stage, we are seeking to build a robust and efficient commercial team to accommodate this development. This includes appropriate personnel and third-party relationships and contracts to execute our commercialization strategy. We also expect to incur significant commercialization expenses related to marketing, manufacturing and distribution for those products.

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

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, 2023, the Company had a working capital deficit of approximately $8.1 million and an accumulated deficit of approximately $34.4 million. We will need to raise additional capital within the next 12 months to sustain operations. In addition, if Stockholder Approval is not obtained by January 1, 2025, the Company may be obligated to cash settle the Series B Convertible Preferred Stock.

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 for self-sustaining cash flows. These circumstances raise substantial doubt about our ability to continue as a going concern. The September 30, 2023 condensed financial statements incorporated by reference in this Registration Statement 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 ENTADFI or 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.

Management and Board Changes

Effective as of August 16, 2023, Joseph Hernandez resigned as Chairman, Chief Executive Officer, and a member of the Board of Directors (the "Board") of the Company.

Effective August 16, 2023, the Board appointed Jon Garfield, the Company's former Chief Financial Officer, to serve as the Company's interim principal executive officer. Effective as of October 4, 2023, Jon Garfield resigned as Chief Financial Officer and interim principal executive officer of the Company. The Company and Mr. Garfield entered into a separation agreement, which provided for two months of severance payment.

Effective as of September 2, 2023, Vuk Jeremic resigned as a member of the Board of the Company as well as from his positions as a member of the Compensation Committee and Nominating and Corporate Governance Committee of the Board. Mr. Jeremic's departure was not the result of any disagreement with management or the Board on any matter relating to the Company's operations, policies or practices.

On October 4, 2023 (the "Effective Date"), the Company appointed Dr. Neil Campbell, 63, as President and Chief Executive Officer of the Company and as a member of the Board of Directors (the "Board") of the Company.

In connection with Dr. Campbell's appointment, the Company and Dr. Campbell entered into an employment agreement (the "Campbell Employment Agreement"), pursuant to which Dr. Campbell would serve as President and Chief Executive Officer of the Company and was paid a signing bonus of $75,000 and an annual base salary of $475,000. Pursuant to the Campbell Employment Agreement, Dr. Campbell was granted a long-term equity incentive grant in the form of an option to purchase 532,326 shares of the Company's common stock. Such award was to vest in quarterly increments over a period of three years, subject to Dr. Campbell's continued employment by the Company on the applicable vesting date. Dr. Campbell's option grant has an exercise price per share equal to $0.4305, which was the closing price of the Company's common stock on Nasdaq on the grant date.

On October 4, 2023, the Company also appointed Bruce Harmon, 65, as Chief Financial Officer of the Company, effective immediately.

In connection with Mr. Harmon's appointment, the Company and Mr. Harmon entered into an employment agreement (the "Harmon Employment Agreement"), pursuant to which Mr. Harmon will serve as Chief Financial Officer of the Company and will be paid an annual base salary of $325,000. In addition, Mr. Harmon is entitled to receive, subject to employment by the Company on the applicable date of bonus payout, an annual target discretionary bonus of up to 30% of his annual base salary, payable at the discretion of the Compensation Committee of the Board. Pursuant to the Harmon Employment Agreement, Mr. Harmon is also eligible to receive healthcare benefits as may be provided from time to time by the Company to its employees generally, and to receive paid time off annually. Pursuant to the Harmon Employment Agreement, Mr. Harmon was granted a long-term equity incentive grant in the form of an option to purchase 177,442 shares of the Company's common stock. Such award vests in quarterly increments over a period of three years, subject to Mr. Harmon's continued employment by the Company on the applicable vesting date. Mr. Harmon's option grant has an exercise price per share equal to $0.4305, which was the closing price of the Company's common stock on Nasdaq on the grant date.

In connection with the acquisition of Proteomedix, Christian Brühlmann was appointed as Chief Strategy Officer and Dr. Ralph Schiess was appointed as Chief Science Officer. Mr. Brühlmann co-founded Proteomedix and served as its Chief Financial and Operations Officer from March 2010 until November 2018. Beginning in December 2018, Mr. Brühlmann served as Proteomedix's Chief Business Officer until the consummation of the Closing. Dr. Schiess co-founded Proteomedix in March 2010 and served as its Chief Executive Officer from its inception until December 2019. Dr. Schiess then served as Proteomedix's Chief Scientific Officer from January 2020 to May 2023. Dr. Schiess returned to his role as Chief Executive Officer in June 2023 and served until the consummation of the Closing.

On and effective December 21, 2023, Erin Henderson resigned as Chief Business Officer to pursue other opportunities. On January 17, 2024, the Company entered into a Separation Agreement and General Release with Ms. Henderson, pursuant to which the Company agreed to engage The Aetos Group, a management consulting company founded and managed by Ms. Henderson ("Aetos"), to perform certain consulting services for the Company. On January 17, 2024, the Company entered into a Consulting Agreement with Aetos, pursuant to which Aetos will provide consulting services to the Company until April 25, 2024 and receive a monthly fee of approximately $27,083.

On and effective January 10, 2024, Dr. Neil Campbell resigned as Chief Executive Officer, President and Director. The Company entered into a Release of Claims with Dr. Campbell, pursuant to which Dr. Campbell will receive a one-time severance payment of $158,333. On January 12, 2024, the Board appointed Dr. Ralph Schiess, the Company's Chief Science Officer, to serve as the Company's Interim Chief Executive Officer. As Interim Chief Executive Officer, Dr. Schiess shall have general supervision and direction of the business and affairs of the Company.

Recent Acquisitions:

Proteomedix

On December 15, 2023, Onconetix entered into a Share Exchange Agreement (the "Share Exchange Agreement"), by and among (i) Onconetix, (ii) Proteomedix (iii) each of the holders of outstanding capital stock or Proteomedix Convertible Securities (other than Proteomedix Stock Options) named therein (collectively, the "Sellers") and (iv) Thomas Meier, in the capacity as the representative of Sellers in accordance with the terms and conditions of the Share Exchange Agreement (the "Sellers' Representative").

Pursuant to the Share Exchange Agreement, subject to the terms and conditions set forth therein, the Sellers agreed to sell to Onconetix, and Onconetix agreed to buy, all of the issued and outstanding equity interests of Proteomedix (the "Purchased Shares") in exchange for newly issued shares of common stock of Onconetix, par value $0.00001 per share ("Buyer Common Stock"), and newly issued shares of preferred stock of Onconetix, par value $0.00001 per share ("Series B Convertible Preferred Stock"), as further described below (the "Share Exchange" and the other transactions contemplated by the Share Exchange Agreement, the "Transactions").

The consummation (the "Closing") of the Share Exchange was subject to customary closing conditions and the execution of the Subscription Agreement (as defined below) entered into with an investor (the "Investor"). The Share Exchange closed on December 15, 2023 (the "Closing Date").

Consideration

In full payment for the Purchased Shares, Onconetix issued shares (the "Exchange Shares") consisting of: (i) 3,675,414 shares of Buyer Common Stock equal to approximately 19.9% of the total issued and outstanding Buyer Common Stock and (ii) 2,696,729 shares of Series B Convertible Preferred Stock convertible into 269,672,900 shares of Buyer Common Stock. The aggregate value of the Exchange Shares at Closing was equal to approximately Seventy-Five Million U.S. Dollars ($75,000,000) (the "Exchange Consideration") less the value of the Proteomedix Shares for which the Proteomedix Stock Options are exercisable immediately prior to the Closing, subject to adjustment for indemnification as described below.

Tungsten Advisors acted as financial advisor to Proteomedix. As part of compensation for services rendered by Tungsten Advisors, $7,500,000 in Exchange Shares was issued to certain affiliates of Tungsten Advisors (the "Advisor Parties") out of the total Exchange Consideration issued by Onconetix.

As a result of the Transactions, Proteomedix became a direct, wholly-owned subsidiary of Onconetix. It is anticipated that, following the Conversion (as defined below) and closing of the investment pursuant to the Subscription Agreement (as defined below), Sellers will own 79.8% of the outstanding equity interests of Onconetix, the Investor will own 5.9% of the outstanding equity interests of Onconetix, and the stockholders of Buyer immediately prior to the Closing will own 5.4% of the outstanding equity interests of Onconetix.

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

Indemnification. Until the earlier of (i) Stockholder Approval or (ii) June 30, 2024 (the "Claim Deadline"), Onconetix may assert Claims against Proteomedix and Sellers for any and all Losses incurred by Onconetix with respect to: (i) any inaccuracy in or breach of any of the representations or warranties made by Proteomedix contained in the Share Exchange Agreement or (ii) any breach or non-fulfillment of any covenant, agreement or obligation to be performed by Proteomedix pursuant to the Share Exchange Agreement. Until the Claim Deadline, the Sellers' Representative, acting on behalf of the Sellers, may assert Claims against Onconetix for any Loss incurred by the Sellers with respect to: (i) any inaccuracy in or breach of any of the representations or warranties of Onconetix contained in the Share Exchange Agreement or (ii) any breach or non-fulfillment of any covenant, agreement or obligation to be performed by Onconetix pursuant to the Share Exchange Agreement.

The number of shares of Buyer Common Stock issued upon Conversion shall be increased or decreased by a number determined by dividing the Net Adjustment by the ten-day volume-weighted average price ("VWAP") of the Buyer Common Stock for the ten (10)-day period preceding the third day prior to the Closing Date and rounding down to the nearest whole share; provided, however, that (i) there shall be no adjustment to the number of shares of Buyer Common Stock issued upon Conversion if the Net Adjustment is less than $1,000,000 and (ii) the number of shares of Buyer Common Stock issued upon Conversion shall not be increased or decreased by more than 10% of the number of shares of Buyer Common Stock that would be issuable absent such adjustment. As used herein, "Net Adjustment" means the absolute value of the difference between the aggregate adjustment in favor of each party with respect to Losses that is agreed by Buyer and the Sellers' Representative or determined by a mutually acceptable dispute resolution firm.

From and after the Closing and until the first anniversary of the Closing, Sellers, severally and not jointly, are required to indemnify Onconetix and its affiliates and their respective representatives (collectively, the "Buyer Indemnitees") against (i) any inaccuracy in or breach of any of the representations or warranties of such Seller contained in the Share Exchange Agreement and (ii) breach or non-fulfillment of any covenant, agreement or obligation to be performed by such Seller pursuant to the Share Exchange Agreement. Any payment due from any Seller in respect of an indemnification claim by any Buyer Indemnitee shall solely be satisfied by recourse to the Exchange Shares and the shares of Buyer Common Stock issuable upon the Conversion, with each share of Buyer Common Stock valued at the same price per share of Buyer Common Stock used to determine the Exchange Ratio.

Shareholder Approval

The issuance of the Conversion Shares, amendment of Onconetix's certificate of incorporation to authorize sufficient additional shares of Buyer Common Stock to permit the Conversion and the appointment of certain individuals to the Board requires the approval of Onconetix's stockholders. Onconetix agreed to prepare and file with the Securities and Exchange Commission ("SEC") a proxy statement (a "Proxy Statement") for the purpose of soliciting proxies from the stockholders of Onconetix for the matters to be acted on at the special meeting of the stockholders of Onconetix. Onconetix also agreed to prepare a registration statement on Form S-1 or Form S-4 in connection with the registration under the Securities Act of 1933, as amended (the "Securities Act"), of the issuance of Buyer Securities to be issued under the Share Exchange Agreement and containing a Proxy Statement.

Series B Convertible Preferred Stock

Upon Stockholder Approval, each share of Series B Convertible Preferred Stock shall automatically convert into 100 shares of Buyer Common Stock in accordance with the terms of the Certificate of Designation (the "Conversion"), a copy of which is attached hereto as Exhibit 4.1. If Stockholder Approval is not obtained by January 1, 2025, Onconetix shall be obligated to cash settle the Series B Convertible Preferred Stock, as described below. The terms of the Series B Convertible Preferred Stock, as described in the Certificate of Designation, are as follows:

Voting. The shares of Series B Convertible Preferred Stock carry no voting rights except: (i) with respect to the election of the Proteomedix Director (as described below) and (ii) that the affirmative vote of the holders of a majority of the outstanding shares of Series B Convertible Preferred Stock (the "Majority Holders"), acting as a single class, shall be necessary to (A) alter or change adversely the powers, preferences or rights given to the Series B Convertible Preferred Stock, (B) alter or amend the Certificate of Designation, or amend or repeal any provision of, or add any provision to, Onconetix's certificate of incorporation or bylaws, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series B Convertible Preferred Stock, (C) issue further shares of Series B Convertible Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series B Convertible Preferred Stock, or (D) authorize or create any class or series of stock, or issue shares of any class or series of stock, that has powers, preferences or rights senior to the Series B Convertible Preferred Stock

Proteomedix Director. The Majority Holders, voting exclusively and as a separate class, shall be entitled to elect one (1) director of Onconetix. Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the Series B Convertible Preferred Stock. If the holders of Series B Convertible Preferred Stock fail to elect a director, then any directorship not so filled shall remain vacant until such time as the holders of the Series B Convertible Preferred Stock elect a person to fill such directorship; and no such directorship may be filled by stockholders of Onconetix other than by the holders of Series B Convertible Preferred Stock. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of Series B Convertible Preferred Stock shall constitute a quorum for the purpose of electing such director.

Redemption. The shares of Series B Convertible Preferred Stock are not redeemable by Onconetix.

Liquidation Preference. Upon a liquidation, dissolution or winding-up of Onconetix, whether voluntary or involuntary (a "Liquidation"), the holders of Series B Convertible Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of Onconetix the same amount that a holder of Buyer Common Stock would receive if such Holder's Series B Convertible Preferred Stock were fully converted to Buyer Common Stock at the Conversion Ratio (as defined below) plus an additional amount equal to any dividends declared but unpaid to such shares, which amounts shall be paid *pari passu* with all holders of Buyer Common Stock.

Dividends. The holders of the Series B Convertible Preferred Stock shall be entitled to receive, dividends on shares of Series B Convertible Preferred Stock (on an as-if-converted-to-common-stock basis) equal to and in the same form, and in the same manner, as dividends (other than dividends on shares of the Buyer Common Stock payable in the form of Buyer Common Stock) actually paid on shares of the Buyer Common Stock when, as and if such dividends (other than dividends payable in the form of Buyer Common Stock) are paid on shares of the Buyer Common Stock.

Conversion. Following Stockholder Approval, each share of Series B Convertible Preferred Stock shall be converted into shares of Buyer Common Stock (the "Conversion Shares") at a ratio of 100 Conversion Shares for each share of Series B Convertible Preferred Stock (the "Conversion Ratio"). All shares of Series B Convertible Preferred Stock shall automatically and without any further action required be converted into Conversion Shares at the Conversion Ratio upon the latest date on which (i) Onconetix has received the Stockholder Approval with respect to the issuance of all of the shares of Buyer Common Stock issuable upon Conversion in excess of 20% of the issued and outstanding Buyer Common Stock on the Closing Date and (ii) Onconetix has effected an increase in the number of shares of Buyer Common Stock authorized under its certificate of incorporation, to the extent required to consummate the Transactions.

Cash Settlement. If, at any time after the earlier of the date of the Stockholder Approval or January 1, 2025 (the earliest such date, the "Cash Settlement Date"), Onconetix (x) has obtained the Stockholder Approval but fails to or has failed to deliver to a holder certificate or certificates representing the Conversion Shares, or deliver documentation of book entry form of (or cause its transfer agent to electronically deliver such evidence) Conversion Shares on or prior to the fifth business day after the date of the Stockholder Approval, or (y) has failed to obtain the Stockholder Approval, Onconetix shall, in either case, at the request of the holder setting forth such holder's request to cash settle a number of shares of Series B Convertible Preferred Stock, pay to such holder an amount in cash equal to (i) the Fair Value (as defined below) of the shares of Series B Convertible Preferred Stock set forth in such request multiplied by (ii) the Conversion Ratio in effect on the trading day on which the request is delivered to Onconetix, with such payment to be made within two (2) business days from the date of the request by the holder, whereupon, after payment in full thereon by Onconetix, Onconetix's obligations to deliver such shares underlying the request shall be extinguished. "Fair Value" of shares shall be fixed with reference to the last reported closing stock price on the principal trading market of the Buyer Common Stock on which the Buyer Common Stock is listed as of the trading day on which the request is delivered to Onconetix.

Certain Adjustments. If Onconetix, at any time while the Series B Convertible Preferred Stock is outstanding: (A) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of Buyer Common Stock; (B) subdivides outstanding shares of Buyer Common Stock into a larger number of shares; or (C) combines (including by way of a reverse stock split) outstanding shares of Buyer Common Stock into a smaller number of shares, then the Conversion Ratio shall be multiplied by a fraction of which the numerator shall be the number of shares of Buyer Common Stock outstanding immediately after such event and of which the denominator shall be the number of shares of Buyer Common Stock outstanding immediately before such event (excluding any treasury shares of the Corporation). If, at any time while the Series B Convertible Preferred Stock is outstanding, either (A) Onconetix effects any merger or consolidation of Onconetix with or into another person or any stock sale to, or other business combination with or into another person (other than such a transaction in which Onconetix is the surviving or continuing entity and holds at least a majority of the Buyer Common Stock after giving effect to the transaction and its Buyer Common Stock is not exchanged for or converted into other securities, cash or property), (B) Onconetix effects any sale, lease, transfer or exclusive license of all or substantially all of its assets in one transaction or a series of related transactions, (C) any tender offer or exchange offer (whether by Onconetix or another person) is completed pursuant to which more than 50% of the Buyer Common Stock not held by Onconetix or such person is exchanged for or converted into other securities, cash or property, or (D) Onconetix effects any reclassification of the Buyer Common Stock or any compulsory share exchange pursuant to which the Buyer Common Stock is effectively converted into or exchanged for other securities, cash or property (in any such case, a "Fundamental Transaction"), then, in connection with such Fundamental Transaction, the holders of Series B Convertible Preferred Stock shall receive in the Fundamental Transaction, the same kind and amount of securities, cash or property that a holder of Buyer Common Stock would receive if such holder's Series B Convertible Preferred Stock were fully converted to Buyer Common Stock, plus an additional amount equal to any dividends declared but unpaid to such shares, which amounts shall be paid pari passu with all holders of Buyer Common Stock in the Fundamental Transaction (the "Alternate Consideration"). If holders of Buyer Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holders of Series B Convertible Preferred Stock shall be given the same choice as to the Alternate Consideration it receives in such Fundamental Transaction.

Stockholder Subscription Agreement and Debenture

In connection with the Transactions, on December 15, 2023, Onconetix entered into a Subscription Agreement (the "Subscription Agreement") with the Investor for a private placement of $5.0 million of units (the "Units"), each unit comprised of (i) one share of Common Stock and (ii) one pre-funded warrant (collectively, the "Warrants") to purchase 0.3 shares of Common Stock at an exercise price of $0.001 per share, for an aggregate purchase price per Unit of $0.25 (the "Purchase Price"). Additional shares are issuable to the Investor to the extent the Investor continues to hold Common Stock included in the Units and if the VWAP during the 270 days following closing is less than the Purchase Price, as set forth in the Subscription Agreement.

The offering is expected to close following stockholder approval of the issuance of the Conversion Shares. Within 30 days after closing, Onconetix will file a resale registration statement with the SEC registering the resale of the Common Stock issuable pursuant to the Subscription Agreement and the Warrants.

On January 23, 2024, Onconetix issued a non-convertible debenture (the "Debenture") to the Investor in the principal sum of $5.0 million, the payment of which shall offset the Purchase Price for the Units pursuant to the Subscription Agreement.

The Debenture has an interest rate of 4.0% per annum, and the principal and accrued interest are repayable in full upon the earlier of (i) the closing under the Subscription Agreement and (ii) June 30, 2024. Additionally, the $5.0 million subscription amount under the Subscription Agreement shall be increased by the amount of interest payable under the Debenture.

ENTADFI

On April 19, 2023, the Company entered into the Veru APA. Pursuant to, and subject to the terms and conditions of, the Veru APA, the Company purchased substantially all of the assets related to Veru's ENTADFI business and assumed certain liabilities of Veru. The Transaction closed on April 19, 2023.

The Company purchased substantially all of Veru's assets, rights and property related to ENTADFI for a total possible consideration of $100.0 million (as described below). The acquisition of ENTADFI capitalizes on the demonstrable success of the FDA-approved drug ENTADFI for treating benign prostatic hyperplasia and counteracting negative sexual side effects seen in men on alternative BPH therapies.

Pursuant to the terms of the Veru APA, the Company agreed to provide Veru with initial consideration totaling $20.0 million, consisting of (i) $6.0 million paid upon the closing of the Transaction, (ii) an additional $4.0 million in the form of a non-interest bearing note payable due on September 30, 2023, and (iii) an additional $10.0 million in the form of two equal (i.e. each for $5.0 million) non-interest bearing notes payable, each due on April 19, 2024 and September 30, 2024. On September 29, 2023, the Company entered into an amendment (the "Amendment") of the Veru APA. Pursuant to the 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.

The terms of the Series A Preferred Stock are set forth in the Certificate of Designations, which was filed with the State of Delaware on September 29, 2023. Pursuant to the Certificate of Designations, each share of Series A Preferred Stock will convert one year from the date of issuance of the Series A Preferred Stock into that number of shares of the Company's common stock determined by dividing the Stated Value (as defined in the Certificate of Designations) of $1,000 per share by the Conversion Price (as defined in the Certificate of Designations) of $0.5254 per share, subject to adjustment as provided in the Certificate of Designations, subject to certain shareholder approval limitations. The Series A Preferred Stock is entitled to share ratably in any dividends paid on the Company's common stock (on an as-if-converted-to-common-stock basis), has no voting rights except as to certain significant matters specified in the Certificate of Designations, and has a liquidation preference equal to the Stated Value of $1,000 per share plus any accrued but unpaid dividends thereon. The Series A Preferred Stock is redeemable in whole or in part at the Company's option at any time. The Certificate of Designations authorized the issuance of up to 10,000 shares of Series A Preferred Stock.

The Series A Preferred Stock issued to Seller is initially convertible, in the aggregate, into approximately 5,709,935 shares of the Company's common stock, subject to adjustment and certain shareholder approval limitations specified in the Certificate of Designations. Pursuant to the Amendment, the Company agreed to use commercially reasonable efforts to obtain such shareholder approval by December 31, 2023. The Company also agreed to include the shares of common stock issuable upon conversion of the Series A Preferred Stock in the next resale registration statement filed with the SEC.

Additionally, the terms of the Veru APA require the Company to pay Veru up to an additional $80.0 million based on the Company's net sales from the ENTADFI business after closing. The Milestone Payments are payable as follows: (i) $10.0 million is payable if the Company's annual net sales from the ENTADFI business equal or exceed $100.0 million, (ii) $20.0 million is payable if the Company's annual net sales from the ENTADFI business equal or exceed $200.0 million, and (3) $50.0 million is payable if annual net sales from the ENTADFI business equal or exceed $500.0 million. No more than one Milestone Payment shall be made for the achievement of each net sales milestone. There can be no assurance that the net sales milestones for payment of any of the Milestone Payments will be reached.

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

WraSer

On June 13, 2023 (the "Execution Date"), the Company entered into an asset purchase agreement with WraSer, LLC, a Mississippi limited liability company, Xspire Pharma, LLC, a Mississippi limited liability company (collectively, the "Seller"), and Legacy-Xspire Holdings, LLC, a Delaware limited liability company and the parent company of the Seller ("Parent") (the "WraSer APA"). Pursuant to, and subject to the terms and conditions of, the WraSer APA, on the Closing Date (as defined below) the Company will purchase six FDA-approved pharmaceutical assets across several indications, including cardiology, otic infections, and pain management (the "WraSer Assets").

Under the terms of the WraSer APA, the Company will purchase the WraSer Assets for (i) $3.5 million in cash at signing of the WraSer APA (the "Signing Cash"); (ii) $4.5 million in cash on the later of (x) 90 days after the signing of the WraSer APA or (y) the date that all closing conditions under the WraSer APA are met or otherwise waived (the "Closing Date"); (iii) 1.0 million shares of the Company's common stock (the "Closing Shares") issuable on the Closing Date, and (iv) $500,000 in cash one year from the Closing Date. The closing of the transaction is subject to certain customary closing conditions and the delivery to the Company of financial statements of Seller and Parent for the fiscal years ended December 31, 2022 and 2021 audited by a qualified auditor reasonably acceptable to the Company.

Within 90 days of the Closing Date, the Company will use its best efforts to file with the SEC, (at its sole cost and expense,) a registration statement to register on Form S-3 registering under the Securities Act of 1933, as amended (the "Securities Act"), the resale of the Closing Shares and will use its best efforts to have the registration statement declared effective as soon as practicable after filing.

In conjunction with the WraSer APA, the Company and the Seller entered into a Management Services Agreement (the "MSA") on the Execution Date. Pursuant to the terms of the MSA, the Company was to act as the manager of the Seller's business during the period between the Execution Date and Closing Date. During this period, the Company was to make advances to WraSer, if needed to sustain operations. The Company's involvement as manager of the Seller's business ended when WraSer filed for relief under chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court (see below). If, on the Closing Date, the Seller's cash balance is in excess of the target amount specified in the MSA of $1.1 million (the "Cash Target"), the Company was to apply that excess to the $4.5 million cash payment due upon closing. Conversely, if there is a shortfall, the Company would have been required to remit the difference to the Seller over time. Specifically, as the Company collected accounts receivable generated after the Closing Date, the Company would have been required to remit 50% of the collections to the Seller until the shortfall is paid in full. The MSA terminates on the Closing Date.

The WraSer APA can be terminated prior to closing as follows (i) upon agreement with all parties; (ii) upon breach of contract of either party, uncured within 20 days of notice. If the WraSer APA is terminated upon agreement with all parties or upon uncured breach of contract by the Seller, the initial $3.5 million payment is retained by the Sellers. If it is determined that there is an uncured breach of contract by the Seller, and the WraSer APA is terminated, the Company will have an unsecured claim against WraSer for the $3.5 million payment made by the Company upon execution of the WraSer APA. The closing of the Transaction is subject to various closing conditions, including submission of the FDA transfer documentation to transfer ownership of the acquired product regulatory approvals to the Company.

On September 26, 2023, WraSer and its affiliates filed for relief under chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court.

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

In October 2023, we were alerted by WraSer that its sole manufacturer for the active pharmaceutical ingredient ("API") for Zontivity, the key driver for the WraSer acquisition, would no longer manufacture the API for Zontivity. We believed that this development constituted a Material Adverse Effect under the APA enabling us to terminate the APA and MSA. On October 20, 2023, we filed a motion for relief from the automatic stay in the Bankruptcy Court to exercise our termination rights under the WraSer APA, as amended. On December 18, 2023, the Bankruptcy Court entered an Agreed Order lifting the automatic stay to enable us to exercise our rights to terminate the APA and the MSA without prejudice to the parties' respective rights, remedies, claims and defenses they had against one another under the APA and MSA. On December 21, 2023, we filed a Notice with the Bankruptcy Court terminating the APA and MSA. WraSer has advised us that it does not believe that a Material Adverse Event occurred. Due to the WraSer bankruptcy filing and our status as an unsecured creditor of WraSer, it is also unlikely that we will recover the $3.5 million Signing Cash or any costs and resources in connection with services provided by the Company under the WraSer MSA.

Agreement with Cardinal Health

On September 21, 2023, the Company entered into an Exclusive Distribution Agreement (the "Exclusive Distribution Agreement"), effective as of September 20, 2023 (the "Effective Date"), with Cardinal Health 105, LLC ("Cardinal Health"). Pursuant to, and subject to the terms and conditions of, the Exclusive Distribution Agreement, the Company engaged Cardinal Health as its exclusive third-party logistics distribution agent for sales of all of the Company's commercial assets. The term of the Distribution Agreement is three years from the Effective Date and automatically renews for additional terms of one year each unless terminated pursuant to the terms of the Exclusive Distribution Agreement. Under the terms of the Exclusive Distribution Agreement, the Company must pay to Cardinal Health a one-time start-up fee of $15,500, and upon launch of ENTADFI, a monthly account management fee of $7,000, and other fees for various services, including post-launch program implementation, information systems, warehouse operations, and financial services.

Corporate Name Change and Amendment to Bylaws

On December 15, 2023, the Company filed an amendment to its A&R COI with the Secretary of State of Delaware to change its corporate name from "Blue Water Biotech, Inc." to "Onconetix, Inc."

In connection with the name change, the Company also amended the Company's bylaws to reflect the new corporate name.

On May 31, 2023, the Board amended the Company's bylaws to reduce the quorum requirement at meetings of the Company's stockholders from a majority of the voting power of the outstanding shares of stock of the Company entitled to vote, to one-third of the voting power of the outstanding shares of stock of the Company entitled to vote, effective immediately. No other changes were made to the bylaws.

Warrant Inducement

On July 31, 2023, the Company entered into the Inducement Letter with the Holder of the Existing PIOs. Pursuant to the Inducement Letter, the Holder agreed to exercise for cash its Existing PIOs to purchase an aggregate of 2,486,214 shares of the Company's common stock, at a reduced exercise price of $1.09 per share, in exchange for the Company's agreement to issue Inducement PIOs to purchase up to 4,972,428 shares of the Company's common stock. The Inducement PIOs have substantially the same terms as the Existing PIOs. On August 2, 2023, the Company consummated the Warrant Inducement. The Company received aggregate net proceeds of approximately $2.3 million from the Warrant Inducement, after deducting placement agent fees and other offering expenses payable by the Company.

The Company engaged Wainwright to act as its 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 PIOs as well as a management fee equal to 1.0% of the gross proceeds from the exercise of the Existing PIOs. The Company also agreed to reimburse Wainwright for its expenses in connection with the exercise of the Existing PIOs and the issuance of the Inducement PIOs, up to $50,000 for fees and expenses of legal counsel and other out-of-pocket expenses and agreed to pay Wainwright for non-accountable expenses in the amount of $35,000. In addition, the exercise for cash of the Existing PIOs triggered the issuance to Wainwright or its designees, warrants to purchase 149,173 shares of common stock, which were issuable in accordance with the terms of Contingent Warrants issuable to Wainwright in connection with the August 2022 Private Placement Transaction, and have the same terms as the Inducement PIOs, except for an exercise price equal to $1.3625 per share. The Company also agreed to issue warrants to Wainwright upon any exercise for cash of the Inducement PIOs, that number of shares of common stock equal to 6.0% of the aggregate number of such shares of common stock underlying the Inducement PIOs that have been exercised, also with an exercise price of $1.3625. The maximum number of warrants issuable under this provision is 298,346.

Nasdaq Compliance

On September 18, 2023, we received notice from Nasdaq staff indicating that, based upon the closing bid price of the Common Stock for the prior 30 consecutive business days, we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). We have 180 days from September 18, 2023, or through March 16, 2024, to regain compliance with the Bid Price Rule.

On August 22, 2023, we received a notice from Nasdaq that we were not in compliance with Nasdaq Listing Rule 5250(c)(1), which requires listed companies to timely file all required periodic financial reports with the SEC, given our failure to timely file our quarterly report on Form 10-Q for the quarter ended June 30, 2023. On October 20, 2023, we filed our Form 10-Q for the period ended June 30, 2023, and on November 1, 2023, we announced that we had regained compliance with Nasdaq Listing Rule 5250(c)(1).

Corporate Information

We were incorporated in Delaware on October 26, 2018. Our principal executive offices are located at 201 E. Fifth Street, Suite 1900, Cincinnati, Ohio 45202, and our telephone number is (513) 620-4101. Our corporate website address is *www.onconetix.com*. The information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

The Offering

Outstanding Common Stock:	22,324,576 shares of our Common Stock are outstanding as of January 25, 2024.
Common Stock Offered:	Up to 885,796 shares of Common Stock for sale by the Selling Stockholders (which include our employees, consultants, executive officers and directors) for their own account pursuant to the 2022 Plan.
Selling Stockholders:	The Selling Stockholders are set forth in the section entitled "Selling Stockholders" of this reoffer prospectus on page 40. The amount of securities to be offered or resold by means of the reoffer prospectus by the designated Selling Stockholders may not exceed, during any three month period, the amount specified in Rule 144(i).
Use of proceeds:	We will not receive any proceeds from the sale of our Common Stock by the Selling Stockholders. We would, however, receive proceeds upon the exercise of the stock options by those who receive options under the Plan and exercise such options for cash. Any cash proceeds will be used by us for general corporate purposes.
Risk Factors:	The securities offered hereby involve a high degree of risk. See "Risk Factors."
Nasdaq Capital Market trading symbol:	ONCO

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY AND MARKET DATA

Special Note Regarding Forward-Looking Statements

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

- our 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;
- the success, cost and timing of our future clinical trials;
- our ability to obtain and maintain the necessary regulatory approvals to market and commercialize our products and future product candidates;
- the potential that results of pre-clinical and clinical trials indicate any future product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current product candidates;
- 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 and products that are or become available;
- our ability to commercialize ENTADFI and Proclarix and integrate the assets and commercial operations acquired;
- our ability to successfully compete against current and future competitors;
- our ability to expand our organization to accommodate growth and our ability to retain and attract 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 product candidates;
- market acceptance of our products and product candidates, the size and growth of the potential markets for our current product candidates and any future product candidates we may seek to develop, and our ability to serve those markets; and
- the successful development of our commercialization capabilities, including sales and marketing capabilities.

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.

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics such as those we are developing.

Small molecule drugs are subject to regulation under the Food, Drug, and Cosmetic Act, or FDCA, and biological products are additionally subject to regulation under the Public Health Service Act, or PHSA, and both are subject to additional federal, state, local and foreign statutes and regulations. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

United States

U. S. Biopharmaceuticals Regulation

The process required by the FDA before drug and biologic product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and animal studies performed in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with FDA's Good Clinical Practice, or GCP, regulations to establish the safety and efficacy of a drug candidate and safety, purity and potency of a proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a new drug application, or NDA, or biologics license application, or BLA, as applicable, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practice requirements, or cGMPs, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of an NDA, or licensure of a BLA, to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and harmacodynamics characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent institutional review board for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

For purposes of biopharmaceutical development, human clinical trials are typically conducted in three sequential phases that may overlap or be combined;

- *Phase 1.* The investigational product is initially introduced into patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- *Phase 2.* The investigational product is administered to a limited patient population to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

- *Phase 3.* The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the application. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research patients or patients are being exposed to an unacceptable health risk. Similarly, an institutional review board can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the institutional review board's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information, which is publicly available at *www.clinicaltrials.gov*.

NDA/BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA, as applicable, requesting approval to market the product for one or more indications. The application must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of an application requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies. The FDA has sixty days from the applicant's submission to either issue a refusal to file letter or accept the application for filing, indicating that it is sufficiently complete to permit substantive review.

Once an NDA or BLA has been accepted for filing, the FDA's goal is to review standard applications within 10 months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine whether a drug is safe and effective for its intended use and a BLA to determine whether a biologic is safe, pure and potent. FDA also reviews whether the facility in which the product is manufactured, processed, packed or held meets standards designed to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an application, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an application and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be manufactured, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the application, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional information or clarification, which may include the potential requirement for additional clinical studies. The FDA may delay or refuse approval of an application if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the application with a risk evaluation and mitigation strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast-track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast-track product has opportunities for frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast-track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product with a fast-track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. Priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Biopharmaceutical manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;

- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labelling, advertising and promotion of biopharmaceutical products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labelling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labelling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

U.S. Market Exclusivity

A biological product can obtain pediatric market exclusivity in the U.S., which, if granted, adds six months to existing exclusivity periods, including some regulatory exclusivity periods tied to patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHSA attempts to minimize duplicative testing.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be interchanged after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and the FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until 12 years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the U.S. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

Pediatric Study Plan and Pediatric Exclusivity

Under the Pediatric Research Equity Act, as amended, or the PREA, certain NDAs and certain NDA supplements must contain data that can be used to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The PREA requires that a sponsor who is planning to submit a marketing application for a product candidate that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or the PSP, within 60 days of an end-of-phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the phase 3 or phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Unless otherwise required by regulation, the PREA does not apply to a drug for an indication for which orphan designation has been granted, except that the PREA will apply to an original NDA for a new active ingredient that is orphan-designated if the drug is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

A drug can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Patent Term Restoration and Extension

Depending upon the timing, duration and specifics of the FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension. The provisions of the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Many other countries also provide for patent term extensions or similar extensions of patent protection for biologic products. For example, in Japan, it may be possible to extend the patent term for up to five years and in Europe, it may be possible to obtain a supplementary patent certificate that would effectively extend patent protection for up to five years.

Federal and State Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws and regulations restrict business practices in the biopharmaceutical industry. These laws may impact, among other things, our current and future business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we market, sell and distribute our products for which we obtain marketing approval. These laws include anti-kickback and false claims laws and regulations, data privacy and security, and transparency laws and regulations, including, without limitation, those laws described below.

The U.S. federal Anti-Kickback Statute prohibits any person or entity from, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act or the civil monetary penalties laws.

Federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which can be enforced by individuals through civil whistleblower and qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, which include certain healthcare providers, healthcare clearinghouses and health plans, that create, receive, maintain or transmit individually identifiable health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which are not pre-empted by HIPAA, differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, and state and local laws that require the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant criminal, civil and administrative penalties including damages, fines, imprisonment, disgorgement, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, implementation of corporate compliance programs, reporting of payments or transfers of value to healthcare professionals, and additional data privacy and security requirements.

Healthcare Reform

Coverage and Reimbursement

The future commercial success of our products will depend in part on the extent to which third-party payors, such as governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors, provide coverage of and establish adequate reimbursement levels for our product candidates. Third-party payors generally decide which products they will pay for and establish reimbursement levels for those products. In particular, in the United States, no uniform policy for coverage and reimbursement exists. Private health insurers and other third-party payors often provide coverage and reimbursement for products based on the level at which the government, through the Medicare program, provides coverage and reimbursement for such products, but also on their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement can differ significantly from payor to payor.

In the United States, the European Union, or EU, and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of products, particularly for new and innovative products, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage. These pressures can arise from rules and practices of managed care groups, judicial decisions and laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for products. For example, federal and state governments reimburse products at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of products. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Similarly, because certain of our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of products, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party payor reimbursement may not be available to enable us to realize an appropriate return on our investment in product development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our product candidates, if approved, or exclusion of our product candidates from coverage and reimbursement. The cost containment measures that third-party payors and providers are instituting and any healthcare reform could significantly reduce our revenue from the sale of any approved product candidates.

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts, which include major legislative initiatives to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

There have been several U.S. government initiatives over the past few years to fund and incentivize certain comparative effectiveness research, including creation of the Patient-Centered Outcomes Research Institute under the ACA. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates.

The ACA became law in March 2010 and substantially changed the way healthcare is financed by third-party payors, and significantly impacts the U.S. pharmaceutical industry. Among other measures that may have an impact on our business, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increased the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Additionally, the ACA extended manufacturers' Medicaid rebate liability, expands eligibility criteria for Medicaid programs, and expanded entities eligible for discounts under the Public Health Service Act. At this time, we are unsure of the full impact that the ACA will have on our business.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect such challenges and amendments to continue. Since January 2017, Former President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain ACA provisions or otherwise circumvent requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high-cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on nonexempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In December 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, as amended, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and, following passage of subsequent legislation, including the BBA, will continue through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was enacted which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. In August 2022, Congress passed the Inflation Reduction Act of 2022, which included a provision allowing Medicare to negotiate drug prices directly with pharmaceutical manufacturers. This provision may impact pricing strategies and determinations in the future. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and is implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019. On January 31, 2019, the HHS Office of Inspector General proposed modifications to U.S. federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. In addition, CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than $35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These measures could reduce future demand for our products or put pressure on our pricing.

Additionally, in May 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our product candidates. For example, in the EU, we must obtain authorization of a clinical trial application, or CTA, in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a drug, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Further, some countries outside of the United States, including the EU member states, Switzerland and the United Kingdom, have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EU, the collection and use of personal health data is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR became effective on May 25, 2018, repealing its predecessor directive and increasing responsibility and liability of pharmaceutical companies in relation to the processing of personal data of EU subjects. The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to process personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern potentially burdensome documentation requirements, granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them, the information provided to the individuals, the transfer of personal data out of the EU, security breach notifications, and security and confidentiality of the personal data. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement and fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. Data protection authorities from the different EU member states may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the EU. Guidance on implementation and compliance practices are often updated or otherwise revised.

European Union

European Union Coverage Reimbursement and Pricing

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies, or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company.

EU Drug regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions such as in China and Japan. Although many of the issues discussed above with respect to the United States apply similarly in the context of the EU, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. Failure to comply with applicable foreign regulatory requirements may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-clinical studies and clinical trials

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice (GLP) as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization (ICH) guidelines on good clinical practices (GCP) as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the EU, it must appoint an entity within the EU to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

Certain countries outside of the United States, including the EU, have a similar process that requires the submission of a clinical study application (CTA) much like the IND prior to the commencement of human clinical studies. A CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved by the national health authority and the ethics committee has granted a positive opinion in relation to the conduct of the trial in the relevant member state(s), in accordance with a country's requirements, clinical study development may proceed.

The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, CTAs must be submitted to the competent authority in each EU member state in which the trial will be conducted. Under the new Regulation on Clinical Trials, which is currently expected to become applicable by early 2022, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with good manufacturing practice (GMP). Other national and EU-wide regulatory requirements also apply.

Marketing Authorizations

To market a medicinal product in the EU and in many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a Marketing Authorization (MA). To obtain regulatory approval of an investigational medicinal product under EU regulatory systems, we must submit a marketing authorization application (MAA.) The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of Mas:

- the "Union MA", which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and which is valid throughout the entire territory of the EU. The Centralized Procedure is mandatory for certain types of products, such as (i) medicinal products derived from biotechnology medicinal products, (ii) designated orphan medicinal products, (iii) advanced therapy products (such as gene therapy, somatic cell therapy or tissue-engineered medicines), and (iv) medicinal products containing a new active substance indicated for the treatment certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, other auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or that the granting of authorization would be in the interest of public health in the EU; and

- "National Mas", which are issued by the competent authorities of the EU member states and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in an EU member state, this National MA can be recognized in another member state through the Mutual Recognition Procedure. If the product has not received a National MA in any member state at the time of application, it can be approved simultaneously in various member states through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the Reference member state.

Under the above-described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Under the Centralized Procedure, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days. Where there is a major public health interest and an unmet medical need for a product, the CHMP may perform an accelerated review of a MA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the US PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. The benefits of a PRIME designation include the appointment of a CHMP rapporteur before submission of a MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Mas have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance, unless the EMA decides, on justified grounds relating to pharmacovigilance, to mandate one additional five-year renewal period.

Data and marketing exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving MA, new chemical entity, or reference product candidates, generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Pediatric Development

In the EU, MAAs for new medicinal products candidates have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan (PIP) agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of authorization).

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

All new MAA must include a risk management plan (RMP) describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area (EEA) which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

For other countries outside of the EU, such as countries in Latin America or Asia (e.g. China and Japan), the requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Privacy and data protection laws

We are also subject to laws and regulations in non-US countries covering data privacy and the protection of health-related and other personal information. For instance, EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal information that identifies or may be used to identify an individual, such as names, contact information, and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations,

As of May 2018, the General Data Protection Regulation (GDPR) replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

Japan

Japanese drug regulation

Non-clinical studies and clinical trials

Being a member of the International Conference on Harmonization (ICH), Japan has pharmaceutical regulations fundamentally similar to those of the United States or EU.

Non-clinical studies are performed to demonstrate the health safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of Japanese good laboratory practice (GLP) which reflect the Organization for Economic Co-operation and Development requirements. Currently, Japan and EU have a mutual recognition agreement for GLP, and data generated compliant with EU requirements will be accepted by the Japanese authorities. There is no similar agreement with the United States.

Clinical trials of medicinal products in Japan must be conducted in accordance with Japanese regulations based on ICH guidelines governing good clinical practices (GCP). They focus on ethics of the clinical trial and protection of the privacy of the trial subjects. If the sponsor of the clinical trial is not established within Japan, it must appoint an entity within the country to act as its caretaker who should be authorized to act on the sponsor's behalf. The sponsor must take out a clinical trial insurance policy, and, according to the industry agreement, should put in place a common compensation policy for the injuries from the trial.

Prior to the commencement of human clinical studies, the sponsor must complete evaluation of the safety of the investigative product, and submit a clinical trial notification and the protocol to the authorities in advance, upon agreement of the IRB of the participating institutions. When the authorities do not comment on the notification, the sponsor may proceed with the clinical trial.

Any substantial changes to the trial protocol or other information submitted must be cleared by the IRB and notified to the authorities. Medicines used in clinical trials must be manufactured in accordance with good manufacturing practice (GMP).

Product approval

To market a medicinal product in Japan, we must obtain regulatory approval. To obtain regulatory approval of an investigational medicinal product, we must submit a new drug application. The process for doing this depends, among other things, on the nature of the medicinal product and there are currently a few different pathways for approval. If the product is designed for treating certain "difficult diseases" or those whose patient size is limited, we may be able to obtain designation as an orphan drug product if it demonstrates unique therapeutic value. Approval application for such designated orphan products will be processed on an expedited basis and the authorities' requirement for clinical data will be much limited. Separately, the latest amendment to the law introduced separate pathways for (i) truly innovative products with a unique mode of action and (ii) those which will satisfy unmet medical needs. These products will also be processed on an expedited basis.

The evaluation of applications will be based on an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Once the review organization complete its review task, the matter will be considered by the advisory committee of experts, and the government will grant approval upon positive recommendation from the committee.

The volume and quality of the clinical data will be the key determinant of the approval decision. Clinical trial data generated overseas will be accepted as part of the data package consistent with the ICH recommendation. Typically, a limited dose response clinical trial for Japanese subjects is required to ensure that data are extrapolatable for the Japanese population. In a more recent development, the authorities encourage manufacturers to organize an international joint clinical trial with some Japanese participation under a joint protocol, to expedite the clinical trial process. Regulatory approval does not expire.

Licensing requirement

Separate from the approval requirement, it is also mandatory to possess a distribution license of an appropriate class for the manufacturer to commercially distribute the product in Japan. Non-Japanese companies who possess only the product approval may designate an appropriate license holder in Japan to commercially distribute the product, rather than distributing it on its own. The license is valid for 5 years.

Employees

As of January 25, 2024, we had 5 full-time and 11 subcontracted employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees.

Properties and Facilities

We currently lease an office located at 201 E Fifth Street, Suite 1900, Cincinnati, OH 45202, which is renewed on a monthly basis.

Additionally, Proteomedix leases office and lab space located at Wagistrasse 23, 8952 Schlieren, Switzerland. This lease expires on June 30, 2025, subject to renewal for successive two-year terms.

Legal Proceedings

From time to time we may be involved in various disputes and litigation matters that arise in the ordinary course of business. We are currently not a party to any material legal proceedings.

Other

We were incorporated on October 22, 2018 under the laws of the State of Delaware. Our principal executive offices are located at 201 E Fifth Street, Suite 1900, Cincinnati, OH 45202, and our telephone number is (513) 620-4101. Our corporate website address is *www.onconetix.com*. We make available free of charge on or through our Internet website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements on Schedule 14A, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such materials with, or furnish them to, the Securities and Exchange Commission (the "SEC"). Alternatively, you may also access our reports at the SEC's website at www.sec.gov.

RISK FACTORS

Our business involves a high degree of risk and uncertainty, including the following risks and uncertainties:

Investing in our common stock involves a high degree of risk. You should carefully consider the following information about these risks before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, reputation, financial condition, results of operations and future growth prospects, as well as our ability to accomplish our strategic objectives. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

There is substantial doubt about our ability to continue as a "going concern."

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, 2023, the Company had cash of approximately $7.7 million, a working capital deficit of approximately $8.1 million and an accumulated deficit of approximately $34.4 million.

The Company will require significant additional capital to fund its 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, the commercialization of ENTADFI and Proclarix, and the development and commercialization of its current product candidates and future product candidates. In addition, if Stockholder Approval is not obtained by January 1, 2025, the Company may be obligated to cash settle the Series B Convertible Preferred Stock. Management's plans include generating product revenue from sales of ENTADFI, which is subject to further successful commercialization activities, and Proclarix, which may still be subject to further successful commercialization activities within certain jurisdictions. Certain of the commercialization activities are outside of the Company's control, including but not limited to, securing contracts with wholesalers and third party payers, securing contracts with third-party logistics providers, obtaining required licensure in various jurisdictions, as well as attempting to secure additional required funding through equity or debt financings if available. However, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all. If the Company is unable to secure additional capital, it may be required to delay or curtail any future clinical trials, development and/or commercialization of products and 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. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of time within one year after the date of the issuance of the condensed financial statements incorporated by reference in this Registration Statement.

We entered into an asset purchase agreement and management services agreement with WraSer, which have been terminated because we believe that a material adverse event has occurred with respect to the WraSer Assets. However, the termination is subject to WraSer's right to challenge the termination and assert claims against us

On June 13, 2023, we entered into the WraSer APA and MSA with WraSer in connection with the purchase of the WraSer Assets. Under the WraSer APA, we paid $3.5 million in cash to WraSer at signing (the "Signing Cash").In October 2023, we were alerted by WraSer that its sole manufacturer for the active pharmaceutical ingredient ("API") for Zontivity, the key driver for the WraSer acquisition, would no longer manufacture the API for Zontivity. We believed that this development constituted a Material Adverse Effect under the APA enabling us to terminate the APA and MSA. On October 20, 2023, we filed a motion for relief from the automatic stay in the Bankruptcy Court to exercise our termination rights under the WraSer APA, as amended. On December 18, 2023, the Bankruptcy Court entered an Agreed Order lifting the automatic stay to enable us to exercise our rights to terminate the APA and the MSA without prejudice to the parties' respective rights, remedies, claims and defenses they had against one another under the APA and MSA. On December 21, 2023, we filed a Notice with the Bankruptcy Court terminating the APA and MSA. WraSer has advised us that it does not believe that a Material Adverse Event occurred. Due to the WraSer bankruptcy filing and our status as an unsecured creditor of WraSer, it is also unlikely that we will recover the $3.5 million Signing Cash or any costs and resources in connection with services provided by the Company under the WraSer MSA.

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

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

The issuance or conversion of securities would result in significant dilution in the equity interest of existing shareholders and adversely affect the marketplace of the securities.

The issuance or conversion of common shares or other securities convertible into common shares would result in significant dilution in the equity interest of existing shareholders and adversely affect the market price of the common shares. We have issued 3,000 shares of Series A Preferred Stock to Veru which are initially convertible one year from issuance, in the aggregate, into 5,709,935 shares of the Company's common stock, subject to adjustment and certain shareholder approval limitations specified in the Certificate of Designations. We have issued 2,696,729 shares of Series B Preferred Stock to former shareholders of Proteomedix which are initially convertible, in the aggregate, into 269,672,900 shares of the Company's common stock, subject to adjustment and certain shareholder approval limitations specified in the Certificate of Designations.

We may have violated Section 13(k) of the Exchange Act (implementing Section 402 of the Sarbanes-Oxley Act of 2002) and may be subject to sanctions as a result.

Section 13(k) of the Exchange Act provides that it is unlawful for a company that has a class of securities registered under Section 12 of the Exchange Act to, directly or indirectly, including through any subsidiary, extend or maintain credit in the form of a personal loan to or for any of its directors or executive officers. In the fiscal year ended December 31, 2022 and the nine months ended September 30, 2023, we paid certain expenses of our former Chief Executive Officer and Chairman of the Board, which may be deemed to be personal loans made by us to our former Chief Executive Officer and Chairman of the Board that are not permissible under Section 13(k) of the Exchange Act. Issuers that are found to have violated Section 13(k) of the Exchange Act may be subject to civil sanctions, including injunctive remedies and monetary penalties, as well as criminal sanctions. The imposition of any of such sanctions on us could have a material adverse effect on our business, financial position, results of operations or cash flows.

Misconduct and errors by our current and former employees and our third-party service providers could cause a material adverse effect on our business and reputation.

Our employees and third-party service providers are integral to our business operations, including confidential information. If any such information were leaked to unintended recipients due to human error, theft, malicious sabotage or fraudulent manipulation, we may be subject to liability for loss of such information. Further, if any of our employees or third-party service providers absconded with our proprietary data or know-how in order to compete with us, our competitive position may be materially and adversely affected.

Any improper conduct or use of funds by any of our employees or third-party service providers in contravention of our protocols and policies may lead to regulatory and disciplinary proceedings involving us. We may be perceived to have facilitated or participated in such conduct and we could be subject to liability, damages, penalties and reputational damage. It is impossible to completely identify and eradicate all risks of misconduct or human errors, and our precautionary measures may not be able to effectively detect and prevent such risks from happening.

Occurrence of any of the above risks could result in a material adverse effect on our business and results of operations, as we are exposed to potential liability to borrowers and investors, reputational damage, regulatory intervention, financial harm. Our ability to attract new and retain existing borrowers and investors and operate as an ongoing concern may be impaired.

We may consider strategic alternatives in order to maximize stockholder value, including financing, strategic alliances, licensing arrangements, acquisitions or the possible sale of our business. We may not be able to identify or consummate any suitable strategic alternatives and any consummated strategic alternatives may not be successful.

We may consider all strategic alternatives that may be available to us to maximize stockholder value, including financings, strategic alliances, licensing arrangements, acquisitions or the possible sale of our business. Our exploration of various strategic alternatives may not result in any specific action or transaction. To the extent that this engagement results in a transaction, our business objectives may change depending upon the nature of the transaction. There can be no assurance that we will enter into any transaction as a result of the engagement. Furthermore, if we determine to engage in a strategic transaction, we cannot predict the impact that such strategic transaction might have on our operations or stock price. We also cannot predict the impact on our stock price if we fail to enter into a transaction.

In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our business activities because they may be deemed to be at too early of a stage of development for collaborative effort. Any delays in entering into new strategic partnership agreements harm our business prospects, financial condition and results of operations.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

As a result of our failure to timely file our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, we are currently ineligible to file new short form registration statements on Form S-3, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all.

Form S-3 permits eligible issuers to conduct registered offerings using a short form registration statement that allows the issuer to incorporate by reference its past and future filings and reports made under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In addition, Form S-3 enables eligible issuers to conduct primary offerings "off the shelf" under Rule 415 of the Securities Act of 1933, as amended, or the Securities Act. The shelf registration process, combined with the ability to forward incorporate information, allows issuers to avoid delays and interruptions in the offering process and to access the capital markets in a more expeditious and efficient manner than raising capital in a standard registered offering pursuant to a Registration Statement on Form S-1.

As a result of our failure to timely file our Quarterly Report on Form 10-Q for quarter ended June 30, 2023, we are currently ineligible to file new short form registration statements on Form S-3 and we will be unable to conduct "off the shelf" offerings under Rule 415 of the Securities Act using our currently effective Registration Statement on Form S-3 (File No. 333-270383) after we file our annual report for the fiscal year ending December 31, 2023. As a result, we may be unable to conduct an "at the market" offering pursuant to our At The Market Offering Agreement with H.C. Wainwright & Co., LLC after such date. In addition, if we seek to access the capital markets through a registered offering during the period of time that we are unable to use Form S-3, we may be required to publicly disclose the proposed offering and the material terms thereof before the offering commences, we may experience delays in the offering process due to SEC review of a Form S-1 registration statement and we may incur increased offering and transaction costs and other considerations. Disclosing a public offering prior to the formal commencement of an offering may result in downward pressure on our stock price. In addition, our inability to conduct an offering "off the shelf" may require us to offer terms that may not be advantageous (or may be less advantageous) to us or may generally reduce our ability to raise capital in a registered offering. If we are unable to raise capital through a registered offering, we would be required to conduct our financing transactions on a private placement basis, which may be subject to pricing, size and other limitations imposed under Nasdaq rules.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We have identified weaknesses in our internal controls, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and Nasdaq rules and regulations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. We must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K for each year, as required by Section 404 of the Sarbanes-Oxley Act ("Section 404"). This requires significant management efforts and requires us to incur substantial professional fees and internal costs to expand our accounting and finance functions. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements, or may identify other areas for further attention or improvement. Furthermore, we cannot be certain that our efforts will be sufficient to remediate or prevent future material weaknesses or significant deficiencies from occurring.

We do not yet have effective disclosure controls and procedures, or internal controls over all aspects of our financial reporting. Specifically, we have identified the following control deficiencies which we believe are material weaknesses.

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

- We did not have an effective risk assessment process over the identification of fraud risks surrounding the authorization, identification, approval and reporting of personal expenses charged to the Company's corporate credit cards.

- We did not design and maintain effective monitoring of compliance with established accounting policies and procedures.

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

- We failed to employ a sufficient number of staff to maintain optimal segregation of duties, maintain adequate internal controls surrounding information technology procedures, such as a lack of a written information security policy, maintain adequate controls over the approval and posting of journal entries, and to provide optimal levels of oversight in order to process financial information in a timely manner, analyze and account for complex, non-routine transactions, and prepare financial statements.

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

We cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future.

As a result of the material weaknesses in our internal controls over financial reporting described above, and other matters raised or that may in the future be raised by the SEC, we may face for the prospect of litigation or other disputes which may include, among others, claims invoking the federal and state securities laws, contractual claims or other claims arising from the material weaknesses in our internal control over financial reporting and the preparation of our financial statements, any of which claims could result in adverse effects to our business. As of the date hereof, we have no knowledge of any such litigation or dispute.

We expect to rely on third party manufacturers for ENTADFI and Proclarix.

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

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

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

Disruptions to or significantly increased costs associated with transportation and other distribution channels for ENTADFI and/or Proclarix may adversely affect our margins and profitability.

We expect to rely on the uninterrupted and efficient operation of third-party logistics companies to transport and deliver ENTADFI and Proclarix. These third-party logistics companies may experience disruptions to the transportation channels used to distribute our products, including disruptions caused by the COVID-19 pandemic, increased airport and shipping port congestion, a lack of transportation capacity, increased fuel expenses, and a shortage of manpower or capital or due to other business interruptions. Disruptions to the transportation channels experienced by our third-party logistics companies may result in increased costs, including the additional use of airfreight to meet demand. Disruptions to this business model or our relationship with the third party if, for example, performance fails to meet our expectations, could harm our business.

We may fail or elect not to commercialize our products.

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

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

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

Physicians may not prescribe our products, which would prevent our products from generating revenue. Market acceptance of our products by physicians, patients and payors, will depend on a number of factors, many of which are beyond our control, including the following:

- the clinical indications for which our products are approved, if at all;
- acceptance by physicians and payors of our products as safe and effective treatment or test;
- the cost in relation to alternative treatments or tests;
- the relative convenience and ease of administration of our products for the conditions for which they are intended;
- the availability and efficacy of competitive drugs or tests;
- the effectiveness of our sales and marketing efforts;
- the extent to which our products are approved for inclusion on formularies of hospitals and managed care organizations;
- the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid;
- limitations or warnings contained in a product's FDA or other applicable regulatory agency's approved labeling; and
- prevalence and severity of adverse side effects.

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

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

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

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

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

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

We may not be able to successfully implement our strategy to grow sales of ENTADFI and Proclarix in the U.S. market or, if authorized, in any foreign market.

We may not be able to expand sales of ENTADFI or Proclarix through partnering with telemedicine or other partners or with commercial diagnostic providers or through our own commercialization efforts. We may not be able to command a price with private and government payors for ENTADFI or Proclarix that would justify our devotion of significant resources to attempting to grow sales of ENTADFI or Proclarix. We may not be able to compete efficiently or effectively in a mature BPH market which is heavily generic. Failure to grow sales of ENTADFI or Proclarix would have a negative effect on our revenue and future plans.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

Our continued eligibility for listing on Nasdaq depends on our ability to comply with Nasdaq's continued listing requirements.

On September 18, 2023, we received notice from Nasdaq staff indicating that, based upon the closing bid price of the Common Stock for the prior 30 consecutive business days, we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq, as set forth in Nasdaq Listing Rule 5550(a)(2). We have 180 days from September 18, 2023, or through March 16, 2024, to regain compliance with the Bid Price Rule.

If Nasdaq delists our common stock from trading on its exchange for failure to meet the Bid Price Rule or any other listing standards, we and our stockholders could face significant material adverse consequences including:

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

SELLING STOCKHOLDERS

The following table sets forth (a) the name and position or positions with the Company of each Selling Stockholder; (b) the aggregate of (i) the number of shares of Common Stock held by each Selling Stockholder as of the date of this prospectus and (ii) the number of shares issuable upon exercise of options granted to each Selling Stockholder under the 2019 Plan and the 2022 Plan that are being registered pursuant to this Registration Statement for resale by each Selling Stockholder as of the date of this prospectus; (c) the number of shares of Common Stock issuable upon exercise of options that each Selling Stockholder may offer for sale from time to time pursuant to this prospectus, whether or not such Selling Stockholder has a present intention to do so; and (d) the number of shares of Common Stock to be beneficially owned by each Selling Stockholder following the sale of all shares that may be so offered pursuant to this prospectus, assuming no other change in ownership of Common Stock by such Selling Stockholder after the date of this prospectus. Unless otherwise indicated, beneficial ownership is direct and the person indicated has sole voting and investment power.

The Selling Stockholders may, from time to time, resell all, a portion or none of the shares of our Common Stock covered by this reoffer prospectus.

Inclusion of an individual's name in the table below does not constitute an admission that such individual is an "affiliate" of the Company.

Selling Stockholder	Principal Position with the Company (1)	Shares Owned Prior to Resale		Number of Shares Offered for Resale	Shares Beneficially Owned After Resale	
		Number(2)	Percent(3)		Number	Percent(3)
Erin Henderson	Former Chief Business Officer	342,682(4)	1.5%	317,930	24,752	*
James Sapirstein	Director	56,935(5)	*	56,935	—	—
Simon Tarsh	Director	10,433(6)	*	10,433	—	—
Timothy Ramdeen	Director	8,746(7)	*	8,746	—	—
Brian Price	Consultant	32,552(8)	*	32,552	—	—
Sunetra Gupta	Advisory Board Member	459,200(9)	2.1%	459,200	—	—

* Less than 1%.

(1) All positions described are with the Company, unless otherwise indicated.

(2) The number of shares owned prior to resale by each Selling Stockholder shares of Common Stock owned on or about the date hereof by the Selling Stockholders and shares of Common Stock that are issued or to be issued, or which may be acquired upon the exercise of stock options issued or to be issued, or vesting of restricted stock awards issued or to be issued, pursuant to the 2019 Plan and the 2022 Plan.

(3) Percentage is computed with reference to 22,324,576 shares of our Common Stock outstanding as of January 30, 2024. In addition, we deemed outstanding shares of Common Stock subject to options or warrants held by each person for purposes of computing the percentage of ownership for such person. However, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

(4) Includes 24,752 shares of Common Stock, 150,000 restricted shares of Common Stock, and 167,930 shares of Common Stock underlying options.

(5) Includes 6,360 restricted shares of Common Stock and 50,575 shares of Common Stock underlying options.

(6) Includes 6,360 restricted shares of Common Stock and 4,073 shares of Common Stock underlying options.

(7) Includes 6,360 restricted shares of Common Stock and 2,386 shares of Common Stock underlying options.

(8) Includes 32,552 shares of Common Stock underlying options.

(9) Includes 459,200 shares of Common Stock underlying options.

The Company may supplement this prospectus from time to time as required by the rules of the Commission to include certain information concerning the security ownership of the Selling Stockholders or any new Selling Stockholders, the number of securities offered for resale and the position, office or other material relationship which a Selling Stockholder has had within the past three years with the Company or any of its predecessors or affiliates.

USE OF PROCEEDS

We will not receive any proceeds from the resale of our Common Stock by the Selling Stockholders pursuant to this prospectus. However, we will receive the exercise price of any Common Stock issued to the Selling Stockholders upon cash exercise by them of their options. We would expect to use these proceeds, if any, for general working capital purposes. We have agreed to pay the expenses of registration of these shares.

PLAN OF DISTRIBUTION

In this section of the prospectus, the term "Selling Stockholder" means and includes:

- the persons identified in the table above as the Selling Stockholders;
- those persons whose identities are not known as of the date hereof but may in the future be eligible to receive options under the 2019 Plan or the 2022 Plan; and
- any of the donees, pledgees, distributees, transferees or other successors in interest of those persons referenced above who may: (a) receive any of the shares of our Common Stock offered hereby after the date of this prospectus and (b) offer or sell those shares hereunder.

The shares of our Common Stock offered by this prospectus may be sold from time to time directly by the Selling Stockholders. Alternatively, the Selling Stockholders may from time to time offer such shares through underwriters, brokers, dealers, agents or other intermediaries. The Selling Stockholders as of the date of this prospectus have advised us that there were no underwriting or distribution arrangements entered into with respect to the Common Stock offered hereby. The distribution of the Common Stock by the Selling Stockholders may be effected: in one or more transactions that may take place on The Nasdaq Capital Market (including one or more block transactions) through customary brokerage channels, either through brokers acting as agents for the Selling Stockholders, or through market makers, dealers or underwriters acting as principals who may resell these shares on The Nasdaq Capital Market; in privately-negotiated sales; by a combination of such methods; or by other means. These transactions may be effected at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at other negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the Selling Stockholders in connection with sales of our Common Stock.

The Selling Stockholders may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In such transactions, broker-dealers may engage in short sales of the shares of our Common Stock in the course of hedging the positions they assume with the Selling Stockholders. The Selling Stockholders also may sell shares short and redeliver the shares to close out such short positions. The Selling Stockholders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of shares of our Common Stock. The broker-dealer may then resell or otherwise transfer such shares of Common Stock pursuant to this prospectus.

At the time a particular offering of shares of our Common Stock is made, a prospectus supplement, if required, will be distributed, which will set forth the name of the Selling Stockholders, the aggregate amount of shares of our Common Stock being offered and the terms of the offering, including, to the extent required, (1) the name or names of any underwriters, broker-dealers or agents, (2) any discounts, commissions and other terms constituting compensation from the Selling Stockholders and (3) any discounts, commissions or concessions allowed or reallowed to be paid to broker-dealers.

The Selling Stockholders also may lend or pledge shares of our Common Stock to a broker-dealer. The broker-dealer may sell the shares of Common Stock so lent, or upon a default the broker-dealer may sell the pledged shares of Common Stock pursuant to this prospectus.

The Selling Stockholders will act independently of us in making decisions with respect to the timing, manner, and size of each resale or other transfer. There can be no assurance that the Selling Stockholders will sell any or all of the shares of our Common Stock under this prospectus. Further, we cannot assure you that the Selling Stockholders will not transfer, distribute, devise or gift the shares of our Common Stock by other means not described in this prospectus. In addition, any Shares covered by this prospectus that qualify for sale under Rule 144 of the Securities Act may be sold under Rule 144 rather than under this prospectus.

The Selling Stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities. There is no underwriter or coordinating broker acting in connection with the proposed sale of shares of Common Stock the Selling Stockholders.

Although the shares of Common Stock covered by this prospectus are not currently being underwritten, the Selling Stockholders or their underwriters, brokers, dealers or other agents or other intermediaries, if any, that may participate with the selling security holders in any offering or distribution of Common Stock may be deemed "underwriters" within the meaning of the Securities Act and any profits realized or commissions received by them may be deemed underwriting compensation thereunder.

Under applicable rules and regulations under the Exchange Act, any person engaged in a distribution of shares of the Common Stock offered hereby may not simultaneously engage in market making activities with respect to the Common Stock for a period of up to five days preceding such distribution. The Selling Stockholders will be subject to the applicable provisions of the Exchange Act and the rules and regulations promulgated thereunder, including without limitation Regulation M, which provisions may limit the timing of purchases and sales by the Selling Stockholders.

In order to comply with certain state securities or blue sky laws and regulations, if applicable, the Common Stock offered hereby will be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the Common Stock may not be sold unless they are registered or qualified for sale in such state, or unless an exemption from registration or qualification is available and is obtained.

We will bear all costs, expenses and fees in connection with the registration of the Common Stock offered hereby. However, the Selling Stockholders will bear any brokerage or underwriting commissions and similar selling expenses, if any, attributable to the sale of the shares of Common Stock offered pursuant to this prospectus. We have agreed to indemnify the Selling Stockholders against certain liabilities, including liabilities under the Securities Act, or to contribute to payments to which any of those security holders may be required to make in respect thereof.

LEGAL MATTERS

The validity of the securities being offered herein has been passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES LAWS VIOLATIONS

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 shareholders 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.

You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.

Additional risks and uncertainties not presently known or that are currently deemed immaterial may also impair our business operations. The risks and uncertainties described in this document and other risks and uncertainties which we may face in the future will have a greater impact on those who purchase our common stock. These purchasers will purchase our common stock at the market price or at a privately negotiated price and will run the risk of losing their entire investment.

ONCONETIX, INC.

885,796 Shares of
Common Stock

PROSPECTUS

February 1, 2024

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 3. Incorporation of Documents by Reference

We are "incorporating by reference" in this prospectus certain documents we file with the Commission, which means that we can disclose important information to you by referring you to those documents. The information in the documents incorporated by reference is considered to be part of this prospectus. Statements contained in documents that we file with the Commission and that are incorporated by reference in this prospectus will automatically update and supersede information contained in this prospectus, including information in previously filed documents or reports that have been incorporated by reference in this prospectus, to the extent the new information differs from or is inconsistent with the old information. We have filed or may file the following documents with the Commission and they are incorporated herein by reference as of their respective dates of filing.

(i) our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 as filed with the SEC on March 9, 2023;

(ii) our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 as filed with the SEC on May 12, 2023; the quarter ended June 30, 2023 as filed with the SEC on October 20, 2023; and the quarter ended September 30, 2023 as filed with the SEC on November 17, 2023;

(iii) our Current Reports on Form 8-K dated March 29, 2023, April 20, 2023, April 24, 2023, June 6, 2023, June 14, 2023, July 6, 2023, July 11, 2023, July 25, 2023, July 25, 2023, July 31, 2023, August 1, 2023, August 3, 2023, August 10, 2023, August 22, 2023, August 28, 2023, September 8, 2023, September 22, 2023, October 3, 2023, October 10, 2023, December 18, 2023, December 27, 2023, December 28, 2023, January 12, 2024, January 19, 2024 and January 29, 2024.

(iv) the description of our securities registered under Section 12 of the Exchange Act as filed as Exhibit 4.2 on Annual Report on Form 10-K for the year ended December 31, 2021 as filed with the SEC on March 31, 2022.

All documents that we file with the Commission pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act subsequent to the date of this prospectus that indicate that all securities offered under this prospectus have been sold, or that deregisters all securities then remaining unsold, will be deemed to be incorporated in this prospectus by reference and to be a part hereof from the date of filing of such documents.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus, or in any subsequently filed document that also is deemed to be incorporated by reference in this prospectus, modifies, supersedes or replaces such statement. Any statement so modified, superseded or replaced shall not be deemed, except as so modified, superseded or replaced, to constitute a part of this prospectus. None of the information that we disclose under Items 2.02 or 7.01 of any Current Report on Form 8-K or any corresponding information, either furnished under Item 9.01 or included as an exhibit therein, that we may from time to time furnish to the Commission will be incorporated by reference into, or otherwise included in, this prospectus, except as otherwise expressly set forth in the relevant document. Subject to the foregoing, all information appearing in this prospectus is qualified in its entirety by the information appearing in the documents incorporated by reference.

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost (other than exhibits, unless such exhibits are specifically incorporated by reference), by contacting Bruce Harmon, c/o Onconetix, Inc., at 201 E. Fifth Street, Suite 1900, Cincinnati, OH 45202. Our telephone number is (513) 620-4101. Information about us is also available at our website at http://www.onconetix.com. However, the information on our website is not a part of this prospectus and is not incorporated by reference.

Item 4. Description of Securities

Not applicable.

Item 5. Interests of Named Experts and Counsel

Not applicable.

Item 6. Indemnification of Officers and Directors

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 shareholders 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 7. Exemption from Registration Claimed

Not applicable.

Item 8. Exhibits

The following exhibits are filed with this Registration Statement.

Number	Description
4.1	2019 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.1 to our Registration Statement on Form S-1/A, dated February 8, 2022.)
4.2	2022 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.2 to our Registration Statement on Form S-1/A, dated February 8, 2022.)
4.3	2019 Equity Incentive Plan Form of Stock Option Grant Agreement. (Incorporated by reference to Exhibit 10.3 to our Registration Statement on Form S-1/A, dated February 8, 2022.)
4.4	2022 Equity Incentive Plan Form of Incentive Stock Option Agreement (Employee). (Incorporated by reference to Exhibit 10.4 to our Registration Statement on Form S-1/A, dated February 8, 2022.)
4.5	2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Consultant). (Incorporated by reference to Exhibit 10.5 to our Registration Statement on Form S-1/A, dated February 8, 2022.)
4.6	2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Non-Employee Director). (Incorporated by reference to Exhibit 10.6 to our Registration Statement on Form S-1/A, dated February 8, 2022.)
4.7	2022 Equity Incentive Plan Form of Nonstatuory Stock Option Agreement (Employee). (Incorporated by reference to Exhibit 10.7 to our Registration Statement on Form S-1/A, dated February 8, 2022.)
5.1	Opinion of Ellenoff Grossman & Schole LLP (Filed herewith)
23.1	Consent of Mayer Hoffman McCann P.C. (Filed herewith)
23.2	Consent of Ellenoff Grossman & Schole LLP (included in Exhibit 5.1)
24	Powers of Attorney (included on signature page)
107	Filing Fee Table. (Filed herewith)

Item 9. Undertakings.

(II) The undersigned registrant hereby undertakes:

(II) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement

(II) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) 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.

(3) 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.

(4) That prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.

(5) That every prospectus (i) that is filed pursuant to paragraph (4) immediately preceding, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act of 1933 and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes 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.

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

(7) To respond to requests for information that is incorporated by reference into the joint proxy statement/prospectus pursuant to Item 4, 10(b), 11 or 13 of this form, within one business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.

(8) To supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.

(b) 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 Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act 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 and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, on February 1, 2024.

ONCONETIX, INC.

By: /s/ Dr. Ralph Schiess
Dr. Ralph Schiess
Interim Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that we, the undersigned officers and directors of Onconetix, Inc., a Delaware corporation, do hereby constitute and appoint Dr. Ralph Schiess as his or her true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments, exhibits thereto and other documents in connection therewith) to this Registration Statement and any subsequent registration statement filed by the registrant pursuant to Rule 462(b) of the Securities Act of 1933, as amended, which relates to this Registration Statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Position	Date
/s/ Dr. Ralph Schiess Dr. Ralph Schiess	Interim Chief Executive Officer (Principal Executive Officer)	February 1, 2024
/s/ Bruce Harmon Bruce Harmon	Chief Financial Officer (Principal Financial Officer)	February 1, 2024
/s/ James Sapirstein James Sapirstein	Non-Executive Chairman of the Board	February 1, 2024
/s/ Timothy Ramdeen Timothy Ramdeen	Director	February 1, 2024
/s/ Simon Tarsh Simon Tarsh	Director	February 1, 2024

Exhibit 5.1

Ellenoff Grossman & Schole LLP

1345 AVENUE OF THE AMERICAS, 11th FLOOR
NEW YORK, NEW YORK 10105
TELEPHONE: (212) 370-1300
FACSIMILE: (212) 370-7889
www.egsllp.com

February 1, 2024
Onconetix, Inc.
201 E. Fifth Street, Suite 1900
Cincinnati, OH 45202

Re: Registration Statement on Form S-8

Ladies and Gentlemen:

We have acted as counsel to Onconetix, Inc., a Delaware corporation (the "Company"), in connection with the preparation of the Company's Registration Statement on Form S-8 (the "Registration Statement") being filed with the Securities and Exchange Commission (the "SEC") under the Securities Act of 1933, as amended (the "Securities Act"). The Registration Statement has been filed to (i) register 550,000 shares (the "Plan Shares") of Company common stock to be issued pursuant to the Onconetix, Inc. 2022 Equity Incentive Plan (as amended, the "2022 Plan"), (ii) register for resale up to 885,796 shares (collectively, the "Resale Shares") of common stock issued or issuable upon vesting or exercise of restricted stock awards or options issued under the Onconetix, Inc. 2019 Equity Incentive Plan (as amended, the "2019 Plan"), the 2022 Plan, such Resale Shares or related awards being held by current and former executive officers and directors of the Company, and (iii) serve as a post-effective amendment, pursuant to Rule 429 under the Securities Act, to our (a) Registration Statement on Form S-8 (File No. 333-265843) filed with the SEC on June 27, 2022 and (b) Registration Statement on Form S-8 (File No. 333-268357) filed with the SEC on November 14, 2022.

In arriving at the opinions expressed below, we have examined and relied on the following documents:

(1) the Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws of the Company, each as amended as of the date hereof;

(2) the 2019 Plan;

(3) the 2022 Plan; and

(4) records of meetings and consents of the Board of Directors of the Company provided to us by the Company.

In addition, we have examined and relied on the originals or copies certified or otherwise identified to our satisfaction of all such corporate records of the Company and such other instruments and other certificates of public officials, officers and representatives of the Company and such other persons, and we have made such investigations of law, as we have deemed appropriate as a basis for the opinions expressed below. In such examination, we have assumed, without independent verification, the genuineness of all signatures (whether original or photostatic), the accuracy and completeness of each document submitted to us, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as facsimile, electronic, certified, conformed or photostatic copies thereof. We have further assumed the legal capacity of natural persons, that persons identified to us as officers of the Company are actually serving in such capacity, that the representations of officers and employees of the Company are correct as to questions of fact and that each party to the documents we have examined or relied on (other than the Company) has the power, corporate or other, to enter into and perform all obligations thereunder and also have assumed the due authorization by all requisite action, corporate or other, of the execution and delivery by such parties of such documents, and the validity and binding effect thereon on such parties. We have also assumed that the Company will not in the future issue or otherwise make unavailable so many shares of its common stock that there are insufficient authorized and unissued shares of common stock for issuance of the shares issuable upon exercise of the options being registered in the Registration Statement. We have not independently verified any of these assumptions.

The opinions expressed in this opinion letter are limited to the General Corporation Law of the State of Delaware. We are not opining on, and we assume no responsibility for, the applicability or effect on any of the matters covered herein of: (a) any other laws; (b) the laws of any other jurisdiction; or (c) the laws of any country, municipality or other political subdivision or local government agency or authority. The opinions set forth below are rendered as of the date of this opinion letter. We assume no obligation to update or supplement such opinions to reflect any change of law or fact that may occur.

Based upon and subject to the foregoing, it is our opinion that the Plan Shares and Resale Shares have been duly authorized and, upon issuance and payment therefor in accordance with the terms of the 2019 Plan or 2022 Plan, as applicable, and the awards, agreements or certificates issued thereunder, will be validly issued, fully paid and nonassessable.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement. In giving such consent, we do not thereby admit that we are experts with respect to any part of the Registration Statement within the meaning of the term "expert" as used in Section 11 of the Securities Act or the rules and regulations promulgated thereunder by the SEC, nor do we admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the SEC promulgated thereunder.

Yours truly,

/s/ Ellenoff Grossman & Schole LLP

Ellenoff Grossman & Schole LLP

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form S-8 of our report dated March 8, 2023, with respect to the financial statements of Onconetix, Inc. (formerly known as Blue Water Vaccines Inc.) (the "Company") as of December 31, 2022 and 2021, and for each of the two years in the period ended December 31, 2022, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ Mayer Hoffman McCann P.C.

Los Angeles, California
February 1, 2024

Exhibit 107

Calculation of Filing Fee Tables

Form S-8
(Form Type)

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

Table 1: Newly Registered Securities

Security Type	Security Class Title	Fee Calculation Rule	Amount Registered(1)	Proposed Maximum Offering Price Per Share	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Equity	Common Stock	Other	1,435,796(2)	$ 0.20(3)	$ 287,159	0.00014760	$ 42.38
Equity	Common Stock	Other	2,600,000(4)	N/A	N/A	N/A	N/A
Total Offering Amounts					N/A		$ 42.38
Total Fee Offsets							$ -
Net Fee Due							$ 42.38

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), this Registration Statement on Form S-8 shall also cover any additional shares of the Registrant's common stock that become issuable in respect of the securities identified in the above table by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the Registrant's receipt of consideration which results in an increase in the number of the outstanding shares of the Registrant's common stock. In addition, this Registration Statement covers the resale by certain selling stockholders named in the prospectus included in and filed with this Registration Statement of certain of the shares of Registrant's common stock subject to this Registration Statement, for which no additional registration fee is required pursuant to Rule 457(h)(3).

(2) Shares of common stock issuable pursuant to the Onconetix, Inc. 2022 Equity Incentive Plan, as amended (the "2022 Plan"). The proposed maximum offering price per share and registration fee were calculated in accordance with Rule 457(c) based on the average of the high and low prices reported in the consolidated reporting system within 5 business days prior to the date of filing the Registration Statement.

(3) Estimated solely for the purpose of calculating the registration fee pursuant to Rules 457(c) and 457(h) of the Securities Act, based on $0.20, the average of the high and low sales price of a share of common stock as reported on The Nasdaq Stock Market, LLC on January 30, 2024.

(4) Shares of common stock issuable pursuant to the Onconetix, Inc. 2019 Equity Incentive Plan and the 2022 Plan have been previously registered on a registration statement on Form S-8 (File No. 333-268357). As described in more detail in the Explanatory Note, pursuant to Rule 429 under the Securities Act, this Registration Statement is deemed to be a post-effective amendment to the Registrant's registration statement on Form S-8 (File No. 333-265843) filed with the Securities and Exchange Commission (the "SEC") on June 27, 2022 and the Registrant's registration statement on Form S-8 (File No. 333-268357) filed with the SEC on November 14, 2022.