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

FORM 10-K

(Mark One)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41294

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

Delaware	**81-2262816**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
201 E. Fifth Street, Suite 1900 Cincinnati, OH	**45202**
(Address of principal executive offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common stock, $0.00001 par value	**ONCO**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 726(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

Based on the closing price as reported on the Nasdaq Capital Market, the aggregate market value of the Registrant's Common Stock held by non-affiliates on June 30, 2023 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $13.0 million. Shares of Common Stock held by each executive officer and director and by each stockholder affiliated with a director or an executive officer have been excluded from this calculation because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of April 11, 2024, the registrant had 22,327,701 shares of common stock, $0.00001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Report") contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," but are also contained elsewhere in this Report.

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;
- our ability to commercialize or monetize ENTADFI and Proclarix and integrate the assets and commercial operations acquired in the share exchange with Proteomedix AG ("Proteomedix");
- the successful development of our commercialization capabilities, including sales and marketing capabilities.
- our ability to maintain the necessary regulatory approvals to market and commercialize our products;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current products;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated, or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- our reliance on third parties, including manufacturers and logistics companies;
- the success of competing therapies or diagnostics and products that are or become available;

- our ability to successfully compete against current and future competitors;
- our ability to expand our organization to accommodate potential growth and our ability to attract, motivate and retain key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our products;
- market acceptance of our products, the size and growth of the potential markets for our current products, and our ability to serve those markets; and
- disruptions in the business of the Company or Proteomedix, which could have an adverse effect on their respective businesses and financial results.

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

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

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

The following is a summary of certain risks, uncertainties and other factors related to our company. These do not represent all of the risks we face. You should carefully consider all of the risk factors presented in "Item 1A. Risk Factors" and all other information contained in this Report including the financial statements in order to provide a more complete picture of the risk factors we face.

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows and prospects that you should consider before making a decision to invest in our common stock. These risks are discussed more fully in "Risk Factors" beginning on page 42 of this Report. These risks include, but are not limited to, the following:

- Company shareholders may not realize a benefit from the ENTADFI or Proteomedix AG ("Proteomedix") acquisitions commensurate with the ownership dilution they have experienced in connection with the transactions.
- We may fail or elect not to commercialize our products.
- 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.
- ENTADFI is subject to competition from other benign prostatic hyperplasia ("BPH") drugs and larger, well-established companies with substantially greater resources than us.
- Proclarix is subject to competition from other prostate cancer diagnostics and larger, well-established companies with substantially greater resources than us.
- We may not be able to successfully implement our strategy to grow sales of ENTADFI in the U.S. market and Proclarix in the European market, or, if authorized, grow sales of either in any other market.
- We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant net losses since inception, have only generated minimal revenue, and anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve or maintain profitability. Our stock is a highly speculative investment.
- We depend entirely on the success of a limited number of products. If we do not successfully commercialize one or more of our products or we experience significant delays in doing so, these products may not be profitable.
- There is substantial doubt about our ability to continue as a "going concern," and we will require significant additional capital to make the investments we need to execute our business plan. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate commercialization efforts or certain operations, and we may be unable to continue as a going concern in the long term. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.
- We may not be able to gain and retain market acceptance for our products.
- We expect to rely on third party manufacturers for ENTADFI and Proclarix.
- Legislation, such as the Inflation Reduction Act, may impact our ability to market and commercialize ENTADFI and reduce our profitability from such asset.
- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our products, others could compete against us more directly, which would harm our business, possibly materially.
- If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

- Healthcare reform in the United States has been implemented in the past, and we expect further changes to be proposed in the future, leading to potential uncertainty in the healthcare industry. Violations of healthcare laws can have an adverse impact on our ability to advance ENTADFI and our operating results.

- The market price of our common stock has been extremely volatile and may continue to be highly volatile due to numerous circumstances beyond our control, and stockholders could lose all or part of their investment.

- The Committee on Foreign Investment in the United States ("CFIUS") may delay, prevent or impose conditions on the Conversion (as defined below) of newly issued shares of preferred stock of the Company, par value $0.00001 per share ("Series B Preferred Stock"), or may later review the Conversion and impose civil penalties or recommend to the President of the United States that other remedial actions be taken if CFIUS determines there are unresolved national security concerns.

- There can be no assurance that we will be able to comply with the continued listings of the Nasdaq Stock Market, LLC ("Nasdaq").

- We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

- Our amended and restated certificate of incorporation ("Amended and Restated Certificate of Incorporation") and our amended and restated bylaws ("Amended and Restated Bylaws"), and Delaware law may have anti-takeover effects that could discourage, delay, or prevent a change in control, which may cause our stock price to decline.

- A possible "short squeeze" due to a sudden increase in demand of our common stock that largely exceeds supply may lead to price volatility in our common stock.

- We entered into an asset purchase agreement and management services agreement with WraSer LLC, a Mississippi limited liability company ("WraSer"), which we have terminated because we believe that a material adverse event has occurred with respect to the six FDA-pharmaceutical assets across several indications, including cardiology, otic infections, and pain management we acquired from WraSer (the "WraSer Assets"). However, the termination is subject to WraSer's right to challenge the termination and assert claims against us.

- We may have violated Section 13(k) of the Exchange Act of 1934, as amended ("Exchange Act") (implementing Section 402 of the Sarbanes-Oxley Act of 2002) and may be subject to sanctions as a result.

- 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.

- 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.

- 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.

- 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.

- 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.

PART I

Item 1. Business

Company Overview

We are a commercial stage biotechnology company focused on the research, development, and commercialization of innovative solutions for men's health and oncology. Through our recent acquisition of Proteomedix, we own Proclarix, an in vitro diagnostic test for prostate cancer originally developed by Proteomedix and approved for sale in the European Union under the In Vitro Diagnostic Regulation ("IVDR"), which we anticipate will be marketed in the U.S. as a lab developed test through our license agreement with LabCorp. We also own ENTADFI, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of BPH, a disorder of the prostate.

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

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

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

Prior to the acquisition of ENTADFI, we managed one distinct business segment, which was research and development. Beginning in the second quarter of 2023, as a result of the acquisition of ENTADFI, for which we 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 products approved for sale, namely ENTADFI in the U.S. and Proclarix in Europe.

On December 15, 2023, the Company closed its acquisition of Proteomedix and introduced Onconetix, Inc. as the new name for the combined company. The closing of the acquisition of Proteomedix for all stock consideration provides Proteomedix shareholders with an initial 16.4% ownership stake of Onconetix, and Series B Preferred Stock convertible into 269,672,900 shares of Onconetix Common Stock, subject to Onconetix stockholder approval of the same ("Stockholder Approval").

In light of (i) the time and resources needed to continue pursuing commercialization of ENTADFI, and (ii) the Company's cash runway and indebtedness, the Company has determined to temporarily pause its commercialization of ENTADFI, as it considers strategic alternatives. The Company expects to appoint a new Chief Executive Officer in the second quarter of 2024, after which the new CEO and the Board will reassess its ENTADFI program in light of the foregoing and other relevant factors.

We are currently focusing our efforts on commercializing Proclarix.

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

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

To the extent that we resume the commercialization of ENTADFI, we also expect to incur significant commercialization expenses related to marketing, manufacturing and distribution for ENTADFI. 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.

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

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 December 31, 2023, the Company had a working capital deficit of approximately $11.4 million and an accumulated deficit of approximately $56.8 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 Preferred Stock. Based on the closing price of $0.166 for the Company's stock as of April 5, 2024, the Series B Preferred Stock would be redeemable for approximately $44.8 million.

Until we generate revenue sufficient to support self-sustaining cash flows, if ever, we will need to raise additional capital to fund our continued operations, including our product development and commercialization activities related to our current and future products. There can be no assurance that additional capital will be available to us on acceptable terms, or at all, or that we will ever generate revenue sufficient to provide self-sustaining cash flows. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements of Onconetix, as of and for the year ended December 31, 2023, included elsewhere in this Report do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

Because of the numerous risks and uncertainties associated with our business, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Additionally, even if we are able to generate revenue from Proclarix or ENTADFI, 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 History

Onconetix, Inc. (formerly Blue Water Vaccines Inc. and Blue Water Biotech, Inc.) was founded in October 2018. The Company's initial goal was to develop a transformational universal flu vaccine to treat and prevent infections in patients globally. After deprioritizing our vaccine programs, the Company subsequently shifted its focus toward building a foundation of therapeutic, diagnostic, and service products in the field of men's health and oncology.

Our Interim Chief Executive Officer, Dr. Ralph Schiess, has extensive experience with life sciences companies. Dr. Schiess co-founded Proteomedix, a private commercial-stage diagnostics oncology company that the Company acquired in December 2023 (as further described below) and served as its Chief Executive Officer from Proteomedix's inception until December 2019, as Proteomedix's Chief Scientific Officer from January 2020 to May 2023, and again as Chief Executive Officer since June 2023.

Bruce Harmon, our Chief Financial Officer, has more than 40 years of experience in financial positions with life sciences companies and various other industries. Mr. Harmon has served in a variety of roles, including chief financial officer, controller, chief executive officer, and audit committee chairman. He has been an independent consultant since 2008 through his business, Lakeport Business Services, Inc., and served in the outsourced CFO capacity for multiple publicly traded companies. During this time, Mr. Harmon was CFO of Marizyme Inc. from 2020 to 2021, CFO of bioAffinity Technologies Inc. in 2022, a director of Dale Biotech LLC since 2017, and a director of Patriax Industries since 2023. He has extensive experience with fundraising, public offerings, mergers and acquisitions, and turnarounds. Earlier in his career, he was a member of a team that, at the invitation of the Environmental Programmé, presented a green building product to delegates at the United Nations. He earned a Bachelor of Science degree in accounting from Missouri State University.

Additionally, members of our Board of Directors have extensive expertise in the fields of life sciences, business and finance. Our directors include Simon Tarsh, a retired Deloitte Consulting managing director with experience in life sciences, Timothy Ramdeen, who has nearly a decade of experience in private equity and hedge fund investing, capital markets, and company formation, and James Sapirstein, R.Ph., M.B.A, President, CEO and Chairman of First Wave BioPharma, Inc. (Nasdaq: FWBI).

Corporate Name Change and Amendment to Bylaws

On April 21, 2023, the Company filed an amendment to its Amended and Restated Certificate of Incorporation with the Secretary of State of Delaware to change its corporate name from "Blue Water Vaccines Inc." to "Blue Water Biotech, Inc." The name change was effective as of April 21, 2023. In connection with the name change, the Company amended the Company's bylaws to reflect the corporate name "Blue Water Biotech, Inc.," also effective on April 21, 2023.

On December 15, 2023, the Company filed an amendment to its Amended and Restated Certificate of Incorporation 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.

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"). On March 13, 2024, we submitted a plan of compliance to Nasdaq to discuss our plans to evidence compliance with the Bid Price Rule and we received an additional 180-day period, or until September 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).

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, convertible securities, or stock options of Proteomedix 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.

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 voting equity interests of Proteomedix in exchange for newly issued shares of Common Stock and newly issued shares of Series B Preferred Stock (the "Share Exchange").

The consummation of the Share Exchange (the "Share Exchange Closing") was subject to customary closing conditions and the execution of the Subscription Agreement entered into with Altos Ventures, a shareholder of Proteomedix prior to the closing of the Share Exchange (the "PMX Investor"). The Share Exchange closed on December 15, 2023 (the "Share Exchange Closing Date").

Founded in 2010, Proteomedix develops, markets and sells non-invasive diagnostic tests accompanied by decision support systems to detect and assess the prognosis of cancer. Proteomedix's lead product, Proclarix®, is an in vitro diagnostic test for prostate cancer. Proteomedix is working to address all stages in cancer management by developing tools for both more accurate detection and more efficient treatment of cancer including (i) diagnostic tests to early detect and define the stage of cancer; (ii) prognostic tools for the identification of patients with aggressive disease; and (iii) stratification biomarkers to match patients with therapies that are more likely to be safe and effective.

Currently, prostate cancer stands as the most prevalent and second most fatal cancer type affecting men. The widespread utilization of PSA screening since it became broadly available in the 1980s helped reduce the occurrence of metastatic prostate cancers by over half, but also led to a notable increase in overdiagnosis, sometimes resulting in excessive treatment, severe complications, and potential psychological distress. There exists a considerable population of men each year who are notified of their heightened risk for prostate cancer based on elevated PSA levels, with limited options beyond invasive needle biopsies for managing their cancer risk.

Proclarix addresses the unsolved problem of prostate cancer overdiagnosis, which can lead to negative prostate biopsies that increase costs for the healthcare system and uncertainty for patients. Proclarix is approved for sale in the European Union under the IVDR. Proclarix was first CE marked under the IVD Directive in Europe in January 31, 2019. On October 7, 2022, Proclarix gained CE marking under the IVD Regulation (IVDR) and was registered in the United Kingdom and Switzerland under applicable regulations. Clinical studies have confirmed that Proclarix accurately identifies clinically significant prostate cancer through a risk score derived from a clinical decision support system and could help avoid many unneeded biopsies. Proclarix as a clinical support system is designed to aggregate multimodal information in an effort to develop a patient-centric diagnostic approach. We intend to add more information to the risk score in the future, such as other biomarkers or magnetic resonance imaging data, to provide an even more powerful tool to guide the patient's diagnostic journey. The markers and the bioinformatics algorithm used are patent-protected.

The guidelines of the European Association of Urology ("EAU") and of the American Urological Association/Society of Urologic Oncology ("AUA/SUO") both recommend the use of blood-based biomarker tests, such as Proclarix, to aid in the early detection and evaluation of prostate cancer. Proclarix can be performed in any laboratory using standard equipment. Proteomedix announced commercial availability of Proclarix in Europe on February 26, 2020 and began marketing Proclarix to selected pilot laboratories offering Proclarix in Switzerland, Germany, Italy and the United Kingdom. Proclarix is currently not reimbursed in Europe, and therefore patients pay for Proclarix out of pocket. The number of sold Proclarix tests current corresponds to the early market development stage and selected few laboratories offering Proclarix. In 2023, we had revenues of $67,380 from sales of Proclarix, compared to $79,085 in 2022. In the United States, the development and commercialization of Proclarix is being pursued by Laboratory Corporation of America Holdings, more commonly called Labcorp, pursuant to an exclusive license agreement entered into between Proteomedix and Labcorp in 2023.

Proteomedix was founded by a multi-disciplinary group of scientists and clinicians that include Prof. Emeritus Dr. Thomas Cerny, president of the Swiss Cancer Research Foundation, Prof. Ruedi Aebersold, a pioneer in proteomics technology development, and the late Prof. Wilhelm Krek, a leader in cancer research. Proteomedix's management consists of Dr. Ralph Schiess (Chief Executive Officer), who developed the biomarker technology, and Christian Bruehlmann (Chief Business Officer), with seasoned experience in finance, business development and product management.

Terms of the PMX Transaction

Consideration

In full payment for the Purchased Shares, Onconetix issued shares (the "Exchange Shares") consisting of: (i) 3,675,414 shares of Common Stock equal to approximately 19.99% of the total issued and outstanding Common Stock prior to the acquisition and (ii) 2,696,729 shares of Series B Preferred Stock convertible into 269,672,900 shares of Common Stock. The parties agreed that the aggregate value of the Exchange Shares at the Share Exchange 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 (as defined below) are exercisable immediately prior to the Share Exchange Closing, subject to adjustment for indemnification as described below. Following the Share Exchange Closing, 22,841,975 and 22,324,576 shares of Common Stock were issued and outstanding, respectively.

The fair value of the 3,675,414 shares of Common Stock, was determined using the closing price of the Common Stock as of the Share Exchange Closing Date, which was $0.2382. The fair value of the 2,696,729 shares of Series B Preferred Stock was based on the underlying fair value of the common shares issuable upon conversion, also based on the closing price of the Common Stock as of the Share Exchange Closing Date. The aggregate fair value of the common and preferred shares issued as consideration was equal to approximately $65.1 million.

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

As a result of the PMX Transaction, 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 approximately 87.2% of the outstanding equity interests of Onconetix, the PMX Investor will own approximately 7.5% of the outstanding equity interests of Onconetix, and the stockholders of Onconetix immediately prior to the Share Exchange Closing will own approximately 5.3% of the outstanding equity interests of Onconetix.

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

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 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 Common Stock for the ten (10)-day period preceding the third day prior to the Share Exchange 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 Common Stock issued upon Conversion if the Net Adjustment is less than $1,000,000 and (ii) the number of shares of Common Stock issued upon Conversion shall not be increased or decreased by more than 10% of the number of shares of 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 Onconetix and the Sellers' Representative or determined by a mutually acceptable dispute resolution firm.

From and after the Share Exchange Closing and until the first anniversary of the Share Exchange Closing, Sellers, severally and not jointly, are required to indemnify Onconetix and its affiliates and their respective representatives (collectively, the "Onconetix 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 Onconetix Indemnitee shall solely be satisfied by recourse to the Exchange Shares and the shares of Common Stock issuable upon the Conversion, with each share of Common Stock valued at the same price per share of Common Stock used to determine the Exchange Ratio.

Covenants of the Parties

Each party to the Share Exchange Agreement agreed to use its commercially reasonable efforts to effect the PMX Transaction. Onconetix obtained a duly executed Stockholder Support Agreement (as defined below) from each director and executive officer of Onconetix, and used commercially reasonable efforts to obtain a duly executed Stockholder Support Agreement from each holder of more than five percent (5%) of Onconetix's voting stock.

The Share Exchange Agreement contains certain covenants by each of the parties, to be observed during the period between the Share Exchange Closing and Conversion, including covenants regarding: (1) the provision of access to properties, books and personnel; (2) delivery of Onconetix's financial statements; (3) litigation support; (4) Onconetix's public filings; (5) no insider trading; (6) further assurances; (7) public announcements; (8) confidentiality; (9) indemnification of directors and officers and tail insurance; (10) intended tax treatment of the Share Exchange; (11) Section 16 matters and (12) transfer taxes.

The parties agreed to take all necessary actions to cause Onconetix's board of directors immediately after the Stockholder Approval (the "Post-Stockholder Approval Onconetix Board") to consist of five directors, including: (i) two persons who are designated by Onconetix and reasonably acceptable to Proteomedix; and (ii) three persons who are designated by Proteomedix and reasonably acceptable to Onconetix.

The issuance of the Conversion Shares, amendment of Onconetix's Amended and Restated Certificate of Incorporation to authorize sufficient additional shares of Common Stock to permit the Conversion (to the extent required to consummate the PMX Transaction) and the appointment of the post-Stockholder Approval Onconetix Board requires the approval of Onconetix's stockholders. Onconetix agreed to prepare and file with the 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 Onconetix Securities to be issued under the Share Exchange Agreement.

Sellers, Onconetix and Proteomedix agreed to, at the election of Onconetix (which election it has determined not to exercise) or upon the request of CFIUS, submit to CFIUS a joint declaration or notice with respect to the PMX Transaction as promptly as practicable, but in no event later than sixty (60) days after the date of the Share Exchange Agreement. The parties, in cooperation with each other, agreed to use reasonable best efforts to take all such actions within their respective powers to obtain the approval of CFIUS ("CFIUS Approval"), and, without limiting the foregoing, the parties agreed to, after reasonable negotiation efforts, agree to such requirements or conditions to mitigate any national security concerns as may be requested or required by CFIUS in connection with, or as a condition of, CFIUS Approval, including entering into a mitigation agreement, letter of assurance, or national security agreement, but provided: (1) the parties shall have no obligation to (A) propose, negotiate, commit to or effect, by consent decree, hold separate order, agreement or otherwise, the sale, transfer, license, divestiture or other disposition of, any of the businesses, product lines or assets of Onconetix or any of its affiliates or of the Sellers, (B) terminate existing, or create new, relationships, contractual rights or obligations of Onconetix or its affiliates, (C) effect any other change or restructuring of Onconetix or its affiliates, or (D) otherwise take or commit to take any actions reasonably expected to have a material adverse effect on the operation of the business of the Sellers or that interfere with Onconetix's ability to control Proteomedix or Onconetix's ability to direct the management and policies of the business of Proteomedix in any material respect; and (2) Proteomedix and the Sellers agreed not take or agree to take any of the foregoing actions without the prior written consent of Onconetix.

The parties agreed to use commercially reasonable best efforts to (i) ensure that the application for Onconetix's change of control ("Nasdaq Change of Control Application") is filed with The Nasdaq Stock Market LLC ("Nasdaq") and (ii) to respond to any questions from Nasdaq with respect to the Nasdaq Change of Control Application promptly following receipt of such questions, but in no event later than ten (10) business days following receipt of such questions.

During the time between the Share Exchange Closing and the Conversion, Onconetix also agreed, and agreed to cause its Subsidiaries, to conduct their respective businesses in the ordinary course of business in all material respects and agreed to covenants regarding operation of their respective businesses, including covenants related to (i) amendments to Onconetix's organizational documents; (ii) recapitalization of Onconetix's equity interests; (iii) issuance of additional securities; (iv) incurrence of additional indebtedness; (v) material changes to tax elections; (vi) amendments or termination of material contracts; (vii) records and books; (viii) establishment of any Subsidiary or entry into a new line of business; (ix) maintenance of insurance policies; (x) revaluation of material assets or material changes in accounting methods, principles or policies except to the extent to comply with U.S. GAAP; (xi) waiver or settlement of any claim, action or proceeding, other than waivers not in excess of $500,000; (xii) acquisition of equity interests or assets, or any other form of business combination, outside of the ordinary course of business; (xiii) capital expenditures in excess of $500,000 individually or $1,000,000 in the aggregate; (xiv) adoption of a plan of liquidation, dissolution, merger, consolidation, restructuring, recapitalization or other reorganization; (xv) voluntary incurrence of any liability or obligation in excess of $500,000 individually or $1,000,000 in the aggregate other than pursuant to the terms of a Contract in existence as of the date of the Share Exchange Agreement or entered into in the ordinary course of business, except in connection with a Permitted Financing (as defined below); (xvi) sale, lease, license or other disposition of any material portion of Onconetix properties, assets or rights; (xvii) entry into any agreement, understanding or arrangement with respect to the voting of Common Stock, except in connection with a Permitted Financing; (xviii) taking any action that would reasonably be expected to significantly delay or impair the obtaining of any Consents of any Governmental Authority to be obtained in connection with the Share Exchange Agreement; or (xix) authorizing or agreeing to do any of the foregoing actions.

"Permitted Financing" means one or more debt or equity financing transactions consummated by and funded into Onconetix during the time between the Share Exchange Closing and the Conversion resulting in aggregate gross proceeds of no greater than $25 million.

Governing Law

The Share Exchange Agreement is governed by the laws of the State of Delaware.

Terms of the Series B Preferred Stock

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

Voting. The shares of Series B 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 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 Preferred Stock, (B) alter or amend the Series B Certificate of Designation, or amend or repeal any provision of, or add any provision to, Onconetix's Amended and Restated 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 Preferred Stock, (C) issue further shares of Series B Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series B 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 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 Preferred Stock. If the holders of Series B 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 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 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 Preferred Stock shall constitute a quorum for the purpose of electing such director. On February 6, 2024, the Majority Holders appointed Thomas Meier, PhD, to the Board.

Redemption. The shares of Series B 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 Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of Onconetix the same amount that a holder of Common Stock would receive if such Holder's Series B Preferred Stock were fully converted to 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 Common Stock.

Dividends. The holders of the Series B Preferred Stock shall be entitled to receive, dividends on shares of Series B 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 Common Stock payable in the form of Common Stock) actually paid on shares of the Common Stock when, as and if such dividends (other than dividends payable in the form of Common Stock) are paid on shares of the Common Stock.

Conversion. Following Stockholder Approval, each share of Series B Preferred Stock shall be converted into shares of Common Stock (the "Conversion Shares") at a ratio of 100 Conversion Shares for each share of Series B Preferred Stock (the "Conversion Ratio"). All shares of Series B 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 Common Stock issuable upon Conversion in excess of 20% of the issued and outstanding Common Stock on the Share Exchange Closing Date and (ii) Onconetix has effected an increase in the number of shares of Common Stock authorized under its Amended and Restated Certificate of Incorporation, to the extent required to consummate the PMX Transaction.

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 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 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 Common Stock on which the 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 Preferred Stock is outstanding: (A) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of Common Stock; (B) subdivides outstanding shares of Common Stock into a larger number of shares; or (C) combines (including by way of a reverse stock split) outstanding shares of 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 Common Stock outstanding immediately after such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately before such event (excluding any treasury shares of the Corporation). If, at any time while the Series B 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 Common Stock after giving effect to the transaction and its 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 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 Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (in any such case, a "Fundamental PMX Transaction"), then, in connection with any such transaction in (A) through (D), the holders of Series B Preferred Stock shall receive in such transaction, the same kind and amount of securities, cash or property that a holder of Common Stock would receive if such holder's Series B Preferred Stock were fully converted to 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 Common Stock in the Fundamental PMX Transaction (the "Alternate Consideration"). If holders of Common Stock are given any choice as to the securities, cash or property to be received in a transaction in (A) through (D), then the holders of Series B Preferred Stock shall be given the same choice as to the Alternate Consideration it receives in such transaction.

Lock-Up Agreement

Simultaneously with the execution of the Share Exchange Agreement, the Sellers and the Advisor Parties, as shareholders of Proteomedix, entered into Lock-Up Agreements (each, a "Lock-Up Agreement"). Pursuant to each Lock-Up Agreement, each signatory thereto will agree not to, during the period commencing from the Share Exchange Closing Date and ending on the 6-month anniversary of the date of Stockholder Approval: (i) lend, offer, pledge, hypothecate, encumber, donate, assign, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, the Exchange Shares or the Conversion Shares, (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Exchange Shares or the Conversion Shares, or (iii) publicly disclose the intention to do any of the foregoing, whether any such transaction described in clauses (i), (ii) or (iii) above is to be settled by delivery of the Exchange Shares or the Conversion Shares or other securities, in cash or otherwise (subject to certain exceptions).

Non-Competition and Non-Solicitation Agreement

Simultaneously with the execution of the Share Exchange Agreement, certain executive officers (each, a "Management Shareholder") of Proteomedix each entered into a non-competition and non-solicitation agreement (collectively, the "Non-Competition and Non-Solicitation Agreements") with Onconetix. Under the Non-Competition and Non-Solicitation Agreements, each Management Shareholder agreed not to compete with Proteomedix, and after the Share Exchange Closing, Onconetix, and their respective affiliates during the three-year period following the Share Exchange Closing and, during such three-year restricted period, not to solicit employees or customers of such entities. Each Non-Competition and Non-Solicitation Agreement also contains customary confidentiality and non-disparagement provisions.

Stockholder Support Agreement

Simultaneously with the execution of the Share Exchange Agreement, Onconetix, Proteomedix and certain directors of Onconetix who are stockholders of Onconetix, entered into a Stockholder Support Agreement (the "Stockholder Support Agreement"), pursuant to which, among other things, each such stockholder of Onconetix has agreed (a) to support the adoption of the Share Exchange Agreement and the approval of the PMX Transaction, subject to certain customary conditions, and (b) not to transfer any of their subject shares (or enter into any arrangement with respect thereto), subject to certain customary conditions.

Stockholder Subscription Agreement and Debenture

In connection with the PMX Transaction, on December 18, 2023, Onconetix entered into a Subscription Agreement (the "Subscription Agreement") with the PMX 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 PMX Investor to the extent the PMX Investor continues to hold Common Stock included in the Units and if the VWAP during the 270 days following the Share Exchange Closing is less than the Purchase Price, as set forth in the Subscription Agreement.

The offering contemplated by the Subscription Agreement is expected to close following Stockholder Approval. Within 30 days after closing of the offering, 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, the Company issued a non-convertible debenture (the "Debenture") to the PMX Investor in the principal sum of $5.0 million, the payment of which shall offset the $5 million subscription amount 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. As of April 5, 2024, a total of $5 million of principal was outstanding under the Debenture.

ENTADFI

On April 19, 2023, the Company entered into an asset purchase agreement with Veru Inc., a Wisconsin corporation ("Veru") (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. 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. The Company does not currently have cash to pay the notes due on April 19, 2024 and September 30, 2024 and is exploring options to restructure such notes with Veru.

On September 29, 2023, the Company entered into an amendment (the "Veru Amendment") of the Veru APA. Pursuant to the Veru Amendment, the $4.0 million note payable originally due on September 30, 2023 was deemed paid and fully satisfied upon (1) the payment to Veru of $1 million in immediately available funds on September 29, 2023, and (2) the issuance to Veru by October 3, 2023 of 3,000 shares of Series A Preferred Stock of the Company.

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 stockholder 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 stockholder approval limitations specified in the Certificate of Designations. The Company is still in the process of obtaining such shareholder approval. If the Company does not obtain such stockholder approval, it will not be able to issue Common Stock in excess of the stockholder approval limitations specified in the Certificate of Designations. 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.

As noted above, the Company has determined to temporarily pause its commercialization of ENTADFI, as it considers strategic alternatives. The Company expects to appoint a new Chief Executive Officer in the second quarter of 2024, after which the new CEO and the Board will reassess its ENTADFI program in light of the foregoing and other relevant factors.

WraSer

On June 13, 2023 (the "Execution Date"), the Company entered into an asset purchase agreement with the WraSer Seller and Parent (the "WraSer APA"). Pursuant to, and subject to the terms and conditions of, the WraSer APA, on the WraSer Closing Date (as defined below) the Company 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 "WraSer Closing Date"); (iii) 1.0 million shares of the Company's common stock (the "Closing Shares") issuable on the WraSer Closing Date, and (iv) $500,000 in cash one year from the WraSer Closing Date. The closing of the transaction is subject to certain customary closing conditions and the delivery to the Company of financial statements of WraSer 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 WraSer 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, 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 WraSer 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 WraSer Seller's business during the period between the Execution Date and WraSer 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 WraSer 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 WraSer Closing Date, the WraSer 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 WraSer Seller over time. Specifically, as the Company would have collected accounts receivable generated after the WraSer Closing Date, the Company would have been required to remit 50% of the collections to the WraSer Seller until the shortfall is paid in full. The MSA terminates on the WraSer 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 WraSer Seller, the initial $3.5 million payment is retained by the WraSer Seller. If it is determined that there is an uncured breach of contract by the WraSer 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 was 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, subject to court approval. Shortly after its bankruptcy filing, WraSer filed a motion seeking approval of the WraSer APA as amended. The amendment, among other things, eliminates the $500,000 post-closing payment due June 13, 2024 and staggers the $4.5 million cash payment that the Company would otherwise have to pay at closing to: (i) $2.2 million to be paid at closing, (ii) $2.3 million, to be paid in monthly installments of $150,000 commencing January 2024 (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, WraSer alerted us 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 believe 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.

Business of the Company

Business Model

Proteomedix develops novel diagnostic tests in a highly regulated field. Proteomedix's core competencies include the development of high-quality immunoassays and management of regulatory affairs. Our expertise in immunoassay development is the result of a highly specialized workforce that, together with an external software development company, developed the proprietary software integrated in the company's lead IVD product, Proclarix. Our personnel also have extensive experience in implementing and maintaining a state-of-the-art quality management system to comply with regulatory requirements, including performing clinical studies and managing key opinion leaders ("KOLs"). Our experience and expertise in these fields was obtained by hiring experienced personnel as well as through key advisors.

Proteomedix is initially focusing on seeking to license its intellectual property to third party laboratories. Sales will be through a specialized distributor and/or laboratory partner, but Proteomedix will still provide technical customer support to laboratories that offer the testing service to physicians. Proteomedix does not have production capabilities built up in-house, and instead outsources manufacturing to a CMO in Germany. All of the key reagents used in Proteomedix's IVD kits (i.e., antigens and antibodies) are proprietary and owned exclusively by Proteomedix, which uses an independent supplier in Germany to produce these reagents and supply them to its CMO.

ENTADFI is an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of BPH. To the extent that we resume the commercialization of ENTADFI, Onconetix will initially focus on commercializing ENTADFI through a telemedicine channel. In July 2023, the Company signed an agreement with UpScriptHealth to generate a robust, online telemedicine platform to distribute ENTADFI. Through this platform, UpScriptHealth will support patients with BPH throughout prescription and coverage process, as well as provide eligible patients access to ENTADFI mailed directly to their homes. Additionally, to meet the demands of the supply chain, manufacturing is outsourced to contract manufacturing organizations ("CMOs") in the U.S. The product will be distributed exclusively by Cardinal Health 105, LLC, an Ohio limited liability company ("Cardinal Health") as third-party logistics distribution agent for sales of ENTADFI and any other products the parties mutually agree to. As noted above, the Company has determined to temporarily pause its commercialization of ENTADFI, as it considers strategic alternatives. The Company expects to appoint a new Chief Executive Officer in the second quarter of 2024, after which the new CEO and the Board will reassess its ENTADFI program in light of the foregoing and other relevant factors.

Products

Proclarix

Proteomedix is seeking to develop diagnostic, prognostic and predictive tools to enable more efficient cancer management at all stages of disease progression. Proteomedix's tests use proprietary protein biomarkers to address the limitations in current cancer detection, prognosis, and therapy prediction. In addition, Decision Support Systems support the clinical decision-making by integrating different inputs in a risk score (see Figure 1).

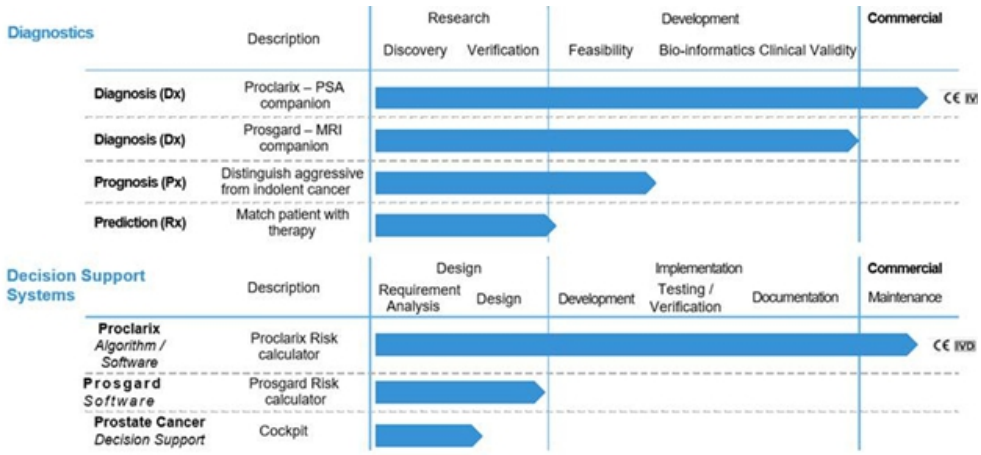

Figure 1: Product Pipeline
Proclarix

Proclarix

Proclarix is used to indicate the risk of clinically significant prostate cancer through a risk score derived from a clinical decision support system (Figure 2). On the reagent side it is comprised of two quantitative Enzyme-linked Immunosorbent Assays ("ELISA") that measure the concentration of thrombospondin 1 ("THBS1") and cathepsin D ("CTSD") in human serum. The clinical decision support system is a web-based software running a proprietary algorithm that integrates the values for THBS1 and CTSD, the patient's age and total and free PSA levels from third party providers (e.g., Roche Diagnostics, Siemens Healthineers) to calculate a risk score.

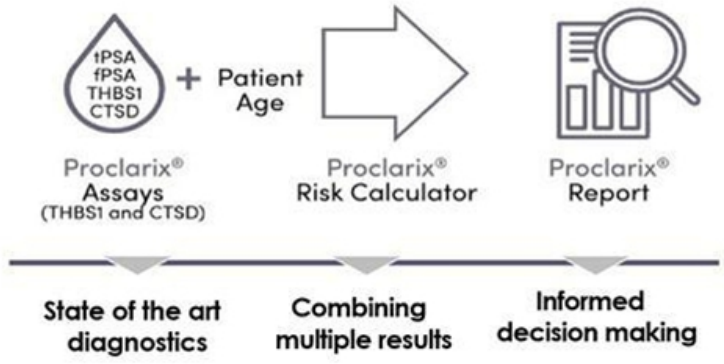

Figure 2: Proclarix: Assays and software algorithm for risk score calculation.

Proclarix is used as an aid in prostate cancer diagnosis as a second-line test after PSA and DRE testing. It enables a personalized decision for each patient based on objective risk parameters (4 serum glycoproteins + age) to triage between biopsy or a monitoring approach. Proclarix has been validated and approved for use in men with elevated total PSA (2.0 to 10.0 ng/mL), a normal DRE not suspicious for cancer and an elevated prostate volume (≥35 mL) (Figure 3). The Proclarix decision support tool returns a risk score that can be used as an aid in discriminating between clinically significant (grade group 2 or higher [GG2+]) and insignificant prostate cancer or benign prostate disease. The risk score of Proclarix gives the physician and patient actionable information to confidently make decisions when considering the necessity of a prostate biopsy which is required for diagnosis of prostate cancer.

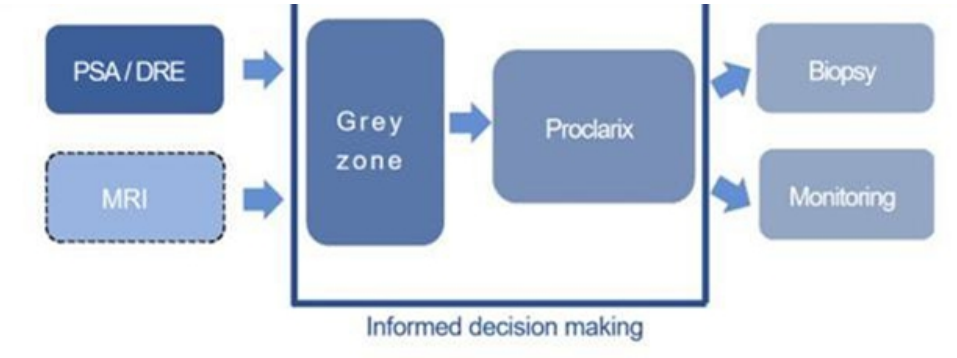

Figure 3: Proclarix: Finding clinically significant prostate cancer in the diagnostic "grey zone."

Clinical Studies

Proteomedix's biomarkers have been tested in clinical studies including a total of more than 2,000 patient samples from multiple clinical sites, and results have been published in peer-reviewed journals. We believe these results demonstrate that Proclarix is a valuable test identifying clinically significant prostate cancer thereby facilitating informed decision making for patients considering a prostate biopsy.

Validation Study. The study leading to the granting of regulatory approval in Europe included 955 samples collected at two clinical sites, a screening center in Innsbruck, Austria, as well as a referral center in Hamburg, Germany. The results of this study demonstrated that by using the Proclarix test the burden of unneeded biopsies could have been lowered by approximately 43% — twice as much compared to clinical comparators percent free PSA ("%fPSA") or PSA density. High sensitivity of 90% and a negative predictive value of 95% for clinically significant prostate cancer indicated that the diagnosis of very few cancers would have been delayed.

PROPOSe Study. The PROPOSe study evaluated the accuracy of Proclarix in prostate biopsy decision making. Ten clinical sites in Germany, Denmark and Austria prospectively enrolled 457 men presenting for prostate biopsy. Proclarix detected clinically significant cancer with high sensitivity above 90% and reliably ruled out patients with no or indolent cancer with a negative predictive value greater than 90%. When the biopsy performed was guided by magnetic resonance imaging ("MRI"), both sensitivity (97%) and negative predictive value (96%) were even higher. Importantly, Proclarix was significantly superior to the current clinical standard, %fPSA, in ruling out unneeded biopsies (22% vs. 14%) and the primary study endpoint was met (p-value < 0.005).

Naples Study. A two-center study evaluated Proclarix and the Prostate Health Index (phi) test from Beckman Coulter, Inc. for predicting clinically significant prostate cancer in a total of 344 men. Both Proclarix and the phi test accurately predicted clinically significant cancer. When using predefined cut-offs recommended by the manufacturers, Proclarix (cut-off 10) outperformed phi (cut-off 27) in terms of specificity and positive predictive value ($p < 0.002$) at similar sensitivities.

Clinical evaluation of Proclarix. Results of multiple clinical evaluations using Proclarix together with MRI for prostate cancer diagnosis showed that Proclarix can be used in a broad range of patients without the need for prostate volume restriction. The aim of one such evaluation was the assessment of the diagnostic performance of Proclarix in combination with MRI. Blood samples from 721 men undergoing MRI followed by biopsy at two clinical centers were analyzed. The combined Proclarix-MRI score's specificity (68%) was significantly ($p<0.001$) better compared to Proclarix (27%) or MRI (28%) alone for diagnosing clinically significant prostate cancer. Importantly, Proclarix by itself was found to be useful in men with indetermined imaging results by outperforming PSA density in terms of specificity (25% vs 13%, $p=0.004$) at 100% sensitivity. In another evaluation of a study of 517 men with suspected prostate cancer, Proclarix performed well in accurately diagnosing prostate cancer in the overall study population and in a subset of men with elevated PSA 2 to 10 ng/mL, prostate volume ≥35 mL, and normal DRE (n=281). In addition, a sub-analysis of was performed specifically analyzing 169 men with an indeterminate MRI result and Proclarix was more accurate in selecting appropriate candidates for prostate biopsy when compared to PSA density and online risk calculators. A third evaluation describes which patients with suspected prostate cancer can benefit from Proclarix after MRI and concluded that Proclarix outperformed PSA density in the selection of candidates for prostate biopsy, especially in men with PI-RADS 1-3. In these studies, Proclarix proved to be effective before, after, and together with MRI assessment to identify men at risk of clinically significant prostate cancer and those who can safely avoid biopsy. Proclarix in combination with MRI reliably predicted clinically significant prostate cancer and ruled out men with no or indolent cancer.

Clinical Guidelines

Guidelines assist clinicians in making informed treatment decisions, taking into account the available scientific data. To reduce the number of negative biopsies in asymptomatic men with a PSA level between 3–10 ng/mL and a normal DRE, the EAU guidelines recommend using an online risk-calculator that is correctly calibrated to the population prevalence, MRI of the prostate or an additional biomarker test such as Proclarix. The EAU guidelines specifically state that Proclarix has been correlated with the detection of significant prostate cancer, notably in case of equivocal MRI results.

Proclarix was also included in the 2023 AUA/SUO clinical practice guideline. The AUA/SUO guideline covers recommendations on the early detection of prostate cancer and provides a framework to facilitate clinical decision-making in the implementation of prostate cancer screening, biopsy, and follow-up. The AUA/SUO guideline concludes that the evaluation of prostate cancer risk should be focused on the detection of clinically significant prostate cancer (GG2+). The AUA/SUO guidelines advice that use of laboratory biomarkers such as Proclarix, prostate MRI, and biopsy techniques may improve detection and safety when a prostate biopsy is deemed necessary following prostate cancer screening.

The inclusion of Proclarix in the European and U.S. guidelines is an important recognition of the clinical value of Proclarix. It serves as a validation for the clinical utility and importance of using Proclarix in the detection of prostate cancer and we believe it will lead to broader acceptance of Proclarix and accelerate payor adoption.

Product Quality and Safety

Proteomedix's quality management system is ISO (International Organization for Standardization) 13485:2016 certified for the "Design and development, production and distribution of in-vitro diagnostic reagents and stand-alone software for prostate cancer management". Proteomedix is annually audited by TÜV SÜD Product Service GmbH, an internationally recognized notified body headquartered in Germany. ISO certification is a prerequisite for obtaining CE-mark, the regulatory clearance requirement for market access, recognized by the European Commission ("EC") in the IVDR. Under the IVDR, diagnostic products are categorized under a new system of one of four classifications from class A (low risk) to class D (highest risk). Proclarix, as class C device, was assessed by TÜV SÜD for conformity resulting in IVDR certification. The certification of Proclarix under the new IVDR demonstrates compliance to the highest quality standard currently in force for tests used in screening, diagnosis, or staging of cancer. Proteomedix is marketing Proclarix as one of the first IVDR compliant cancer tests demonstrating the commitment to highest analytical and clinical performance.

Prosgard

Prosgard as a clinical support system is designed to aggregate multimodal information in an effort to develop a patient centric diagnostic approach. The vision for Prosgard is to add more information to the existing Proclarix risk score in the future such as other biomarkers, clinical information, or MRI imaging data to provide an even more powerful tool to guide the patient's diagnostic journey.

Prognosis (Px)

A subset of Proteomedix's protein biomarkers also correlate with prostate cancer prognosis. Radical prostatectomy provides excellent cancer control of clinically localized prostate cancer. However, approximately 30% of surgically treated men will experience cancer recurrence within 10 years of surgery. Several clinical parameters and the combination thereof (e.g., the Cancer of the Prostate Risk Assessment ("CAPRA") score) have been shown to be reliable predictors of treatment failure. Still, there is a compelling need to identify novel markers that are specifically linked to the presence of biologically aggressive prostate cancer for improved prediction of outcome in populations with moderately elevated PSA levels.

A novel serum biomarker quintet that improves disease prognosis in men with confirmed prostate cancer

A clinical evaluation of a multivariable model comprising fibronectin 1, galectin-3-binding protein, lumican, matrix metalloprotease 9, thrombospondin-1 and PSA together with clinical Grade Group (GG) and clinical stage (cT) was performed. The prognostic utility of the proposed marker combination was assessed in serum samples from 557 men with confirmed localized prostate cancer. The analysis showed that the proposed model had a better prediction for disease progression and thus prostate cancer aggressiveness compared to the "CAPRA" score. This novel biomarker test has the potential to improve prostate cancer patient management by indicating who needs active treatment. In contrast to the existing biomarker tests from competitors that all need tissue specimens, the test is non-invasive and can be directly measured in patients' blood samples.

Prediction (Rx)

Proteomedix's protein biomarkers further have the potential to predict the response of patients treated with drugs that inhibit the PI3K signaling pathway. Proteomedix analyzed the blood of patients participating in a Phase II trial (SAKK 08/08). The patients were treated with Novartis AG's Everolimus, a drug inhibiting the PI3K pathway signaling by blocking mTOR. A subset of 8 serum biomarkers could individually predict reaching the primary endpoint (progression free survival at 12 weeks) with an accuracy of at least 75%.

Decision Support Systems

Recent initiatives are incorporating as well as interpreting clinical information from various sources (e.g., biomarker information and other patient data) enabling physicians to have more comprehensive biochemical insight into each patient's disease in order to determine the optimal treatment plan for the patient. Collating multiple data sources in clinical workflows allows precision-medicine resulting in cost-effective diagnostics and therapies. Proclarix already consists of a decision support system integrating different values in a risk score. In the future, additional clinical information like the results of an MRI scan could be integrated in the report to provide a complete picture of the diagnostic situation of the patient to enable effective patient management.

ENTADFI®

ENTADFI is an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of BPH. BPH, a condition in men in which the prostate gland is enlarged but not cancerous, is a common problem that affects the quality of life in approximately half of men over the age of 50 and 90% of men over the age of 85. Men with BPH suffer from challenges with urination flow, frequency, and urgency, and about 70% of men with BPH also experience sexual dysfunction. In 2022, there was approximately 44 million total prescriptions and 20 million new prescriptions related to BPH symptoms. ENTADFI is an oral, once daily treatment for BPH that combines finasteride, a 5α- reductase inhibitor, and tadalafil, a phosphodiesterase 5 ("PDE5") inhibitor, offering a more effective treatment option compared to other available therapies. Clinical trials have shown that ENTADFI is more effective in treating BPH symptoms, including urinary frequency, urgency, weak stream, and difficulty initiating or maintaining urination, compared to finasteride monotherapy. Additionally, ENTADFI has demonstrated a favorable safety profile, with fewer adverse sexual side effects compared to finasteride. ENTADFI reduces potential adverse sexual side effects, making it preferred choice for men seeking relief from BPH symptoms without compromising their sexual health. ENTADFI has received FDA approval for the indication of initiating treatment of the signs and symptoms of BPH in men with enlarged prostate for up to 26 weeks.

Commercialization Strategy

Proclarix

Proclarix is currently not reimbursed in Europe, and therefore patients pay for Proclarix out of pocket. We intend to pursue reimbursement from public and private payors in key European markets to secure broad adoption in the longer term. The market introduction of Proclarix has followed a two-phased approach: first a market preparation phase in which we reach out to key opinion leaders in selected European countries to solicit their support for Proclarix, followed by a market development phase where we begin commercializing Proclarix in those markets with focused marketing and sales activities to urologists and general practitioners. We intend to secure access to testing through partnerships with reference diagnostic labs. We have initiated outreach to commercial laboratories and hospital laboratories that are routinely serving study sites and academic collaboration partners, and have established pilots with laboratories in Switzerland, Germany, Italy, and the United Kingdom.

In the United States, Proteomedix entered into an exclusive partnership with Labcorp in 2023 pursuant to which Labcorp has the exclusive right to develop and commercialize Proclarix, and other products developed by Labcorp using Proteomedix's intellectual property covered by the license, in the United States for identification, screening, staging, predisposition, diagnosis, prognosis, monitoring, prevention or treatment selection with respect to prostate cancer. In consideration for granting Labcorp an exclusive license, Proteomedix received an upfront license fee and is entitled to royalty and milestone payments based upon sales of licensed products or services in the United States. Labcorp is wholly responsible for the cost of research, development and commercialization of licensed products or services in the United States but has the right to offset a portion of those costs against future royalty and milestone payments otherwise due to Proteomedix.

ENTADFI

As noted above, the Company has determined to temporarily pause its commercialization of ENTADFI, as it considers strategic alternatives. The Company expects to appoint a new Chief Executive Officer in the second quarter of 2024, after which the new CEO and the Board will reassess its ENTADFI program in light of the foregoing and other relevant factors. To the extent that we resume the commercialization of ENTADFI, in order to provide ENTADFI to patients suffering from BPH, we have established relationships with key vendors to distribute, commercialize, and market ENTADFI. On the distribution side, we have partnered with Cardinal Health to serve as our third-party logistics provider. Under our agreement, Cardinal Health with serve as our exclusive distributor of ENTADFI, and we intend to leverage its title model services, allowing us to utilize its state wholesale pharmacy license portfolio to ship ENTADFI to states where we do not currently hold a license. Utilizing Cardinal Health's title model program will maximize access for ENTADFI across the U.S. while we pursue licenses for Onconetix.

In the commercialization plan for ENTADFI, we have partnered with UpScriptHealth to generate an online telemedicine platform where patients with BPH can interact with a healthcare provider, receive support through the prescription process, as well as provide eligible patients access to ENTADFI mailed directly to their homes. UpScriptHealth is a leading provider of telehealth services, has over 20 years of experience generating effective, web-based campaigns for life science companies with a wide range of services, including virtual prescribing, coverage and benefit support, as well as long-term adherence support. In recent years, telehealth has become increasingly popular for both patients and providers and represents a significant opportunity for the commercialization of ENTADFI. Through telemedicine, we will be able to provide BPH patients with access to ENTADFI without another trip to a doctor's office or pharmacy, which can be incredibly burdensome for patients and provide them with a time-saving option for receiving medication.

The current commercialization strategy for ENTADFI centers around our telemedicine platform, and we believe this may be more cost effective versus more traditional sales representative approaches that target physicians. We plan to generate targeted marketing and advertising materials to support our web platform, which will drive traffic to the site and maximize ENTADFI sales. Under the current sales model, we will be offering ENTADFI for cash-paying patients and do not currently plan on seeking reimbursement from insurance or Medicare and Medicaid channels. Though this may change in the future, we believe there is a significant market opportunity for patients to use the web portal to access ENTADFI and receive medication by cash pay.

Sales, Distribution, Marketing and Advertising

In clinical diagnostics high throughput assay parameters like PSA typically are performed on closed, fully integrated systems that use proprietary reagents. Integrated systems are provided by a few mid-sized to large diagnostic companies (e.g., Roche Diagnostics, Abbott Laboratories, Siemens Healthineers AG, DiaSorin S.p.A.) with a worldwide distribution network. Reagents are provided in a closed-system approach, access is through collaboration agreements only. Business development discussions with multiple diagnostic companies have already started.

Lower volume parameters are run on smaller, open systems that are used in laboratories for tests with lower throughput to complement the test menu. Access to these open systems presents an option for direct commercialization in selected markets during market introduction. First, the goal is to establish commercial proof of concept and drive initial market adoption.

Market adoption of a new test is driven by KOLs and clinical urology centers. Publication of clinical studies proving the medical benefit of the test and KOLs advocating it at scientific conferences will trigger the usage by other physicians. Additionally, demand is created through urology centers specialized in prostate cancer that cover a large geographical area. Their influence on other urologists and general practitioners in the region will lead to multiplier effects. Diagnostic testing in clinical urology centers is provided either by an in-house hospital laboratory or a commercial laboratory where Proclarix will be implemented.

General practitioners recruit patients for screening and decide whether to refer a patient to a specialist. They have an important gatekeeper role and Proclarix is a helpful tool for this triage. Marketing outreach of commercial laboratory networks (e.g., Unilabs, Switzerland; Sonic Healthcare, Australia; Labcorp, U.S.A.) provides an opportunity to directly address the large number of general practitioners and urologists in private practices through their specialized sales force.

Market Opportunity

Proclarix

Proclarix, the first diagnostic product of Proteomedix, is addressing unmet medical needs related to prostate cancer, which is the second most frequently diagnosed cancer in men, with an estimated 1.4 million new cases and more than 395,000 deaths worldwide in 2020, according to World Cancer Research Fund International.

The PSA test represents the current standard of care in prostate cancer diagnosis. It accurately identifies individuals with no sign of disease. Approximately 10% of all men have elevated PSA levels, commonly referred to as the diagnostic “grey zone”, of which only 20-40% present clinically with cancer. Proclarix is intended for use in diagnosing these patients where it is difficult to decide if a biopsy is necessary to verify a potential clinically significant cancer diagnosis. The high unmet need for improved patient stratification or diagnostic triage in this segment is addressed only by a few tests. Compared to those tests Proclarix has important competitive advantages: (i) it shows comparable or often superior clinical performance, (ii) it is blood-based and therefore minimally invasive and (iii) it is highly reproducible in comparison to e.g., urine-based tests. The use of Proclarix does not require prior prostate massage. Samples are stable and can be shipped at ambient temperature. Proclarix has a high accuracy and negative predictive value (NPV) and is easy to automate on equipment readily available as well as adaptable to current laboratory practice and thus clinical routine.

The worldwide market for in vitro diagnostic ("IVD") products was valued at $117.8 billion in 2022. Europe and North America are the largest markets, followed by Asia, mainly Japan and China, according to MarketsandMarkets.

About two-thirds of prostate cancer diagnoses occur in countries ranking very high in the Human Development Index, where only 18% of the world's male population resides, according to the American Cancer Society. This underscores a significant market demand for improved diagnostic tools, especially in regions with robust healthcare infrastructure where early detection and treatment are paramount. Our innovative test aims to meet this demand by offering enhanced accuracy, accessibility, and efficiency, positioning it as a valuable asset in the fight against prostate cancer while also presenting lucrative commercial opportunities for stakeholders.

Currently, standard prostate cancer screening combines a digital rectal exam ("DRE") with the measurement of PSA. PSA is not a highly cancer specific marker, meaning it picks up many benign conditions of raised PSA levels in the blood—such as clinically not significant enlargement of the prostate or inflammation. The consequences are prostate cancer overdiagnosis, leading to unnecessary prostate biopsies. It is currently estimated that more than 60% of men that undergo a biopsy have no clinically significant prostate cancer, but due to the biopsy become exposed to potential side effects such as infections, bleeding and incontinence.

The use of MRI for the diagnosis of prostate cancer has been rapidly adopted during the last decade. There is clinical evidence that MRI allows clinicians to verify diagnosis and improve localization, risk stratification and staging of clinically significant prostate cancer over other methods. MRI-guided biopsy has a higher accuracy than ultrasound-guided biopsy. However, MRI-based diagnosis of prostate cancer is hampered by the relatively high costs of US$415 – US$900 and limited availability. Still, up to one-third of MRIs are inconclusive. Thus, there is a clear need for an improved non-invasive diagnostic test with higher specificity for clinically significant prostate cancer to aid in selecting patients undergoing MRI, MRI-guided biopsy, and biopsy. Proper classification in clinically significant cancer and non-significant type or non-cancer conditions such as benign prostate hyperplasia is important to prevent overtreatment and its associated side-effects and costs. Proteomedix is developing diagnostic tools for disease prognosis and monitoring that are essential for reliable, patient-friendly, and cost-effective disease management. Proteomedix's biomarkers have shown the potential to distinguish between those prostate cancer patients who are more likely to respond to certain drug-based interventions. With this information, better choices for drug therapies can be made to maximize the likelihood of efficacious treatment. Proteomedix's biomarkers could also aid in clinical drug development.

ENTADFI

BPH is a condition that affects men, primarily those over 50 years old, and is caused by swelling in the prostate gland due to hormonal changes and cell growth during the aging process. It is estimated that about 50% of men between the ages of 51 and 60 have BPH, and that number increases to about 70% among men 60-69 and around 80% of men over 70 years of age, according to Yale Medicine. This translates to upwards of 55 million men in the United States at risk or experiencing symptoms of BPH each year. Men with BPH may suffer from a range of symptoms, including increased urinary frequency, urgency, and an inability to completely empty the bladder. While there are surgical interventions to treat BPH, many men choose prescription medications to treat their symptoms and, with certain medications, decrease the size of the prostate.

Two medications commonly used to treat BPH are tamsulosin, brand name Flomax®, and finasteride, sold under the brand name Proscar®. According to ClinCalc.com, tamsulosin was the 24th most commonly prescribed medication in 2020 and has increased in rank consistently since 2014. This resulted in over 24.6 million prescriptions and an average per prescription cost of $54.40, resulting in over $1.3 billion in sales. Finasteride, ranked the 90th most commonly prescribed medication in the U.S. in 2020, has also seen consistent increases in utilization since 2013. Over 8 million finasteride prescriptions in 2020 resulted in over $162 million in sales based on an average price per prescription of $19.83.

ENTADFI, which can treat BPH without negative sexual side effects seen in some men on finasteride alone, represents a novel therapeutic treatment for patients. There is a significant market opportunity for an additional therapeutic option in BPH, shown both by the prevalence in older men and by the high, and increasing, number of BPH prescriptions written each year.

Competition

ENTADFI Competitive Analysis

Treatments for men with BPH and lower urinary tract symptoms ("LUTS") fall into five drug classes each with a different mechanism of action in alleviating symptoms: (i) alpha blockers that target alpha receptors to relax prostatic smooth muscle, (ii) 5-alpha reductase inhibitors ("5ARIs") that block the enzyme 5-alpha reductase to decrease cell growth, (iii) PDE5 inhibitors that decrease urethral smooth muscle tone, (iv) anticholinergics that block the action of acetylcholine to relax the smooth muscle of the bladder and (v) beta-3 agonists that increase bladder capacity by relaxing smooth muscle. Figure 4 below lists the current AUA- and EUA-recommended therapies for BPH and BPH with LUTS, their mechanisms of action, and potential side effects. Several of these medications are commercially available as generics.

	Class	MOA	Drug (Brand)	Adverse Effects
For BPH	Alpha-Blockers	Relax prostate smooth muscle by targeting alpha-receptors	Alfuzosin (Uroxatral)[a] Doxazosin (Cardura)[a] Tamsulosin (Flomax)[a] Terazosin (Hytrin)[a] Silidosin (Rapaflo)[a]	Erectile dysfunction, abnormal ejaculation, orthostatic hypotension, dizziness, headache, fatigue
For BPH	5-Alpha Reductase Inhibitors (5ARIs)	Blocks 5-AR enzyme to decrease prostate cell growth	Dutasteride (Avodart)[a] Finasteride (Proscar)[a]	Libido impairment, abnormal ejaculation, erectile dysfunction, gynecomastia, breast pain/tenderness
For BPH	Phosphodiesterase 5 Inhibitors (PDE5s)	Decrease urethra smooth muscle tone	Tadalafil (Cialis)[a,b]	Back pain, headache, flushing, dyspepsia, myalgia, nausea
For Overactive Bladder Related to LUTS	Anticholinergics	Relaxes bladder smooth muscle by reducing the effect of acetylcholine	Oxybutynin (Ditropan XL)[a] Tolterodine (Detrol)[a] Solifenacin (Vesicare)[a]	Urinary retention, dry mouth, constipation, diarrhea, headache, dizziness
For Overactive Bladder Related to LUTS	Beta-3 Agonists	Increases bladder capacity by relaxing the bladder smooth muscle	Mirabegron (Myrbetriq)[a]	Urinary retention, hypertension, nasopharyngitis, urinary tract infection, headache

[a] FDA approved to treat BPH; [b] FDA approved to treat erectile dysfunction; [c] FDA approved to treat overactive bladder

Figure 4. Current AUA and EAU recommended therapies for BPH and BPH with LUTS.

Should we decide to resume commercialization of ENTADFI, Potential competitors with respect to ENTADFI in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies. Many of our competitors have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we have. We may be unable to compete successfully against current and future competitors, and competitive pressures could have a negative effect on our net revenues and profit margins.

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

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

ENTADFI Competitive Advantages

Adherence to the prescribed treatment regimen is an ongoing issue in BPH therapy. Adherence rates are low for BPH treatments, as BPH medicines are typically taken chronically and are often taken for up to 6 to 12 months prior to significant symptom relief.[1] Adherence rates are particularly low in patients taking multiple BPH treatments concurrently, with reported adherence rates as low as 9%.[2] Delayed symptom relief, adversely impacting quality of life, is thought to be a major factor resulting in poor patient adherence to prescribed treatment schedules.[3] Importantly, discontinuation of treatment or non-adherence to a prescribed treatment protocol are independent risk factors for BPH related hospitalization or surgery.[4] A recent study suggested that first-time 5ARI patients with low adherence to their treatment schedule are 27% more likely to need BPH-related surgery.[5] A more effective, rapid acting therapy with a simple treatment regimen could significantly improve patient compliance, reduce the need for medical or surgical intervention and improve the patient's quality of life.

1 Casabé A et al. J Urol. 191:727-733 2014.; Cindolo L, et al. European Urology. 68(3):418-425 2015.
2 Cindolo L, et al. European Urology 68(3):418-425 2015.
3 Casabé A et al. J Urol. 191:727-733 2014.
4 Cindolo L, et al. BMC Urol 2015; 96(15): 1-7.
5 Zhang H, et al. J Urol. 204(2):325–331 2020.

ENTADFI is a combination of finasteride, a 5ARI, and tadalafil, a PDE5 inhibitor, that is indicated for use in the treatment of BPH is men with an enlarged prostate for up to 26 weeks of treatment. Tadalafil has been shown to be effective in reducing the erectile dysfunction symptoms of BPH, although the exact mechanism by which the drug reduces the symptoms of LUTS is unknown.[6] Finasteride acts to shrink the prostate by preventing the conversion of testosterone to dihydrotestosterone.[7] This fixed combination of two different, clinically effective, BPH medications delivers rapid and sustained relief from the symptoms of BPH. The combination of tadalafil and finasteride has demonstrated significant clinical efficacy within four weeks of treatment with significant improvement in sexual functioning.[8] A single capsule formulation of these two drugs removes the barriers to treatment adherence associated with delayed or poor symptom relief and a complex treatment regimen involving separate individual medications.[9]

Proclarix Competition Analysis

The molecular diagnostics field is intensely competitive and characterized by rapid technological changes, frequent new product introductions, changing customer preferences, emerging competition, evolving industry standards, reimbursement uncertainty and price competition. Moreover, recent consolidation in the industry permits larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

The market for assessing men at risk for prostate cancer is large, with many competitors some of which possess substantially greater financial, selling, logistical and laboratory resources, more experience in dealing with third-party payors, and greater market penetration, purchasing power and marketing budgets, as well as more experience in providing diagnostic services. Some companies and institutions are developing liquid biopsy (blood and urine)-based tests and diagnostic tests based on the detection of proteins, mRNA, nucleic acids, or the presence of fragments of mutated genes that are associated with prostate cancer. These competitors could have technological, financial, reputational, and market access advantages over us.

There are a number of tests already on the market or in clinical testing or commercial development that are also intended to triage diagnostics in men with moderately elevated PSA levels. Of these tests the majority also target solely PSA as a biomarker. Certain isoforms of PSA are differentiated, or transcript levels (mRNA) are determined in addition to protein levels. Of these tests the best established is %fPSA, which is also available from all suppliers of the PSA test, including market leaders Abbott Laboratories, Roche Diagnostics, Siemens Healthineers AG and Beckman Coulter, Inc. However, the sensitivity and specificity improvements are very modest.

The 4Kscore from OPKO Health, Inc. (Nasdaq: OPK) and the phi score from Beckman Coulter, Inc. measure additional forms of PSA and related proteins but they do not include additional biomarkers either. The 4Kscore test is a blood based 4-plex test which combines the results of the blood test with clinical information in an algorithm that calculates a patient's percent risk for aggressive prostate cancer prior to an initial or repeat biopsy (no previous diagnosis of prostate cancer). The 4Kscore test received marketing approval from the FDA in December 2021. The phi score combines the results of three blood tests to provide information about what elevated PSA levels might mean and the probability of finding prostate cancer on biopsy. The IsoPSA test of Cleveland Diagnostics, Inc. analyzes structural changes of PSA to detect underlying cancer biology.

Over the last decade, gene-based testing in urine targeting additional biomarkers became available. The PCA3 test from Gen-Probe Inc. (now a part of Hologic, Inc.) was the first genetic assay to be introduced to the market. The SelectMDx test from MdxHealth SA measures a combination of two genes and integrates them together with PSA value, prostate volume, patient age and digital rectal exam to a risk score. The assay targets mRNA transcripts in the patient's urine. mRNA is normally not sufficiently shed into urine to allow for direct analysis. Therefore, this test method requires prostate massage prior to sample collection and the urine samples will be collected in a specialized practice. The ExoDx IntelliScore from Exosome Diagnostics, Inc., a subsidiary of Bio-Techne Corporation, measures PCA3 as well as other gene transcripts in exosomes harvested from urine. The method does not require prostate massage, however, because mRNA is relatively unstable, the samples require cold storage in shipment and relatively rapid testing turn-around.

The Stockholm3 test is part of an academic initiative, OncoWatch, led by the Karolinska Institute, Sweden and funded by the European Institute of Innovation and Technology Health program. Established in 2020, A3P Biomedical AB (publ) is commercializing the Stockholm3 test. It is a blood-based test that predicts the risk for aggressive prostate cancer at biopsy by analyzing five protein markers, more than 100 genetic markers and clinical data.

Except for PCA3, Prostate Health Index and 4Kscore, all of the above-mentioned tests are only available as a testing service through specialized reference laboratories, they are not offered as commercial products. Testing is performed centrally as a laboratory developed test ("LDT") by a single diagnostic laboratory. Uptake of LDTs in the United States has been limited, and in Europe they are mostly not known to urologists.

6 CIALIS [Package Insert]. Indianapolis, IN: Eli Lilly and Co; 2011.
7 ENTADFI [Package Insert]. Cincinnati, OH: Blue Water Biotech, Inc; 2023.
8 Casabé A et al. J Urol 191:727-733 2014.
9 Lee LK et al. Patient Prefer Adherence 10:1205-1215 2026; Glina S et al. J Sex Med. 12(1):129-138 2015; Cindolo L et al. BMC Urol 96(15): 1-7 2015.

In recent years, MRI-based diagnosis followed by targeted biopsy is becoming the standard of choice in specialized centers. As MRI instrumentation is costly and its availability is still limited, there is a need for diagnostics supporting the decision to perform MRI that Proclarix can fulfill. MRI is not regarded as competitive to the Proclarix positioning, but complementary.

Competitive Advantages of Proclarix

We believe Proclarix has important competitive advantages:

- *Blood-based test* - *Minimally invasive, high reproducibility, no prostate massage required, suitably stable for shipment, the most common sample type in clinical laboratories and therefore fitting in current lab workflow*
- *Immunoassay-based* - *Compatible with existing laboratory instrumentation in local laboratory*
- *Easy to automate* - *Adaptable to clinical routine, fast time to result*
- *Objective result generation* - *Comparable results independent of operator*
- *Genetics-guided discovery* - *Cancer-related, highly plausible biomarkers*

Proclarix can be applied in any diagnostic laboratory, using readily available immunoassay technology platforms. Furthermore, Proclarix fits very well into the current laboratory workflow, which is important for laboratories that are driven by efficiency and cost.

The stakeholders benefit in various ways from Proclarix:

Patients: Gain more certainty whether a biopsy is really needed through a minimally invasive procedure with a fast time to result. This results in reduced anxiety about prostate cancer diagnosis and less complications and side effects from biopsies.

Physicians: Focus on relevant patients with clinically significant cancer and increased patient satisfaction by significantly reducing unneeded prostate biopsies and its accompanying complications. No need for additional training or new logistic processes: Standard blood-drawing equipment can be used, and the blood sample sent to the current laboratory.

Laboratory: Increase revenue with no additional investment for new equipment because Proclarix is readily applicable in most laboratories.

Payer (insurance company): Increase profits by saving costs for avoided biopsies (accompanied by risk of complications, discomfort) and resulting overtreatment.

Government Regulation

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 diagnostics.

Small molecule drugs, like ENTADFI, are subject to regulation in the United States under the Food, Drug, and Cosmetic Act ("FDCA") and are subject to additional federal, state, local and foreign statutes and regulations. We, along with third-party contractors, are required to navigate the various requirements of the governing regulatory agencies of the countries in which we wish to market products.

United States

U.S. Pharmaceuticals Regulation

The process required by the FDA before drugs 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 for its intended purpose;
- preparation of and submission to the FDA of a new drug application ("NDA") 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 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 to permit commercial marketing of the product for particular indications for use in the United States.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals, like ENTADFI, 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. Pharmaceutical 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. 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 Risk Evaluation and Mitigation Strategy 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 pharmaceutical products. A company can make only those claims relating to safety and efficacy, 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.

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 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. 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. Violation of the federal Anti-Kickback Statue carries criminal penalties and fines as well as administrative sanctions under the Civil Money Penalties Law. 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.

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 ("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. These provisions are intended to punish some of the same conduct in the submission of claims to private payors as the federal False Claims Act covers in connection with governmental health programs. 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, that apply regardless of the payor.

In addition, regulations promulgated pursuant to HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") established privacy and security standards that limit the use and disclosure of individually identifiable health information (known as "protected health information" or "PHI") and require the implementation of administrative, physical and technological safeguards to protect the privacy of PHI and ensure the confidentiality, integrity and availability of electronic PHI. HIPAA applies to "covered entities," including healthcare providers who submit certain standard transactions electronically, health plans, and healthcare clearinghouses, as well as to their "business associates," which are defined as independent contractors or agents of covered entities that create, receive, maintain or transmit PHI in the performance of an administrative function or 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 Covered Recipients, as defined at 42 CFR Subpart I.

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.

Coverage and Reimbursement

The future commercial success of our product candidates 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. 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, 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 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. 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. Our product 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. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our product 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 our approved product.

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 Institutional Review Board ("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 pseudonymized (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.

EU Medical device legislation

Medical device legislation is harmonized in the European Union (EU) through the European Commission's New Legislative Framework. The new regulatory framework for medical devices, published in April 2017, is based on the Medical Devices Regulation (MDR) (EU) 2017/745 applicable for medical devices and active implantable medical devices and the In Vitro Diagnostic Medical Devices Regulation (IVDR) (EU) 2017/746 applicable for in vitro diagnostic medical devices (IVDs). The dates of application of the MDR were May 26, 2021 (Article 123(2) as amended by Regulation (EU) 2020/561 and Regulation 2023/607) and May 26, 2022 (Article 113(2)), respectively. As regulations, the legislation applies to all the EU Member States as drafted and is applicable in the European Economic Area (EEA) which consists of the 27 EU Member States plus Norway, Liechtenstein, and Iceland.

The new regulatory framework in EU was triggered by the breast implant scandal (2012) and various similar case scenarios, where the cause identified significant gaps in the market surveillance and supply chain oversight as well as insufficient controls and compliance to state-of-the-art standards and documentation. Europe's new regulatory framework for IVDs introduced significant changes for IVD manufacturers; the most important is the up-classification of IVDs (introduction of 7 classification rules and four risk classes A to D harmonized with the international classification system), which require independent conformity assessments for most IVD Classes by independent regulatory compliance assessors (Notified Bodies, NB). Other changes under the IVDR are the increased NB-involvement, a new risk-based classification system and classification rules, increased elements and compliance to General Safety and Performance Requirements (GSPR), stricter demands on clinical evidence (scientific validity, analytical and clinical performance), stronger focus for post-market surveillance (PMS) and post-market performance follow-up (PMPF), stricter regulatory responsibilities throughout the supply chain for economic operators (like importers or distributors) and traceability through Unique Device Information (UDI, labelling). Overall, the IVDR is a significant expansion of the previous EU-Directive 98/79/EC (IVDD), which has been effective for IVDs since 1998.

Since 2022, due to different reasons, the European Commission issued various updates to the IVDR to introduce transitional provisions for certain IVDs, which are already on the EU market prior to the Date of Application (legacy devices) and which are not to be substantially changed by function and design (Regulation (EU) 2022/112 and Regulation (EU) 2023/6074). The current accepted transitional periods provided for in IVDR Article 120 will end on either December 31, 2027, or December 31, 2028. Currently a new proposal (2024/0021 (COD)) is even proposing extended transitional periods up to December 31, 2029, for some devices (Class B and Class A sterile) and December 31, 2028, for medium risk IVDs (Class C). Due to these extended transition timelines for legacy devices, many IVD manufacturers are not yet setting compliance to IVDR on their highest priority.

For the Proclarix IVDs (Assays and Risk Calculator software), which are class C devices under IVDR, Proteomedix has already CE marked them in 2019 under IVDD and since then started to comply with IVDR. This includes the performance and safety of the device, specifically clinical performance testing and addressing the clinical evidence for Proclarix.

Irrespective of the amendments for extended transition timelines to IVDR published since 2022 by the European Commission – Proteomedix AG has selected and streamlined the interaction with a NB (TÜV SÜD) for a conformity assessment under IVDR and passed this NB conformity assessment for their Technical Documentation and Quality Management System according to international standard ISO 13485:2016 ("Design and development, production and distribution of in-vitro diagnostic reagents and stand-alone software for prostate cancer management") in July 2022.

Proteomedix AG has agreements signed with Emergo Europe B.V. acting as their EU Authorized Representative (EU AR, also referred as EC REP).

The IVDR-compliance of Proclarix devices makes them as one the first IVDs under the new EU regime and this will have several advantages to other devices marketed under IVDD or without CE mark yet. Because of the mentioned significant changes introduced with the IVDR, other competitors might face problems and delays when trying to get to this stage of IVDR compliance. As mentioned before, every new device or substantially changed device would not be able to use the amended timelines and must fully comply with IVDR before placing them on the EU market. Second, clients (users, laboratories) might expect compliance with the IVDR at some degree as the new normal (of state-of-the-art quality). Third, for the Proclarix devices marketed since 2019 in EU, there is automatically systematic post market surveillance data collected from the field, which further can support the clinical evidence (validity) of the Proclarix devices.

Proteomedix AG also has an appointed Data Protection Officer (DPO) for data safety in line to requirements from General Data Protection Regulation (EU) 2016/679 (GDPR) and Swiss Data Protection Act although there are no personnel data included or affected in the Proclarix IVDs.

Switzerland and United Kingdom (UK) Medical Device Regulation

Switzerland and United Kingdom (UK) are not part of the EU market and in principle, become third countries with different jurisdictions and differing product regulations. However, these two countries still align to a certain degree on the European CE Mark and CE marked devices currently can be marketed without significant additional approval in Switzerland and UK.

For Switzerland, the new EU Regulations (MDR/IVDR) required an update of the Mutual Recognition Agreements to include the EU Regulations, which has so far not been negotiated by the Switzerland–EU Joint Committee for Switzerland and the EU at international treaty level. Therefore, trading of devices can no longer move freely between the Swiss market and the EU market and the sharing of information between authorities (incl. EUDAMED) or the mutual recognition of certificates of conformity are not possible and must be regulated through Swiss law separately in Switzerland. The new Swiss law for medical devices, the Medical Devices Ordinance (MedDO) was introduced in 2020 together with certain obligations for Swiss manufacturers such as registration with Swissmedic. As a consequence, Swiss manufacturers must appoint an EU-based AR and/or importer in line with Article 11 and Article 13 of the IVDR.

For UK, IVD manufacturers must comply with the UK MDR 2002 (Medical device Regulation), which has been revised several times with new guidelines addressed in the Guidance on the Regulation of In Vitro Diagnostic Medical Devices in Great Britain. Similar to EU, IVD manufacturers must identify the appropriate conformity assessment procedure for their device and demonstrate compliance with relevant requirements of the applicable legislation for IVDs in the UK for the purpose of affixing the UKCA mark to their device (UK MDR 2002 Part IV). UKCA marking (UK Conformity Assessed marking) is the UK product marking requirement that will be needed for devices being placed on the market in UK, substituting the EU requirements for CE Marking (CE marking will continue to be accepted in Northern Ireland). Most of these IVDs will then require a designated UK Authorized Body (UKAB)-issued certificate (similar to an EU CE Marking Certificate). EN ISO 13485:2016 is the designated standard under the UK MDR 2002 that covers QMS requirements for medical device manufacturers. In the UK, device manufacturers must further appoint a single “UK Responsible Person” for all of their devices, who will act on the manufacturer’s behalf to perform tasks, including product registration. However, for medical devices with a valid CE marking placed on the UK-market, there was a transition time until 1 July 2023 (no requirement to re-label the device with a UKCA mark), and the UK government recently has extended acceptance of CE marked devices in UK beyond 30 June 2023 (MDR 2002, SI 2002 No 618, as amended).

Therefore, Proteomedix AG with a valid CE mark for EU (IVDR) and appointed EU-AR, and local registration in Switzerland (Swissmedic) is in full compliance to the current changed requirements on the EU, Swiss and UK markets. Proteomedix AG has agreements signed with Emergo Consulting (UK) Ltd. acting as their UK Responsible Person. The requirement to comply with UKCA marking would apply after 30 June 2030.

EU – Impact and market opportunities on other non-EU markets

With the overall intend from regulators to harmonize regulation, the CE marking and compliance to European IVDR for the Proclarix can be considered as a state-of-the-art regulatory compliance with high potential to enter other markets. Some of these like Australia, New Zealand or Singapore and other markets recognize the CE mark and – though they might have separate approval procedures – are expected to mainly rely on the CE Certificate. For example, Australia and New Zealand have a Trans-Tasman Mutual Recognition Arrangement (TTMRA), which means that CE mark can be recognized and sold without additional regulatory processes. Brazil’s medical device market regulator, ANVISA, recently announced updates to the IVD legislation as Resolution (RDC) 830/2023 similar to the EU definition and classification of IVD under IVDR. For US, the FDA recently in January 2024 amended their title of their Quality System regulation part 820 (QSR), and integrated elements and concepts from ISO 13485:2016 into their new Quality Management System Regulation (QMSR).

These examples demonstrate that Proclarix with established CE mark (IVDR) and ISO 13485:2016 QMS has high potential to get faster market access in other non-EU countries, too. It can be expected that more non-EU country legislations will further adapt their approval or acceptance process to the level of IVDR or ISO 13485 in the forthcoming years.

Intellectual Property

Proteomedix's biomarkers were discovered using a genetics-guided discovery approach focusing on the PI3K/PTEN cancer pathway that plays a dominant role in prostate cancer development. Applying proteomics technology to a disease-relevant mouse model allowed the identification of proteins specifically linked to the molecular cause of prostate cancer. The biomarkers and the bioinformatics algorithm used in Proclarix are protected by issued and pending patents in Europe, the United States, and other countries.

Cancer arises from different genetic mutations that can be linked to specific signaling pathways often referred to as cancer pathways. Depending on what pathway is affected in a patient, results in different cancer subtypes that are more or less aggressive and further determines if a patient responds to a certain drug treatment or not.

Proteomedix's biomarkers were discovered by a group of researchers at ETH Zurich using a genetics-guided discovery approach focusing on the PI3K/PTEN cancer pathway that plays a dominant role in prostate cancer development. Using a mouse model and mass-spectrometry based proteomics technology including a glycoprotein enrichment technology led to the identification of proteins directly linked to the molecular cause of cancer and therefore correlating to the disease status in the prostate. Different serum glycoproteins were combined to form multiplexed biomarker signatures predictive for tissue PI3K/PTEN status as well as diagnosis and prognosis of prostate cancer (Figure 5). The genetic-guided proteomics approach enabled the fast discovery and validation of several biomarkers which in different combinations correspond to diagnosis, prognosis and potentially to therapy response.

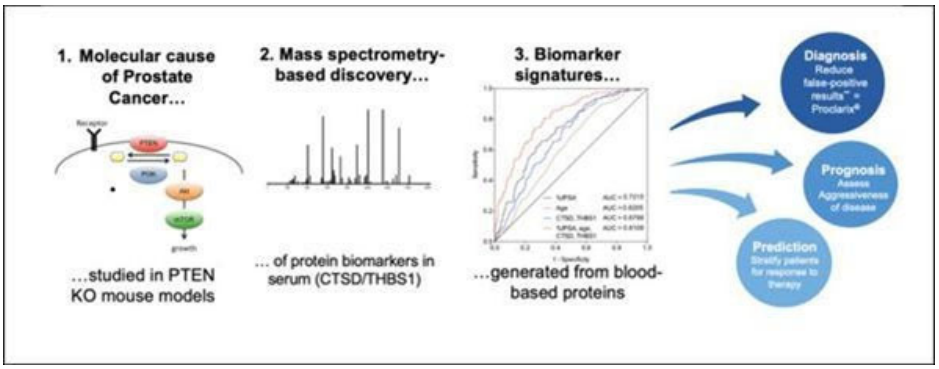

Figure 5: Proteomics approach to improve prostate cancer disease management.

The biomarker assays were transferred from a mass spectrometry-based to an immunoassay-based platform. Immunoassay-based measurement offers several advantages compared to other analytical methods. In general, immunoassays provide a rapid, sensitive, reproducible, cost effective and easily manageable analysis. The reagents used are stable and the method is established in routine diagnostic laboratories guaranteeing broad compatibility of Proteomedix's tests on established automated clinical platforms and thus rapid adoption rates and platform flexibility of the diagnostic tests. The deep knowledge in selecting novel biomarkers, assay development and clinical development enabled Proteomedix to enable several R&D partnerships.

In 2021, Proteomedix entered into a research and development partnership with New Horizon Health Limited, Grand Cayman, Cayman Islands. The partnership builds on complimentary platform and biomarker developments with utility in cancer patient management.

In 2022, Immunovia AB (Sweden) partnered with Proteomedix to leverage Proteomedix's research and development capabilities and advances their research and development efforts. With this partnership, Immunovia gained a more flexible research and development organization, increased its research and development productivity, and refocused internal resources on commercial build up, thus further accelerating the roll-out of their proprietary IMMray™ PanCan-d test. The partnership capitalizes on the combined expertise of two leading innovators in proteomics-based diagnostics, who have both launched innovative oncology tests, Immunovia with IMMray™ PanCan-d in the U.S. and Proteomedix with Proclarix® in Europe.

Patents

Proteomedix has exclusively licensed worldwide rights to one patent family from ETH Zurich and the State Hospital of St. Gallen, which describes and protects the use of the proprietary biomarkers for diagnosing and monitoring prostate cancer. The parent international patent application WO 2009138392 A1 was filed on May 12, 2009, claims a priority date of May 14, 2008 (priority date) and was granted in China (CN201027373B), Europe (EP2281201B1), Japan (JP6025607B) and the United States (US10151755B2/ US9377463B2).

Proteomedix has also obtained a non-exclusive license from ETH Zurich for certain patents pertaining to specific enrichment of glycoproteins, including EP1514107 (expired June 3, 2023) and US7183118 (to expire May 3, 2024), that ETH Zurich licensed from the Institute for Systems Biology (ISB), Seattle. The license enables Proteomedix to use the glycoprotein technology for the development of new diagnostic products.

In addition, a new patent covering the latest development and clinical results was filed by Proteomedix on July 11, 2017, claiming a priority of July 15, 2016. The patent covers the specific test format and algorithm contained in Proteomedix's first product (Proclarix) for the improved diagnosis of prostate cancer. An international application (WO2018011212A1) was filed, and the patent was granted in Europe (EP3270163B1), Japan (JP6979712B2), South Korea (KR102408276B1), Australia (AU2017294979B2), United States (US11320435B2, with term extension of 377 days) and China (CN109477836B) with the application still pending in Canada (CA3028874A1).

A patent application describing and claiming a method combining Proclarix and magnetic resonance imaging to diagnose prostate cancer was filed by Proteomedix on June 29, 2021. The patent was originally filed in Switzerland and subsequently as PCT application (WO2023274742A1) and as national applications in the United States and China.

A patent application describing and claiming a method measuring a blood-based protein combination with prognostic utility in prostate cancer patients was filed by Proteomedix on June 29, 2021. The patent was originally filed in Switzerland followed by an international application (WO2018011212A1). National applications were filed in Europe, United States and China.

Trademarks

The brand "Proteomedix" was filed on June 4, 2010, and registered under no. 602190 in Switzerland on June 22, 2010. This application served as the basis for the international trademark application. The product name "Proclarix" was filed on July 1, 2019, and registered under no. 733974 in Switzerland on July 22, 2019. This application served as the basis for the international trademark application. The product name "Prosgard" was filed on July 1, 2019, and registered under no. 733975 in Switzerland on July 22, 2019.

Exclusive License Agreement with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center

On June 1, 2021 (the "Effective Date"), the Company entered into a license agreement with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center ("CHMC"), to develop and commercialize certain CHMC patents and related technology directed at a VLP vaccine platform that utilizes nanoparticle delivery technology, which may have potential broad application to develop vaccines for multiple infectious diseases ("the CHMC Agreement"). However, as Onconetix has now deprioritized its infectious disease vaccine programs based on a change in clinical focus, we are exploring ways in which CHMC's VLP platform can be used in therapeutic and diagnostic applications in oncology.

The license is exclusive, worldwide, and is for all uses (other than the "Excluded Field" of immunization against, and prevention, control, or reduction in severity of gastroenteritis caused by Rotavirus and Norovirus in China and Hong Kong). The license is sublicensable with prior CHMC written approval consistent with the terms of the CHMC Agreement.

The CHMC Agreement includes the below patents, which we refer to as the "Licensed Patents", and any divisionals, continuations and continuations-in-part thereto (solely to the extent that the claims in the continuations-in-part are directed to the subject matter specifically claimed in the Licensed Patents, and they have the same priority date as the Licensed Patents, but do not include any different or additional claims), and any patents resulting therefrom:

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
12/797,396	8,486,421	Compositions of the vaccine/vaccine platform	1/13/2031	CN107043408B EP2440582B1 JP5894528B2
13/924,906	9,096,644	Method of treatment	9/20/2030	CN107043408B EP2440582B1 JP5894528B2
13/803,057	9,562,077	Compositions of the vaccine platform	11/8/2033	none
16/489,095	pending	pending**	[3/15/2038]*	Pending applications in Canada, China, EU, Hong Kong and Japan
63/149,742 (filed 2/16/2021)	pending	pending**	[February 2042]#	TBD
63/162,369 (filed 3/17/2021)	pending	pending	[March 2042]#	TBD

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.

\# Non-provisional application not yet filed. Expiration projected 21 years from provisional application filing date. Dependent on timely conversion to non-provisional application and issuance of patent.

** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions of the vaccine and vaccine platform.

The CHMC Agreement also grants the Company a non-exclusive limited license to use and copy internally any technical information in existence and known before the Effective Date by CHMC solely as necessary for the use and practice of the Licensed Patents (the "CHMC Technology").

The term of the CHMC Agreement begins on the Effective Date and extends on a jurisdiction by jurisdiction and product by product basis until the later of: (i) the last to expire Licensed Patent; (ii) ten (10) years after the first commercial sale or (iii) entrance onto the market of a biosimilar or interchangeable product. CHMC has reserved the right to practice, have practiced, and transfer the Licensed Patents and CHMC Technology for research and development purposes, including education, research, teaching, publication and public service, but not to use or practice the Licensed Patents or CHMC Technology in the Field of Use for any commercial or profit purpose.

The Licensed Patents granted to the Company under the CHMC Agreement are also subject to any rights of the United States federal, state and/or local Government(s), as well as nonprofit entities, if certain patents or technologies were created in the course of Government-funded or non-profit entity-funded research. The CHMC Agreement also contains compulsory licensing provisions under which CHMC must notify the Company in writing whenever CHMC may become aware of third parties that are interested in obtaining rights to the Licensed Patents or CHMC Technology for purposes that are beyond the scope of the Company's development and commercialization plan. The Company may elect to pursue the new purposes itself (and negotiate commercially reasonable development targets) or enter into sublicense negotiations with the interested third party. However, if the Company fails to meet its development targets for the new purposes or fails to enter into a sublicense agreement with the interested third party within nine (9) months of the notice from CHMC, then the new purpose will be excluded from the license grant and CHMC will be free to pursue licensing of the Licensed Patents or CHMC Technology within the Excluded Field to an interested third party.

Any patented modification, alteration or improvement of any invention claimed in a Licensed Patents or CHMC Technology which is conceived or reduced to practice solely by the Company ("Company Improvement") is owned by the Company; however, for any such Company Improvement, the Company will automatically grant to CHMC a worldwide, perpetual, sublicensable, nonexclusive, paid-up, royalty-free license to use any Company Improvements solely for clinical or non-clinical, non-commercial research, testing, educational and patient care purposes. The CHMC Agreement also provides the Company with an option to license any CHMC or jointly patented modification, alteration or improvement of any invention claimed in a Licensed Patent ("CHMC Improvement" and "Joint Improvement, respectively"), with option fee for each Improvement that the Company elects to include in the license grant of the CHMC Agreement.

The Company is required to pay CHMC an aggregate of up to $59.75 million upon the achievement of specified development milestones, of approximately $0.5 million, regulatory milestones, of approximately $1.25 million and commercial milestones of approximately $58 million (excluding any royalty arrangements). In the event the Company enters into a sublicense agreement with a third party who is not an affiliate, then the Company is obligated to pay CHMC a percentage of all non-royalty sublicensing revenue. Specifically, the Company must pay twenty-five percent (25%) for revenue received from the sublicensee prior to first net sale of a licensed product, fifteen percent (15%) for revenue received after first net sale of a licensed product or five percent after the first sale of a second licensed product. No annual maintenance fee is required.

Pursuant to the CHMC Agreement, the Company paid to CHMC a one-time $25,000 initial license fee; thereafter, in fiscal year ended December 31, 2022, the Company paid $200,000 in deferred license fees.

Under the CHMC Agreement, the Company is obligated to use commercially reasonable efforts to bring licensed products to market through diligent research and development, testing, manufacturing, and commercialization and to use best efforts to make all necessary regulatory filings and obtain all necessary regulatory approvals, and achieve milestones relating to development and sales, and report to CHMC on progress. The Company will also be obligated to pay the agreed upon development milestone payments to CHMC.

Development milestones include: (i) IND filings of each Licensed Product; (ii) Biologics License Applications ("BLAs") or equivalent allowed for Licensed Product in U.S. or E.U.; (iii) first commercial sale of licensed product in the U.S.; (iv) first commercial sale of licensed product in the E.U.; (v) first commercial sale of licensed product in Japan; (vi) first commercial sale in Rest of World (ROW); (vii) conclusion of the first calendar year. Pursuant to the terms of the CHMC Agreement, if the Company fails to achieve milestones or make milestone payments on certain milestones and cannot mutually agree with CHMC on an amendment to the milestones, then CHMC will have the option of converting any and all of such exclusive licenses to nonexclusive licenses.

In addition to the fees discussed above, beginning on the first Net Sale, the Company will pay CHMC running royalties on a quarterly basis as a percentage of Net Sales (as defined in the CHMC Agreement) of the Company, its affiliates, and any subsidiaries. Similarly, in the event the Company enters into a sublicense agreement, the Company shall pay CHMC a percentage of all non-royalty sublicensing revenues received from the sublicensee. There is a 5% royalty rate for products and processes for P-Particle VLP Bivalent vaccine for norovirus and rotavirus; a 4% royalty rate for products and processes for Universal Flu Vaccine(s); and a 2% royalty rate for all other products or processes for other indications. To date, no payments have been made related to the milestones or royalties. Before any Valid Claims (as defined in the CHMC Agreement) exist, the running royalty rates are reduced by fifty percent (50%).

The CHMC Agreement also contains an anti-stacking provision pursuant to which in the event the Company is legally required to pay royalties to one or more third parties whose patent rights dominate the Licensed Patents and would therefore be infringed by exercise of the license rights granted in the CHMC Agreement, the Company may reduce running royalty payments by fifty percent (50%). In the event the Company grants sublicenses, the Company is obligated to pay CHMC as follows: (i) specified percentage of revenue received prior to first Net Sale of first Licensed Product; (ii) specified percentage for revenue received after first Net Sales of first Licensed Product but before first Net Sales of second Licensed Product; or (iii) specified percentage for revenues received after first Net Sales of second Licensed Product.

CHMC reserved the first and sole right, using in-house or outside legal counsel selected by CHMC, to prepare, file, prosecute, maintain, and extend patents and patent applications, and the Company agreed to reimburse CHMC for its legal and administrative costs incurred in the course of doing such. The Company also agreed to reimburse CHMC for incurred legal fees of approximately $177,100 as of the Effective Date. CHMC will provide the Company a reasonable opportunity to comment during prosecution and will consider the Company's comments, but CHMC retained control over all final decisions. If CHMC elects to not be responsible for the prosecution or maintenance of any such patents, the Company will receive sixty (60) days' prior written notice upon which the Company may elect, at the Company's expense, to assume the responsibilities and obligations to prosecute and maintain the patents (among other things); thereafter, the Company will use reasonable efforts to give CHMC an opportunity to comment, but the final decision with respect to such matter will remain with the Company.

The CHMC Agreement contains no CHMC representations or warranties. The CHMC Agreement also requires the Company to indemnify CHMC and other related parties against all claims, suit, actions, demands, judgments, or investigations arising out of any product the Company produces under the CHMC Agreement, as set forth in the CHMC Agreement, and requires the Company, beginning with the earlier of the first clinical trial or commercial sale or other commercialization to obtain liability insurance.

CHMC will have the first and sole right but not the obligation, at its own expense, to initiate an infringement suit or other appropriate actions against third party infringers and receives all therefrom. For joint suits initiated against third party infringers and receives damages or profits recovered therefrom. In the event CHMC does not, within six (6) months after becoming aware of infringement, secure cessation of the infringement, the Company will have the right to initiate suit at its own expense. Any damages or profits that the Company recovers will be treated as Net Sales subject to royalties after the Company has been compensated for its costs in handling such action. In the event of a joint infringement suit, the Company and CHMC will agree in writing who will control the action and how cost and recoveries will be shared.

The Company may terminate the CHMC Agreement for convenience at any time prior to first commercial sale of a product or process by providing one hundred and eighty (180) days' written notice to CHMC. It may also terminate for a CHMC uncured material breach. CHMC may terminate the CHMC Agreement for an uncured Company material breach or insolvency or bankruptcy. In the event the Company's material breach is for failure to meet any of the milestone payments, the Company is entitled to a nonexclusive license to continue developing indications that have already entered development at any stage or in which the Company has invested in developing. CHMC may also terminate the CHMC Agreement to the fullest extent permitted by law in the countries of the worldwide territory, in the event the Company or its affiliates challenge or induce others set up challenges to the validity or enforceability of any of the Licensed Patents and the Company will be obligated reimburse CHMC for its costs, including reasonable attorneys' fees.

Manufacturing and Supply

We currently do not own or operate any manufacturing facilities. For Proclarix, we outsource manufacturing to a CMO in Germany. The manufacturing of Proclarix is outsourced to a CMO in Germany. All of the key reagents used in Proteomedix's IVD kits (i.e., antigens and antibodies) are proprietary and owned exclusively by Proteomedix. These reagents are produced by an independent supplier in Germany and shipped to the CMO for manufacturing of the IVD kits. The development and production of the Proclarix risk calculator software and the hosting of the Proclarix risk calculator software are performed by external suppliers. For ENTADFI, we utilize third-party manufacturers for the pharmaceuticals, bottle fill, finish, labeling, bottle serialization, warehousing, and distribution.

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 ENTADFI and any other products the parties mutually agree to. 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 if we proceed with commercialization of ENTADFI, upon its launch, 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.

Employees

As of April 5, 2024, we had 12 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. The lease will automatically renew unless terminated. Either party may terminate the lease with 12 months' written notice.

Corporate Information

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 SEC. Alternatively, you may also access our reports at the SEC's website at www.sec.gov.

Buyback Program

On November 10, 2022, the Company's Board of Directors approved a share repurchase program to allow for the Company to repurchase up to 5 million shares of common stock, with discretion to management to make purchases subject to market conditions. The maximum purchase price is $2.00 per share and there is no expiration date for this program.

During the fiscal year ended December 31, 2023, the Company repurchased 57,670 shares of common stock, for an aggregate of approximately $59,000, at an average price of $1.02 per share.

Fundraising Activities

April 2022 Private Placement

On April 19, 2022, we consummated the closing of a Private Placement (the "April 2022 Private Placement"), in which we received approximately $6.9 million in net cash proceeds, pursuant to the terms and conditions of the Securities Purchase Agreement, dated as of April 13, 2022 (the "April Purchase Agreement"), by and among the Company and certain purchasers named on the signature pages thereto. At the closing of the April 2022 Private Placement, the Company issued 590,406 shares of common stock, pre-funded warrants to purchase an aggregate of 590,406 shares of common stock and preferred investment options to purchase up to an aggregate of 1,180,812 shares of common stock. The purchase price of each share of common stock together with the associated preferred investment option was $6.775, and the purchase price of each pre-funded warrant and associated preferred investment option was $6.774. The aggregate net cash proceeds to the Company from the April 2022 Private Placement were approximately $6.9 million, after deducting placement agent fees and other offering expenses.

H.C. Wainwright & Co., LLC ("Wainwright") acted as the exclusive placement agent for the April 2022 Private Placement and received a cash fee of approximately $600,000, which was equivalent to 7.5% of the aggregate gross proceeds of the offering, and received warrants (the "April Wainwright Warrants") to purchase up to 70,849 shares of our common stock, which was equivalent to 6.0% of the shares and pre-funded warrants sold in the April 2022 Private Placement. We also paid Wainwright a management fee equal to approximately $80,000, which is equivalent to 1.0% of the aggregate gross proceeds from the offering, and reimbursed certain out-of-pocket expenses up to an aggregate amount of $85,000. We also agreed, upon any exercise for cash of any preferred investment options, to issue to Wainwright warrants to purchase the number of shares equal to 6.0% of the aggregate number of placement shares underlying the preferred investment options that have been exercised (the "April Contingent Warrants"), up to a maximum of 70,849 shares. The maximum number of April Contingent Warrants were exchanged for August Contingent Warrants (as defined below) in connection with the August 2022 Private Placement (as defined below).

In connection with the April 2022 Private Placement, we entered into a registration rights agreement with the purchasers, dated as of April 13, 2022 (the "April Registration Rights Agreement"), pursuant to which we filed a registration statement covering the resale of registrable securities under the April Registration Rights Agreement, which was declared effective on May 20, 2022.

Upon the occurrence of any Event (as defined in the April Registration Rights Agreement), which, among others, includes the purchasers being prohibited from reselling the securities acquired in the April 2022 Private Placement for more than ten (10) consecutive calendar days or more than an aggregate of fifteen (15) calendar days during any 12-month period, we are obligated to pay to each purchaser, on each monthly anniversary of each such Event, an amount in cash, as partial liquidated damages and not as a penalty, equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such purchaser pursuant to the April 2022 Purchase Agreement.

August 2022 Private Placement

On August 11, 2022, the Company consummated the closing of a private placement (the "August 2022 Private Placement"), pursuant to the terms and conditions of a securities purchase agreement, dated as of August 9, 2022. At the closing of the August 2022 Private Placement, the Company issued 1,350,000 shares of common stock, pre-funded warrants to purchase an aggregate of 2,333,280 shares of common stock and preferred investment options to purchase up to an aggregate of 4,972,428 shares of common stock. The purchase price of each share of common stock together with the associated preferred investment option was $2.715, and the purchase price of each pre-funded warrant together with the associated preferred investment option was $2.714. The aggregate net cash proceeds to the Company from the August 2022 Private Placement were approximately $8.7 million, after deducting placement agent fees and other offering expenses. In addition, the investors in the August 2022 Private Placement, who are the same investors from the April 2022 Private Placement, agreed to cancel preferred investment options to purchase up to an aggregate of 1,180,812 shares of the Company's common stock issued in April 2022. The pre-funded warrants had an exercise price of $0.001 per share. During 2022, an aggregate of 1,686,640 of the pre-funded warrants were exercised. The remaining 646,640 of pre-funded warrants were exercised during the year ended December 31, 2023. The preferred investment options are exercisable at any time on or after August 11, 2022 through August 12, 2027, at an exercise price of $2.546 per share, subject to certain adjustments as defined in the agreement. During the year ended December 31, 2023, 2,486,214 of these preferred investment options were exercised at a reduced exercise price of $1.09, in connection with the Warrant Inducement Transaction discussed below.

Wainwright acted as the exclusive placement agent for the August 2022 Private Placement. The Company agreed to pay Wainwright a placement agent fee of approximately $750,000 and a management fee of approximately $100,000, which equal to 7.5% and 1.0%, respectively, of the aggregate gross proceeds from the August 2022 Private Placement and reimbursed certain out-of-pocket expenses up to an aggregate of $85,000. In addition, the Company issued warrants to Wainwright (the "August Wainwright Warrants") to purchase up to 220,997 shares of common stock. The August Wainwright Warrants are in substantially the same form as the preferred investment options, except that the exercise price is $3.3938. The form of the preferred investment options is a warrant, and as such the preferred investment options, the pre-funded warrants, and the August Wainwright Warrants are collectively referred to as the "August 2022 Private Placement Warrants". Further, upon any exercise for cash of any preferred investment options, the Company agreed to issue to Wainwright additional warrants to purchase the number of shares of common stock equal to 6.0% of the aggregate number of shares of common stock underlying the preferred investment options that have been exercised, also with an exercise price of $3.3938 (the "August Contingent Warrants"). The maximum number of August Contingent Warrants issuable under this provision is 298,346, which includes 70,849 of April Contingent Warrants that were modified in connection with the August 2022 Private Placement.

In connection with the August 2022 Private Placement, the Company entered into a Registration Rights Agreement with the purchasers, dated as of August 9, 2022 (the "August Registration Rights Agreement"). The August Registration Rights Agreement provides that the Company shall file a registration statement covering the resale of all of the registrable securities (as defined in the August Registration Rights Agreement) with the SEC no later than the 30th calendar day following the date of the August Registration Rights Agreement and have the registration statement declared effective by the SEC as promptly as possible after the filing thereof, but in any event no later than the 45th calendar day following August 9, 2022 or, in the event of a full review by the SEC, the 80th day following August 9, 2022. The registration statement on Form S-1 required under the Registration Rights Agreement was filed with the SEC on August 29, 2022 and became effective on September 19, 2022.

Upon the occurrence of any Event (as defined in the August Registration Rights Agreement), which, among others, prohibits the purchasers from reselling the securities for more than ten consecutive calendar days or more than an aggregate of fifteen calendar days during any 12-month period, and should the registration statement cease to remain continuously effective, the Company is obligated to pay to each purchaser, on each monthly anniversary of each such Event, an amount in cash, as partial liquidated damages and not as a penalty, equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such purchaser in the August 2022 Private Placement.

Warrant Inducement Transaction

On July 31, 2023, the Company entered into a common stock preferred investment options exercise inducement offer letter (the "Inducement Letter") with a certain holder (the "Holder") of existing preferred investment options ("PIOs") to purchase shares of the Company's common stock at the original exercise price of $2.546 per share, issued on August 11, 2022 (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 exercised price of $1.09 per share, in exchange for the Company's agreement to issue new PIOs (the "Inducement PIOs") on substantially the same terms as the Existing PIOs as described below, to purchase up to 4,972,428 shares of the Company's common stock (the "Inducement PIO Shares").

On August 1, 2023, the Company and the Holder entered into a letter agreement to amend the Inducement Letter to clarify, among other things, that (i) the Inducement PIOs shall be immediately exercisable at any time on or after the date of issuance and have a term of exercise of five (5) years from the date of issuance, and (ii) the Company shall not be required to hold a meeting of stockholders to approve the issuance of the Inducement PIO Shares. Except for the change in exercise period, the terms of the Inducement PIOs remain unchanged.

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, 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.

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.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Report, including our financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," 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.

Risks Related to our Financial Position and Need for Capital

We have a very limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

To date, we have devoted substantially all of our resources to performing research and development, hiring personnel, licensing and developing our technology, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio, potential asset and business acquisitions, expenditures associated with the commercial launch of ENTADFI, and raising capital to support and expand such activities. As an organization, we have not yet demonstrated an ability to successfully manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization or arrange for a third party to conduct these activities on our behalf. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our products. We are in the process of transitioning from a company with a research and development focus to a company capable of supporting commercial activities and may not be successful in such a transition.

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

We are a commercial-stage biotechnology company that was incorporated in October 2018. Our net loss was $37.4 million and $13.4 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $56.8 million. We also generated negative operating cash flows of $13.6 million for the year ended December 31, 2023.

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

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

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of December 31, 2023, the Company had cash of approximately $4.6 million, a working capital deficit of approximately $11.4 million and an accumulated deficit of approximately $56.8 million.

On January 23, 2024, the Company issued the Debenture in exchange for $4.6 million in net cash proceeds. The Debenture is repayable in full upon the earlier of (i) the closing under the Subscription Agreement and (ii) June 30, 2024.

We estimate that, based on our existing cash as of the date of this Report, we will not have cash on hand sufficient to fund our operations for at least the 12 months following the date of this Report. We believe that we will need to raise substantial additional capital to fund our continuing operations, satisfy existing and future obligations and liabilities, and otherwise support the Company's working capital needs and business activities, including making the remaining payments to Veru, and the commercialization of Proclarix and ENTADFI (should we decide to resume its commercialization). In addition, if Stockholder Approval is not obtained by January 1, 2025, the Company may be obligated to cash settle the Series B Preferred Stock. The Company does not currently have sufficient cash to redeem the shares of Series B Preferred Stock. Based on the closing price of $0.166 for the Company's stock as of April 5, 2024, the Series B Preferred Stock would be redeemable for approximately $44.8 million. Management's plans include generating product revenue from sales of Proclarix, which may still be subject to further successful commercialization activities within certain jurisdictions. In addition, should we decide to resume the commercialization of ENTADFI, we plan to also generate product sales from ENTADFI, which is subject to further successful commercialization activities. 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 commercialization of products, and it may take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of time within one year following the date of this Report. Our future capital requirements will depend on many factors, including:

- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for Proclarix, and ENTADFI (if we decide to resume its commercialization), and other products for which we have received or will receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire, and retain skilled personnel;
- the revenue, if any, received from commercial sales of Proclarix and ENTADFI (if we decide to resume its commercialization), or other products for which we may receive marketing approval;
- the costs to establish, maintain, expand, enforce, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending, and enforcing our patents or other intellectual property rights; and
- the costs of operating as a public company.

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

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

Due to recent financial constraints, the Company may be unable to timely pay amounts due to Veru, from whom we purchased ENTADFI in April 2023. The Company is currently in ongoing discussions with Veru to negotiate our payment obligations in connection with our acquisition of ENTADFI. However, no definitive terms or extensions have been agreed to, to date. While we are hopeful that we can come to mutually agreeable terms regarding a settlement, payment plan, and/or extension with Veru, we may not have sufficient funds to pay amounts due to Veru in the near term, if at all, including but not limited to $10 million, $5 million of which is due on each of April 19, 2024 and September 30, 2024, and Veru may take action against us, including filing legal proceedings against us seeking amounts due and interest or attempting to terminate its relationship with us. If Veru were to take legal action against us, we may be forced to scale back our business plan and/or seek bankruptcy protection. We may be subject to litigation and damages for our failure to pay due to Veru, and may be forced to pay interest and penalties, which funds we do not currently have. We are currently considering strategic options for ENTADFI and plan to seek to raise funding in the future to support our operations, and to pay amounts due to Veru, through a combination of equity offerings, debt financing or other capital sources, including potential collaborations, licenses, sales, and other similar arrangements, which may not be available on favorable terms, if at all. The sale of additional equity or debt securities, if accomplished, may result in dilution to our stockholders.

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

As of December 31, 2023, we had total current liabilities of approximately $17.2 million, including accounts payable of approximately $5.3 million, accrued expenses of approximately $2.2 million, and approximately $9.6 million (net of discount) related to the notes payable due to Veru. As of the same date, we had cash of only $4.6 million. We are currently considering strategic options for ENTADFI and plan to seek to raise funding in the future to support our operations. If those to whom these payments are due were to demand immediate payment, as they are entitled to do, and we are not able to make the required payments, we would be subject to liability if our creditors chose to enforce their rights, which could result in our bankruptcy and insolvency, at worst. Under such a scenario, our assets would be distributed to our creditors leaving nothing to be distributed to our stockholders.

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 financing, 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 or acquire 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, license, or acquisition, we will achieve the results, revenue or specific net income that justifies such transaction.

Raising additional capital may cause dilution to our existing stockholders and investors, restrict our operations or require us to relinquish rights to our products on unfavorable terms to us.

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under other types of contracts, or upon the exercise or conversion of outstanding options, warrants, convertible debt or other similar securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in terms of the payment of dividends or in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends and may require us to grant security interests in our assets. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or products or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may need to curtail or cease our operations.

Due to the significant resources required for the commercialization of our products, and depending on our ability to access capital, we must prioritize commercialization of certain products. Moreover, we may expend our limited resources on products that do not yield a successful product and fail to capitalize on products that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our products, we must decide which products to pursue and advance and the number of resources to allocate to each. Our decisions concerning the allocation of management and financial resources toward particular products may not lead to the development of any viable commercial products and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate, license, or collaborate with third parties in respect of certain products may subsequently also prove to be less than optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our products or misread trends in the pharmaceutical or diagnostic industry, our business could be seriously harmed. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other products and/or product candidates that may later prove to have greater commercial potential than those we choose to pursue or relinquish valuable rights to such products and/or product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited, each of which could harm our business.

As of December 31, 2023, we had U.S. federal, foreign, and state net operating loss carryforwards of approximately $27.9 million, $18.0 million, and $23.8 million, respectively. Under Sections 382 and 383 of the Internal Revenue Code, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-ownership change net operating loss carryforwards and other pre-ownership change tax attributes, such as research tax credits, to offset its post-ownership change income and taxes may be limited. In general, an ownership change will occur when the percentage of the Corporation's ownership (by value) of one or more "5-percent stockholders" (as defined in the Code) has increased by more than 50 percent over the lowest percentage owned by such stockholders at any time during the prior three years (calculated on a rolling basis). Similar rules may apply under state tax laws. An entity that experiences an ownership change generally will be subject to an annual limitation on its pre-ownership change tax loss and credit carryforwards equal to the equity value of the corporation immediately before the ownership change, multiplied by the long-term, tax-exempt rate posted monthly by the U.S. Internal Revenue Service (subject to certain adjustments). The annual limitation would be increased each year to the extent that there is an unused limitation in a prior year. In the event that it is determined that we have in the past experienced an ownership change as a result of transactions in our stock, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be limited in our ability to use our net operating loss carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. Any limitations on the ability to use our net operating loss carryforwards and other tax assets could harm our business.

Our insurance coverage may be inadequate or expensive.

We are subject to claims in the ordinary course of business. These claims may involve substantial amounts of money and involve significant defense costs. It is not possible to prevent or detect all activities giving rise to claims and the precautions we take may not be effective in all cases. We maintain voluntary and required insurance coverage, including, among others, general liability, property, director and officer, business interruption, cyber and data breach. Our insurance coverage is expensive and maintaining or expanding our insurance coverage may have an adverse effect on our results of operations and financial condition.

Our insurance coverage may be insufficient to protect us against all losses and costs stemming from operational and technological failures and we cannot be certain that such insurance will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large retention, or deductible, or co-insurance requirements, could have an adverse effect on our business, financial condition, and results of operations.

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 the WraSer 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. In October 2023, WraSer alerted us that its sole manufacturer for the 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 WraSer APA enabling us to terminate the WraSer APA and the WraSer 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 WraSer APA and the WraSer MSA without prejudice to the parties' respective rights, remedies, claims, and defenses they had against one another under the WraSer APA and the WraSer MSA. On December 21, 2023, we filed a Notice with the Bankruptcy Court terminating the WraSer APA and the WraSer 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.

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 this Report. As a result, we may be unable to conduct an "at the market" offering pursuant to our At The Market Offering Agreement with Wainwright 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.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual revenue and operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. Our quarterly and annual operating results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. These fluctuations may occur due to a variety of factors, including, but not limited to:

- the level of demand for our diagnostic tests, which may vary significantly;
- the timing and cost of manufacturing our diagnostic tests, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- expenditures that we may incur to acquire, develop, or commercialize additional tests and technologies;

- unanticipated pricing pressures;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- currency fluctuations due to our expectation of generating future revenue from international sales, subjecting us to risks such as currency exchange rate volatility;
- geopolitical instability, economics problems, and other uncertainties in certain foreign countries in which we operate;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners; and
- coverage and reimbursement policies with respect to cancer treatment equipment, and potential future diagnostic tests that compete with our diagnostic tests.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our future financial results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period, and accordingly should not be relied upon as indicative of future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock and warrants could decline substantially. Such a stock price decline could occur even when we have met any publicly stated guidance we may provide, and could in turn negatively impact our business, financial condition and results of operations.

Risks Related to the Commercialization of our Products

We depend entirely on the success of a limited number of products. If we do not successfully commercialize our products or we experience significant delays in doing so, these products may not be profitable.

Our business currently depends heavily on the successful commercialization of our products. We cannot be certain that our products will be successfully commercialized. The manufacturing, safety, efficacy, labeling, sale, marketing, and distribution of our products are, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. The success of our products will depend on several additional factors, including:

- establishing commercial manufacturing capabilities;

- launching commercial sales, marketing and distribution operations;
- establishing relationships with partners having established distribution, marketing and sales capabilities;
- the prevalence and severity of adverse events experienced with our products;
- acceptance of our products by patients, the medical community, and third-party payors;
- a continued acceptable safety profile following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement for our products;
- competing effectively with other therapies and diagnostics, including with respect to the sales and marketing of our products; and
- qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

Many of these factors are beyond our control, including potential threats to our intellectual property rights and changes in the competitive landscape. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our products, which would materially harm our business, financial condition, and results of operations.

Obtaining and maintaining regulatory approval of our products in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.

Obtaining and maintaining regulatory approval of our products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a pharmaceutical product, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of pharmaceutical or diagnostic products with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our vaccine candidates will be harmed.

Modifications to our product, ENTADFI, may require new FDA approvals.

Once a particular product receives FDA approval, expanded uses or uses in new indications may require additional human clinical trials and new regulatory approvals, including additional IND and/or NDA, and premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions. Conducting clinical trials and obtaining approvals can be a time-consuming process, and delays in obtaining required future approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Adverse events involving ENTADFI may result in product recalls that could harm our reputation, business and financial results.

If we or others identify undesirable side effects caused by ENTADFI, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such a product;
- regulatory authorities may require additional warnings or limitations of use in product labeling;
- we may be required to change the way a product is distributed, dispensed, or administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of ENTADFI and could significantly harm our business, prospects, financial condition and results of operations.

Once a product receives FDA approval, the agency has the authority to require the recall of commercialized products in the event of adverse side effects, material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is a reasonable probability that the product would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of adverse side effects, impurities or other product contamination, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of ENTADFI would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within ten working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving ENTADFI in the future. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA and/or other regulatory agencies could take enforcement action for failing to report the recalls when they were conducted.

If we decide to resume the commercialization of ENTADFI, it may not gain market acceptance among regulators, advisory boards, physicians, patients, third-party payors, and others in the medical community.

If we decide to resume the commercialization of ENTADFI, it may fail to receive recommendations for use by regulators, or gain market acceptance by physicians, patients, third-party payors, and others in the medical community. If ENTADFI does not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any product will depend on a number of factors, including but not limited to:

- receiving governing or advisory recommendations for use, as well as recommendations of comparable foreign regulatory and advisory bodies;
- prevalence and severity of the disease targets for which our product is approved;
- physicians, hospitals, third-party payors, and patients considering our product as safe and effective;

- the potential and perceived advantages of our product over existing therapies, including with respect to treatment of disease;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory and advisory bodies;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory and advisory bodies;
- the timing of market introduction of our products as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to competitive products and alternative treatments; and
- the effectiveness of our sales and marketing efforts.

If our product fails to receive recommendations by governing or advisory bodies in either the United States or other countries, or achieve market acceptance among physicians, healthcare providers, patients, third-party payors or others in the medical community, we will not be able to generate significant revenue. Even if our product achieves 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 product, are more cost effective or render our product obsolete.

Even if we are able to commercialize our products, they may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs and diagnostics vary widely from country to country. In the United States, new and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product-licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial marketing approval is granted.

Our ability to commercialize our products successfully also will depend in part on the extent to which coverage and adequate reimbursement for this product and related treatments will be available from government health programs, private health insurers, integrated delivery networks and other third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payment for particular drugs. Increasingly, third-party payors are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient for commercial success. Coverage and reimbursement may impact the demand for, or the price of, our product. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize our product.

There may be significant delays in obtaining coverage and adequate reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Coverage and reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Commercial third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded programs and private payors for our product could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our product and our overall financial condition.

Our products could be subject to marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Our products, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of promotional materials and safety and other post-marketing information and reports, registration and listing requirements, current Good Manufacturing Practice ("cGMP") requirements for product facilities, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and related recordkeeping. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not comply with these restrictions, we may be subject to enforcement actions.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes and facilities or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on our products, manufacturers or manufacturing processes or facilities;
- restrictions on the labeling, marketing, distribution, or use of a product;
- requirements to conduct post-approval clinical trials, other studies, or other post-approval commitments;
- warning or untitled letters;
- withdrawal or recall of our products from the market;

- refusal to approve pending applications or supplements to approved applications that we submit;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approval;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We intend to market future products in international markets. In order to market our future products in regions such as the EEA, Asia Pacific, and many other foreign jurisdictions, we must obtain separate regulatory approvals.

For example, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. Before granting the MA, the European Medicines Agency, or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. In Japan, the Pharmaceuticals and Medical Devices Agency, or the PMDA, of the Ministry of Health Labour and Welfare, or MHLW, must approve an application under the Pharmaceutical Affairs Act before a new drug product may be marketed in Japan.

We have had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Moreover, clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file, we may not receive necessary approvals to commercialize our products in any market.

Legislation, such as the Inflation Reduction Act, may impact our ability to market and commercialize ENTADFI and reduce our profitability from such asset.

Legislation, either in the United States or in a foreign country, may impact our ability to market and commercialize ENTADFI and may reduce our profitability from such asset. For example, the Inflation Reduction Act ("IRA") was signed into law in the United States in 2022 and intended to lower out-of-pocket costs associated with pharmaceutical drugs. Key impacts of the IRA include the following:

- Medicare can now directly negotiate lower prescription drug prices with pharmaceutical manufacturers;
- the cost of insulin for Medicare beneficiaries is now capped at $35;
- all recommended adult vaccines are free; and
- drug companies are required to pay rebates if they raise prices of their products faster than the rate of inflation.

Should we decide to raise the price of ENTADFI, and raise it higher than the rate of inflation, we may be exposed to rebates owed to Medicare. This may affect the profitability of our product and reduce revenues associated with it.

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

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

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 Proclarix and ENTADFI (if we decide to resume its commercialization) to meet demand. ENTADFI and Proclarix are 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 for ENTADFI and to register their activities and manufactured devices in databases and for Proclarix, manufacturers and developers (software) are required to comply with ISO 13485 and the host of the software with ISO 27001; these parties can be then subject to audits or inspections. As a result, the facilities used by any manufacturers of ENTADFI, 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 CMO. Our third-party manufacturers will be required to produce ENTADFI 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 products. 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. For medical devices in United States, the contract manufacturer will be subject to FDA inspections (while in the EU, these would be subject to Notified Body audits (on demand)). Failure by any of our manufacturers to comply with applicable cGMPs, ISO 13485, ISO 27001 or applicable regulations 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, 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.

In light of (i) the time and resources needed to continue pursuing commercialization of ENTADFI, and (ii) the Company's cash runway and indebtedness, the Company has determined to temporarily pause its commercialization of ENTADFI, as it considers strategic alternatives. The Company expects to appoint a new Chief Executive Officer in early April 2024, after which the new CEO and the Board will reassess its ENTADFI program in light of the foregoing and other relevant factors.

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 and other authorized health care practitioners may not prescribe our products, which would prevent our products from generating revenue. Market acceptance of our products by healthcare providers, 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;
- acceptance by healthcare providers 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, healthcare providers 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 healthcare providers 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.

Proclarix is subject to competition from other prostate cancer diagnostics and larger, well-established companies with substantially greater resources than us.

The molecular diagnostics field is intensely competitive and characterized by rapid technological changes, frequent new product introductions, changing customer preferences, emerging competition, evolving industry standards, reimbursement uncertainty and price competition. Moreover, recent consolidation in the industry permits larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

The market for assessing men at risk for prostate cancer is large, with many competitors some of which possess substantially greater financial, selling, logistical and laboratory resources, more experience in dealing with third-party payors, and greater market penetration, purchasing power and marketing budgets, as well as more experience in providing diagnostic services. Some companies and institutions are developing liquid biopsy (blood and urine)-based tests and diagnostic tests based on the detection of proteins, mRNA, nucleic acids, or the presence of fragments of mutated genes that are associated with prostate cancer. These competitors could have technological, financial, reputational, and market access advantages over us.

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

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

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

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

We may not be able to successfully implement our strategy to grow sales of ENTADFI in the U.S. market and Proclarix in the European markets or, if authorized, grow sales of either in any other 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 market, which is heavily generic, or the prostate cancer diagnostics market, which is highly competitive. Failure to grow sales of ENTADFI or Proclarix would have a negative effect on our revenue and future plans.

The commercial success of our in-development and future diagnostic tests and services and our revenue growth depend upon attaining significant market acceptance among payers, providers, clinics, patients, and biopharmaceutical companies.

Our commercial success depends, in part, on the acceptance of our diagnostic tests and services as being safe and relatively simple for medical personnel to learn and use, clinically flexible, operationally versatile and, with respect to providers and payers, cost effective. We cannot predict how quickly, if at all, payers, providers, clinics, and patients will accept future diagnostic tests and services or, if accepted, how frequently they will be used. These constituents must believe that our diagnostic tests offer benefits over other available alternatives.

The degree of market acceptance of our current and future diagnostic tests and services depends on a number of factors, including:

- whether there is adequate utilization of our tests by clinicians, laboratories and other target groups based on the potential and perceived advantages of our diagnostic tests over those of our competitors;
- the convenience and ease of use of our diagnostic tests relative to those currently on the market;
- the effectiveness of our sales and marketing efforts;
- the ability of our distribution partners to meet sales forecasts;

- our ability to provide incremental data that show the clinical benefits and cost effectiveness, and operational benefits, of our diagnostic tests;
- the coverage and reimbursement acceptance of our products and services;
- pricing pressure, including from group purchasing organizations ("GPOs"), seeking to obtain discounts on our diagnostic tests based on the collective bargaining power of the GPO members;
- negative publicity regarding our or our competitors' diagnostic tests resulting from defects or errors; and
- the diagnostic sensitivity and diagnostic specificity of our tests relative to those of our competitors.

Additionally, even if our diagnostic tests achieve widespread market acceptance, they may not maintain that market acceptance over time if competing diagnostic tests or technologies, which are more cost effective or are received more favorably, are introduced. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition, and results of operations.

If we fail to increase our sales and marketing capabilities or develop broad awareness of our diagnostic tests in a cost-effective manner, we may not be able to generate revenue growth.

We plan to dedicate significant resources to the expansion of our distribution network and to supporting their marketing efforts. It will negatively affect our business, financial condition, and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our diagnostic tests in a cost-effective manner is critical to achieving broad acceptance of our diagnostic tests. Promotional activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad use of our diagnostic tests, which in turn could have a material adverse effect on our business, financial condition and results of operations.

If we cannot maintain our current relationships, or enter into new relationships, with CROs, universities, clinics, laboratories or tissue sample banks, our revenue prospects could be reduced.

We engage contract research organizations, universities, clinics, and tissue banks to enroll or access patients primarily to support clinical studies. The ability of our contractors to enroll patients in clinical studies may also fluctuate in the future, which could have a material adverse effect on our product development timelines, financial condition and results of operations. In addition, the termination of these relationships could result in a temporary or prolonged delay in commercial launches resulting in a loss of revenue.

We engage in conversations with diagnostic laboratories regarding potential commercial opportunities on an ongoing basis. There is no assurance that any of these conversations will result in a commercial agreement, or if an agreement is reached, that the resulting relationship will be successful or that clinical or research studies conducted as part of the engagement will produce successful outcomes. Speculation in the industry about our existing or potential relationships with diagnostic laboratories and biopharmaceutical companies can also be a catalyst for adverse speculation about us, our tests and our technology, which can adversely affect our reputation and our business.

We need to ensure strong product performance and quality to maintain and grow our business.

We will need to maintain and continuously improve the performance of our diagnostic tests to maintain CE marking or other applicable market approvals and compliance with QMS (ISO 13485). Poor product performance and quality could lead to customer dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. Our diagnostic tests may contain errors or defects, and while we have made efforts to control them extensively, we cannot assure that our current diagnostic tests, or those developed in the future, will not have performance problems. Any performance issues with our diagnostic tests now or in the future will increase our costs and accordingly adversely affect our business, financial condition, and results of operations.

The sizes of the markets for our diagnostic tests and services and any future diagnostic tests and services may be smaller than we estimate and may decline.

Our estimates of the annual total addressable market for our diagnostic tests and services are based on a number of internal and third-party estimates and assumptions, including, without limitation, the assumed prices at which we can sell our diagnostic tests and services in the market. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors.

As a result, our estimates of the annual total addressable market for our diagnostic tests and services in different market segments may prove to be incorrect. If the actual number of patients who would benefit from our diagnostic tests, the price at which we can sell them or the annual total addressable market for them is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

We have a significant customer concentration, with a limited number of customers accounting for a large portion or all of our revenues.

We derive a large portion or all of our revenues from a few major customers. For the year ended December 31, 2023, we generated 100% of our revenue from one customer, in the context of a partnership with Immunovia AB (Sweden). In 2022, Immunovia AB partnered with Proteomedix to leverage Proteomedix's research and development capabilities and to advance their research and development efforts.

There are inherent risks whenever a large percentage of the total revenue is concentrated with a few customers. It is not possible for us to predict the future level of demand for our products that will be generated by these customers or the future demand for our products by these customers. If any of these customers' demands decline or delayed demands due to market, economic or competitive conditions, we could be pressured to reduce our prices, which could have an adverse effect on our financial position and could negatively affect our revenues and results of operations. If any of our largest customers terminate the purchase of our products, such termination would materially negatively affect our revenues, results of operations and financial condition.

Our results of operations will be materially harmed if we are unable to accurately forecast customer demand for, and utilization of, our diagnostic tests and manage our inventory.

To ensure adequate inventory supply, we must forecast inventory needs and manufacture our diagnostic tests based on our estimates of future demand for our diagnostic tests. Our ability to accurately forecast demand for them could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our diagnostic tests or for those of our competitors, our failure to accurately forecast customer acceptance of new diagnostic tests, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our diagnostic tests, our supply chain, manufacturing partners and/or internal manufacturing team may not be able to deliver components and diagnostic tests to meet our requirements, and this could result in damage to our reputation, sales growth and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which will adversely affect our business, financial condition and results of operations.

The timing of our new product offerings is uncertain.

We have multiple products in various phases of development, and we intend to devote considerable future resources to research and product development, our core business strategy. There can be no assurance that our development activities will always produce tests with the sensitivity and specificity necessary to be clinically and commercially competitive, or that any test will result in a commercially successful product. In addition, before we can develop diagnostic tests for new cancers or other diseases and commercialize any new products, we will need to:

- conduct substantial research and development;
- conduct analytical and clinical performance testing (verification and validation); and
- expend significant funds.

Our product development process involves a high degree of risk and may take several years in some instances. Our product development efforts may fail for many reasons, including, but not limited to:

- failure of the product at the research or development phase;
- difficulty in accessing samples, especially samples with known clinical results; or
- lack of clinical performance data to support the safety and effectiveness of the product.

Few research and development projects result in commercial products, and success in early clinical trials often is not replicated in later studies. At any point, we may abandon development of a product candidate, or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those product candidates. In addition, as we develop products, we will have to make significant investments in product development. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we might choose to abandon the development of the product or product feature that was the subject of the clinical trial, which could harm its business. In addition, our competitors may develop and commercialize competing products faster than we are able to do so.

Our access to samples may hinder our ability to research, develop, and commercialize future products.

Our planned and future products are focused primarily on exploitation of blood plasma or serum as a medium for both biomarker identification and validation and ultimately for our commercial testing applications. Our clinical development relies on our ability to secure access to high quality, well-characterized samples, as well as information pertaining to the samples associated clinical outcomes. Our competitors have demonstrated their ability to obtain these samples and often compete with us for access to such samples. Additionally, the process of negotiating access to samples is lengthy since it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board (ethical) approval, privacy rights, publication rights, intellectual property ownership and research parameters. If we are not able to negotiate access to samples with hospitals, clinical partners, or other companies on a timely basis, or at all, or if competitors secure access to these samples before us, then our ability to research, develop, and commercialize future products will be limited or delayed.

Adherence to complex test protocols is required.

We validate our tests in our lab in Switzerland using blood samples obtained from a variety of sources. Tests results can be affected by a number of variables including how the blood is extracted, how the blood is handled, the type of test tube used, the number and speed of centrifuge spins, the temperature the blood is exposed to during processing, the concentration of the reagents, and the timing of reagent use. All of these and other variables in the process are set forth in an assay protocol that we provide to our distributor lab partners along with training in proper compliance. If, due to human or equipment failure, there is material deviation from the protocols, the accuracy of our tests can be negatively impacted. If that occurs, the reputation of our products and our revenue could be negatively impacted.

Risks Related to our Business and Industry

Our reliance on third parties heightens the risks faced by our business.

We rely on suppliers, vendors, subcontractors, and partners for certain key aspects of our business, including support for information technology systems and certain human resource functions. We do not control these partners, but we depend on them in ways that may be significant to us. However, if these parties fail to meet their defined obligations to us, we may fail to receive the expected benefits. In addition, if any of these third parties fails to comply with applicable laws and regulations in the course of its performance of services for us, there is a risk that we may be held responsible for such violations as well. This risk is particularly serious in emerging markets, where corruption is often prevalent and where many of the third parties on which we rely do not have internal compliance resources comparable to our own. Any such failures by third parties, in emerging markets or elsewhere, could adversely affect our business, reputation, financial condition or results of operations.

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

Our ability to receive revenues is dependent upon the sales and marketing efforts of co-marketing partners and third-party distributors. If we fail to reach an agreement with any commercialization partner, or upon reaching such an agreement that partner fails to sell a large volume of our products, it may have a negative impact on our business, financial condition, and results of operations.

We have no experience manufacturing our products on a commercial scale and are dependent on third parties for the manufacture of our products. If we experience problems with any of these third parties, they could delay our ability to sell our products.

We do not have any manufacturing facilities. We will rely on third-party manufacturers for commercial supply of Proclarix and ENTADFI (if we resume the commercialization of ENTADFI).

We may be unable to establish agreements with third-party manufacturers for commercial supply on terms favorable to us, or at all. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and through quality management system;;
- the possible breach of the manufacturing agreement by the third party, including the inability to supply sufficient quantities or to meet quality standards or timelines; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with U.S. cGMPs, QSR or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with cGMPs or other applicable regulations, even if such failures do not relate specifically to our products, could result in sanctions being imposed on us or the manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or product recalls, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our products and harm our business and results of operations.

Our products may compete with other products and/or product candidates and products for access to these manufacturing facilities. There are a limited number of manufacturers that operate under cGMPs and that might be capable of manufacturing for us.

Any performance failure on the part of our manufacturers, including a failure that may not relate specifically to our products, could adversely impact our ability to generate commercial sales. If our contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer.

Our anticipated future dependence upon others for the manufacture of our products may adversely affect our future profit margins and our ability to commercialize our products on a timely and competitive basis.

Moreover, our manufacturers and suppliers may experience difficulties related to their overall businesses and financial stability, which could result in delays or interruptions of supply of our products.

Manufacturing risks may adversely affect our ability to manufacture our product and could reduce our gross margin and profitability.

Our business strategy depends on our ability to manufacture our products in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third-party suppliers, including manufacturing compliance with federal and state regulations;
- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our failure to increase production of products to meet demand;
- our inability to modify production lines to enable us to efficiently implement changes in response to regulatory requirements; and
- Potential damage to or destruction of our manufacturing equipment or manufacturing facility.

If demand for our products increases in the future, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. Manufacturing of our products may require the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable. Any of these factors may affect our ability to manufacture our product and could reduce our gross margin and profitability.

We maintain single supply relationships for certain key components, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in its manufacturing process increases.

We are dependent on sole suppliers or a limited number of suppliers for certain components that are integral to its finished products. If these or other suppliers encounter financial, operating or other difficulties or if our relationship with them changes, we may be unable to quickly establish or qualify replacement sources of supply and could face production interruptions, delays and inefficiencies. In addition, technology changes by our vendors could disrupt access to the required manufacturing capacity or require expensive, time-consuming development efforts to adapt and integrate new equipment or processes. Our growth may exceed the capacity of one or more of these suppliers to produce the needed equipment and materials in sufficient quantities to support our growth. Any one of these factors could harm our business and growth prospects.

We may not be able to manage our manufacturing and supply chain effectively, which would harm our results of operations.

We must accurately forecast market demand for our products in order to have adequate product inventory available to fulfil our timeline and customer orders timely. Our forecasts will be based on multiple assumptions that may cause our estimates to be inaccurate, and thus affect our ability to ensure adequate manufacturing capability to satisfy market demand. Any material delay in our ability to obtain timely product inventories from our manufacturing facility and our ingredient suppliers could prevent us from satisfying increased consumer demand for our products, resulting in material harm to our brand and business. In addition, we will need to continuously monitor our inventory and product mix against forecasted demand to avoid having inadequate product inventory or having too much product inventory on hand. If we are unable to manage our supply chain effectively, our operating costs may increase materially.

We may in the future have conflicts with our current or future partners or third-party providers that could delay or prevent the commercialization of our current products.

We may in the future have conflicts with our current or future partners or third-party providers, such as conflicts concerning the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the commercialization of our current products, and in turn prevent us from generating revenues:

- unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due to us under a collaboration;
- uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;
- unwillingness by the partner to cooperate in the manufacture of the product, including providing us with product data or materials;
- unwillingness on the part of a partner to keep us informed regarding the progress of its commercialization activities or to permit public disclosure of the results of those activities;
- initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or
- attempts by either party to terminate the agreement.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our products.

We face an inherent risk of product liability exposure related to the commercialization of our products. Product liability claims may be brought against us by patients, healthcare providers or others using, administering, or selling our product.

In addition, we face an inherent risk of product liability as a result of the marketing and sale of Proteomedix's diagnostic tests and services. For example, we may be sued if the diagnostic tests or services cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, medical personnel, care partners and patients collect samples for our diagnostic tests. If these medical personnel, care partners or patients are not properly trained, are negligent or use our diagnostic tests incorrectly, the capabilities of such tests may be diminished, or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies for our diagnostic tests.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt the marketing and sale of our diagnostic tests and services. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;

- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize our products;
- the initiation of investigations by regulators; and
- product recalls, withdrawals or labeling, marketing, or promotional restrictions.

We have product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks. However, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, and such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, we intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim, or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash, and adversely affect our business.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may fail to strengthen our competitive position and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies, and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.

It is essential to our business strategy that our technology and network infrastructure and our physical buildings remain secure and are perceived by our customers and corporate partners to be secure. Despite security measures, however, any network infrastructure may be vulnerable to cyber-attacks by hackers and other security threats. We may face cyber-attacks that attempt to penetrate our network security, sabotage, or otherwise disable our, products and services, misappropriate our or our customers' and partners' proprietary information, which may include personally identifiable information, or cause interruptions of our internal systems and services. Despite security measures, we also cannot guarantee the security of our physical buildings. Physical building penetration or any cyber-attacks could negatively affect our reputation, damage our network infrastructure and our ability to deploy our products and services, harm our relationship with customers and partners that are affected, and expose us to financial liability.

Additionally, there are a number of state, federal and international laws governing the collection, use, processing and protection of health information and personal data. Most states have data security breach laws requiring data protection measures and potentially requiring notification to regulators and impacted consumers. The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (collectively, "HIPAA"), imposes limitations on the use and disclosure of an individual's healthcare information "covered entities," which include by healthcare providers who submit certain standard transactions electronically (mostly related to claims for payment from health insurers), healthcare clearinghouses, and health insurance plans, and also grants individuals rights with respect to their health information. Although we do not currently submit standard transactions electronically and therefore are not a HIPAA covered entity, HIPAA has been in effect for over 20 years and accordingly individuals expect that providers of health care items or services will safeguard their health information in accordance with HIPAA. Moreover, many states' laws impose similar or more stringent limitations on uses and disclosures of healthcare information than does HIPAA, and such laws also provide individuals rights to access, amend, and withhold sharing of their health information. HIPAA also requires reporting of certain impermissible uses and disclosures of health information, including security breaches, to affected individuals, the Office for Civil Rights of the U.S. Department of Health and Human Services, and in some cases the media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services. Most states also have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth.

As of April 5, 2024, we had 12 full-time and 11 subcontracted employees. We will need to increase the size of our organization in order to support our continued commercialization of our products. As our commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources may increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, maintaining, motivating, and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology and finance systems; and
- expanding our facilities.

If our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage any future growth effectively, as well as our ability to develop a sales and marketing force when appropriate. To that end, we must be able to hire, train and integrate additional management, manufacturing, administrative and sales and marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon our personnel and executive officers. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance. Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business.

Members of our management team and board of directors have significant experience as founders, board members, officers, or executives of other companies. As a result, certain of those people have been and may become involved in proceedings, investigations and litigation relating to the business affairs of the companies with which they were, are, or may in the future be, affiliated. This may have an adverse effect on us, could damage our reputation and business.

During the course of their careers, members of our management team and Board have had significant experience as founders, board members, officers or executives of other companies. As a result of their involvement and positions in these companies, certain persons were, are now, or may in the future become, involved in litigation, investigations or other proceedings relating to the business affairs of such companies or transactions entered into by such companies. Any such litigation, investigations or other proceedings may divert our management team's and board's attention and resources away from our affairs and may negatively affect our reputation and our business.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent review of regulatory submissions in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for regulatory submissions to be reviewed by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may be adversely affected by natural disasters, pandemics and other catastrophic events, and by man-made problems such as terrorism and acts of war, that could disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as enterprise financial systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Our contract manufacturers' and suppliers' facilities are located in multiple locations, where other natural disasters or similar events, such as blizzards, tornadoes, fires, explosions or large-scale accidents or power outages, and other public health emergencies could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. A public health emergency could also affect the operations of the FDA and other regulatory or public health authorities, resulting in delays to meetings and ultimately review of regulatory submissions.

Our employees, independent contractors, principal investigators, consultants, and vendors and engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, and vendors may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless, or negligent conduct or unauthorized activity that violates laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs, patient rebate programs, and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to comply with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, we may have to terminate employees or others involved and the impact of such termination can result in our experiencing delays and additional costs associated with replacing the services being provided. If we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results.

Macroeconomic pressures in the markets in which we operate, including, but not limited to, the current conflicts in Ukraine and the Middle East may alter the ways in which we conduct our business operations and manage our financial capacities.

To varying degrees, the ways in which we conduct our business operations and manage our financial capacities are influenced by macroeconomic conditions that affect companies directly involved in or providing services related to the drug development. For example, real GDP growth, business and investor confidence, the conflicts in Ukraine and the Middle East, inflation, employment levels, oil prices, interest rates, tax rates, availability of consumer and business financing, housing market conditions, foreign currency exchange rate fluctuations, costs for items such as fuel and food and other macroeconomic trends can adversely affect not only our decisions and ability to engage in research and development and clinical trials, but also those of our management, employees, third-party contractors, manufacturers and suppliers, competitors, stockholders and regulatory authorities. In addition, geopolitical issues around the world and how our markets are positioned can also impact the macroeconomic conditions and could have a material adverse impact on our financial results.

Economic uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled.

Generally, worldwide economic conditions remain uncertain. Access to capital markets is critical to our ability to operate. Traditionally, biotechnology companies have funded their research, development and commercialization expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research, development, and commercialization efforts. We require significant capital for the commercialization of our products. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. There is no certainty that the capital and credit markets will be available to raise additional capital on favorable terms. If economic conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, if we are unable to access the capital markets on favorable terms, our ability to execute our business plan as scheduled would be compromised. Moreover, we rely and intend to rely on third-parties, including CROs, CMOs and other important vendors and consultants. Global economic conditions may result in a disruption or delay in the performance of our third-party contractors and suppliers. If such third-parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

Conditions in the global economy may adversely affect our business, financial condition and results of operations.

Although demand for in vitro diagnostics is considered inelastic in developed economies, the in vitro diagnostic industry that we sell to may be affected by material changes in supply, market prices, exchange rates and general economic conditions. Delays or reductions in our customers' purchasing or shifts to lower-cost alternatives that result from tighter economic market conditions would reduce demand for our products and services and could, consequently, have a material adverse effect on our business, financial condition, and results of operations.

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.

The 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.

Our industry is subject to rapid change, which could make our solutions and the diagnostic tests we develop and services we offer, obsolete. If we are unable to continue to innovate and improve our diagnostic tests and services, we could lose customers or market share.

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current diagnostic tests and others we are developing obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There have also been advances in methods used to analyze very large amounts of molecular information as well as new imaging-based technologies used of the early assessment and monitoring of disease. We must continuously enhance our offerings and develop new and improved diagnostic tests to keep pace with evolving standards of care. If we do not leverage or scale our sample and data biobank, discover new diagnostic biomarkers or applications, or update our diagnostic tests to reflect new scientific knowledge, including about prostate cancer biology, and information about new cancer therapies or relevant clinical trials, our diagnostic tests could become obsolete and sales of our current diagnostic tests and any new tests we develop could decline or fail to grow as expected. This failure to make continuous improvements to our diagnostic tests to keep ahead of those of our competitors could result in the loss of customers or market share that would adversely affect our business, financial condition, and results of operations. The development of new liquid biopsy and imaging technologies could negatively impact demand for our products.

In the event that our products are the subject of guidelines, clinical studies or scientific publications that are unhelpful or damaging, or otherwise call into question the benefits of our products, we may have difficulty in convincing prospective customers to adopt our test. Moreover, the perception by the investment community or shareholders that recommendations, guidelines, or studies will result in decreased use of our products could adversely affect the prevailing market price for our common stock. Similar challenges apply to all of the products in our pipeline.

We face competition from many sources, including larger companies, and we may be unable to compete successfully.

There are a number of diagnostic solutions companies in the United States, Europe and Asia. Notable competitors in the United States include, but are not limited to OPKO Health, Beckman Coulter, BioTechne, MdxHealth, A3P Biomedical AB. These competitors all provide diagnostic tests or testing services to hospitals, researchers, clinicians, laboratories, and other medical facilities. Many of these organizations are significantly larger with greater financial and personnel resources than us and enjoy significantly greater market share and have greater resources than we do. As a consequence, they may be able to spend more on product development, marketing, sales and other product initiatives than we can. Some of our competitors have:

- substantially greater name recognition;
- broader, deeper, or longer-term relations with healthcare professionals, customers, and third-party payers;
- more established distribution networks;
- additional lines of diagnostic tests and the ability to offer rebates or bundle them to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for diagnostic tests; and
- greater financial and human resources for product development, mergers and acquisitions, sales and marketing and possible patent litigation.

Our continued success depends on our ability to:

- Further penetrate the diagnostic solutions market and increase utilization of our diagnostic tests;
- attract and retain a sufficient number of qualified employees;
- maintain and widen our technology lead over competitors by continuing to innovate and deliver new product enhancements on a continuous basis; and
- cost-effectively manufacture our diagnostic tests and their component parts as well as drive down the cost of service.

As we attain greater commercial success, our competitors are likely to develop diagnostic tests that offer features and functionality similar to our diagnostic tests that are currently on the market. Improvements in existing competitive diagnostic tests or the introduction of new competitive diagnostic tests may make it more difficult for us to compete for sales, particularly if those competitive diagnostic tests demonstrate better reliability, convenience or effectiveness or are offered at lower prices.

Performance issues, service interruptions or price increases by our shipping carriers and warehousing providers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping and delivery services and secure warehousing are essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our diagnostic tests to our customers and for tracking of these shipments, and from time to time require warehousing for our diagnostic tests, sample collection kits and supplies. Should a carrier encounter delivery performance issues such as loss, damage, or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our diagnostic tests and increased cost and expense to our business. In addition, any significant increase in shipping or warehousing rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, civil unrest and disturbances or other service interruptions affecting delivery or warehousing services we use would adversely affect our ability to process orders for our diagnostic tests on a timely basis.

For our clinical studies, we rely on commercial courier delivery services to transport samples to our laboratory facility in a timely and cost-efficient manner and if these delivery services are disrupted, our business will be harmed. Disruptions in delivery service, whether due to labor disruptions, bad weather, natural disaster, civil unrest or disturbances, terrorist acts or threats or for other reasons could adversely affect specimen integrity and our ability to process samples in a timely manner and to service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

We rely on software hosting our online risk calculator needed to be accessed by the user to calculate the test result. Any internet service interruption or hardware failure could affect availability of the online resource and thus negatively impact our business.

Cost-containment efforts of our customers, purchasing groups and governmental purchasing organizations could have a material adverse effect on our future sales and profitability.

In an effort to reduce costs, many hospitals in the United States have become members of GPOs and Integrated Delivery Networks (IDNs). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our diagnostic tests, thereby reducing our revenue and margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative diagnostic tests due to the price or quality offered by other companies, which could result in a decline in our revenue.

We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain the personnel necessary for our success.

We are highly dependent on our senior management and other key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, scientists, clinical specialists, and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales and marketing professionals, scientists, clinical and regulatory specialists could result in delays in product development and harm our business. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations.

Our laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly near our laboratory facility in Zurich-Schlieren, Switzerland. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel.

We may also have difficulties locating, recruiting, or retaining qualified salespeople. Recruiting and retention difficulties can limit our ability to support our research and development and sales programs. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued and may continue to issue equity awards that vest over time. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice, which may lead to more difficulty in retaining qualified salespeople and other talent.

We depend on our information technology systems and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems, including third-party cloud computing infrastructure and operating systems, for significant elements of our operations, including our online risk analysis software.

We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including systems handling human resources, financial controls and reporting, contract management, regulatory compliance and other infrastructure operations.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts (such as ransomware) and natural disasters. Moreover, despite network security and back-up measures, some of our external servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of these systems or those used by our partners or subcontractors could prevent us from conducting our diagnostic products development, preparing and providing reports to researchers, clinicians and our partners, billing payors, handling enquiries, and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our reputation, and we may be unable to regain or repair our reputation in the future.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our products and/or product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current product candidates and future product candidates, the processes used to manufacture them and the methods for using them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products and/or product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the U.S. or in foreign jurisdictions outside of the U.S. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently license or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our products and/or product candidates or technology could be adversely affected.

Others may file patent applications covering products and technologies that are similar, identical, or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, re-examination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices. Such proceedings are also expensive and time consuming.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds/assays that are similar to our products and/or product candidates and/or assays, but that are not covered by the claims of our licensed patents;
- any patents that we obtain from licensing or otherwise may not provide us with any competitive advantages;
- any granted patents that we rely upon may be held invalid or unenforceable as a result of legal challenges by third parties; and
- the patents of others may have an adverse effect on our business.

We are dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our products and/or product candidates, if approved. If we breach any of the agreements under which we license the use, development, and commercialization rights to our products and/or product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business.

Proteomedix owns the patents and patent applications detailed above in the chapter entitled "Intellectual Property". Apart from this we do not currently own any further patents, and we are heavily reliant upon a number of license agreements under which we are granted rights to intellectual property that are important to our business, and we may need or choose to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products and/or product candidates, and what activities satisfy those diligence obligations;
- our obligation to pursue or license others to pursue development of indications we are not currently pursuing;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign the license; and
- the effects of termination.

If disputes over intellectual property that we own or have licensed prevent or impair our ability to maintain our patents or current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected products and/or product candidates.

We have entered into several licenses to support our various programs. Termination of any of these license agreements would have a material adverse impact on our ability to develop and commercialize derived products under each respective agreement.

We may enter into additional licenses to third-party intellectual property that are necessary or useful to our business. Our current licenses and any future licenses that we may enter into impose various royalty payment, milestone, and other obligations on us. Under some license agreements, we may not control prosecution of the licensed intellectual property or may not have the first right to enforce the intellectual property. In those cases, we may not be able to adequately influence patent prosecution or enforcement or prevent inadvertent lapses of coverage due to failure to pay maintenance fees. If we fail to comply with any of our obligations under a current or future license agreement, the licensor may allege that we have breached our license agreement and may accordingly seek to terminate our license. Termination of any of our current or future licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects. Under some license agreements, termination may also result in the transfer of or granting in rights under certain of our intellectual property and information related to the product candidate being developed under the license, such as regulatory information.

The agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected products and/or product candidates.

In addition, if our licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms, our business could suffer. Moreover, our licensors may own or control intellectual property that has not been licensed to us, and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's rights.

Similarly, if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to seek alternative options, such as developing new products and/or product candidates with design-around technologies, which may require more time and investment, or abandon development of the relevant research programs or products and/or product candidates and our business, financial condition, results of operations and prospects could suffer.

Some of the intellectual property owned by Proteomedix and/or covered by our licenses concerns patent applications and provisional applications. We cannot assure investors that any of the currently pending or future patent applications will result in granted patents, nor can we predict how long it will take for such patents to be granted.

Some of intellectual property covered by our licenses concerns certain specified patent rights (including patent applications, provisional patent applications and PCT patent applications). While in some instances, the licensors have agreed to assume responsibility for the preparation, filing, prosecution and maintenance of patent applications covered by the licensed patent rights, we cannot be certain as to when or if final patents will be issued for those patent applications covered by the licensed patent rights. However, the licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are only a licensee and on which our business substantially depends. Even if patents issue from these applications, there is no assurance that the patents will be free from defects or survive validity or enforceability challenges, the licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement or may fail to defend against counterclaims of patent invalidity or unenforceability.

Moreover, it is possible that the patent applications owned by Proteomedix and/or licensed pending patent applications will not result in granted patents, and even if such pending patent applications grant as patents, they may not provide a basis for intellectual property protection of commercially viable vaccine products or may not provide us with any competitive advantages. Further, it is possible that, for any of the patents that may be granted in the future, others will design around the licensed patent rights or identify methods of diagnosis or for preventing or treating infectious diseases that do not concern the rights covered by our patents and/or licenses. Further, we cannot assure investors that other parties will not challenge any patents granted to Proteomedix or the licensors or that courts or regulatory agencies will hold Proteomedix and/or licensor's patents to be valid or enforceable. We cannot guarantee investors that, if required to defend the covered patents, we will have the funds to or be successful in defending challenges made against the Proteomedix and/or licensed patents and patent applications. Any successful third-party challenge to the Proteomedix and/or licensed patents could result in the unenforceability or invalidity of such patents, or to such patents being interpreted narrowly or otherwise in a manner adverse to our interests. Our ability to establish or maintain a technological or competitive advantage over our competitors may be diminished because of these uncertainties.

Even if patents are issued based on patent applications to which we have been granted a license or owned by Proteomedix, because the patent positions of diagnostic methods and/or pharmaceutical and biotechnology products are complex and uncertain, we cannot predict the scope and extent of patent protection for our products and/or product candidates.

Any patents that may be issued based on patent applications that we have been granted licenses to or owned by Proteomedix will not ensure sufficient protection with respect to our activities for a number of reasons, including without limitation the following:

- any issued patents may not be broad or strong enough to prevent competition from other diagnostic and/or vaccine products including identical or similar products;

- if patents are not issued or if issued patents expire, there would be no protections against competitors making generic equivalents;

- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be other patents existing, now or in the future, in the patent landscape for our products and/or product candidates that we seek to commercialize or develop, if any, that will affect our freedom to operate;
- if patents that we have been granted licenses to are challenged, a court could determine that they are not valid or enforceable;
- a court could determine that a competitor's technology or product does not infringe patents that we have been granted licenses to;
- patents to which we have been granted licenses could irretrievably lapse due to failure to pay fees or otherwise comply with regulations, or could be subject to compulsory licensing; and
- if we encounter delays in our development or clinical trials, the period of time during which we could market our products under patent protection would be reduced.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the United States Patent and Trademark Office ("USPTO") and foreign Intellectual Property Offices in several stages over the term of the patent. Maintenance fees are also due for pending patent applications in some countries. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to office actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The life of patent protection is limited, and third parties could develop and commercialize methods, products, and technologies similar or identical to ours and compete directly with us after the patent licensed to us expires, which could materially and adversely affect our ability to commercialize our products and technologies.

The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In Europe, the expiration of an invention patent is 20 years from its filing date. Even if we successfully obtain patent protection for a diagnostic method and/or an approved vaccine candidate, it may face competition, e.g., from biosimilar medications. Diagnostic companies or manufacturers of biosimilar drugs may challenge the scope, validity or enforceability of the patents underlying our technology in court or before a patent office, and the patent holder may not be successful in enforcing or defending those intellectual property rights and, as a result, we may not be able to develop or market the relevant method/product candidate exclusively, which would materially adversely affect any potential sales of that product.

Given the amount of time required for the development, testing and regulatory review of new diagnostic methods and/or vaccine candidates, patents protecting such diagnostic methods and/or vaccine candidates might expire before or shortly after such methods or vaccine candidates are commercialized. As a result, the patents and patent applications owned or licensed to us may not provide us with sufficient rights to exclude others from commercializing methods/products similar or identical to ours. Even if we believe that the patents involved are eligible for certain (and time-limited) patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to such patents, or may grant more limited extensions than requested. For example, depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of the U.S. patents licensed to us may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements.

Moreover, the applicable time period or the scope of patent protection afforded could be less than requested. If we are unable to obtain patent term extension or term of any such extension is less than requested, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The patents and pending patent applications licensed to us for our diagnostic methods and product candidates are expected to expire on various dates. Upon the expiration, we will not be able to assert such licensed patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms or at all.

There may be intellectual property rights existing now, or in the future, relevant to our methods and/or products and/or product candidates that we seek to commercialize or develop, if any, that may affect our ability to commercialize such methods and/or products and/or product candidates. Although the Company is not aware of any such intellectual property rights, a third-party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our methods and/or products and/or product candidates. Even if all our main methods and/or products and/or product candidates are covered by patents, it may be necessary for us to use the patented or proprietary technology of third parties to commercialize our methods and/or products and/or product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. In that event, we may be required to expend significant time and resources to redesign our technology, methods and/or products and/or product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, our business could be harmed.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may infringe the intellectual property rights of others, which may prevent or delay our method and/or product development efforts and stop us from commercializing or increase the costs of commercializing our methods and/or products and/or product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We are not aware of any third-party proprietary rights that our planned methods and/or products will infringe or misappropriate, but we have not conducted any freedom to operate study as we are in the earliest stages of development. We thus cannot guarantee that our methods and/or products and/or product candidates, or manufacture or use of our products and/or product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our methods and/or products and/or product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way around the patent and may need to halt commercialization of our methods and/or products and/or product candidates. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. In addition, we may be obligated to indemnify our licensors and collaborators against certain intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The diagnostic, pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our products and/or product candidates or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and diversion of management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our methods and/or products and/or product candidates to market and be precluded from manufacturing or selling our products and/or product candidates.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than us or the third parties from whom we license intellectual property because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

In addition to the possibility of litigation relating to infringement claims asserted against it, we may become a party to other patent litigation and other proceedings, including *inter partes* review proceedings, post-grant review proceedings, derivation proceedings declared by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future technologies or methods and/or products and/or product candidates or products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Competitors may infringe or otherwise violate our intellectual property, including patents that may be issued to or be licensed by us. As a result, we may be required to file claims in an effort to stop third-party infringement or unauthorized use. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights, and/or that any of our intellectual property, including licensed intellectual property, is invalid and/or unenforceable. This can be prohibitively expensive, particularly for a company of our size, and time-consuming, and even if we are successful, any award of monetary damages or other remedy we may receive may not be commercially valuable. In addition, in an infringement proceeding, a court may decide that our asserted intellectual property is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our intellectual property does not cover its technology. An adverse determination in any litigation or defense proceedings could put our intellectual property at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not being issued.

If the breadth or strength of our patent or other intellectual property rights is compromised or threatened, it could allow third parties to exploit and, in particular, commercialize our technology or methods and/or products or result in our inability to exploit and/or commercialize our technology and methods and/or products without infringing third-party intellectual property rights. Further, third parties may be dissuaded from collaborating with us.

Interference or derivation proceedings brought by the USPTO, or its foreign counterparts may be necessary to determine the priority of inventions with respect to our patent applications, and we may also become involved in other proceedings, such as re-examination proceedings, before the USPTO or its foreign counterparts. Due to the substantial competition in the pharmaceutical space, the number of such proceedings may increase. This could delay the prosecution of our pending patent applications or impact the validity and enforceability of any future patents that we may obtain. In addition, any such litigation, submission or proceeding may be resolved adversely to us and, even if successful, may result in substantial costs and distraction to our management.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and product could be significantly diminished.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its transparency initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail to defend any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our intellectual property may not be sufficient to protect our methods and/or products and/or product candidates from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.

We may be subject to competition despite the existence of intellectual property we license or own or may in the future own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our methods and/or products and/or product candidates or future products and/or product candidates.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license from a third party. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our product; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trial, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party may also challenge the validity, enforceability, or scope of the intellectual property rights that we license or own and the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to our products and/or product candidates in the future. There can be no assurance that we will be able to successfully defend patents we own or license in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, amongst other factors.

Intellectual property rights may be less extensive and enforcement more difficult in jurisdictions outside of the U.S. Therefore, we may not be able to protect our intellectual property and third parties may be able to market competitive products that may use some or all of our intellectual property.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage and changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.

The America Invents Act ("AIA") has been enacted in the United States, resulting in significant changes to the U.S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This is in particular the case in the field of diagnostic patents based on biomarkers (Mayo v. Prometheus, 566 U.S. 66 (2012)), where Proteomedix is active. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Any inability of us to protect our competitive advantage with regard to any of our product candidates may prevent us from successfully monetizing such product candidate and this could materially adversely affect our business, prospects, financial condition and results of operations.

Risks Related to Healthcare Compliance and Other Regulations

If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including administrative, civil, and criminal penalties and our business, operations and financial condition could be adversely affected.

We could be subject to healthcare fraud and abuse laws and health information privacy and security laws of both the federal government and the states in which we conduct our business. The laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- 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.;

- The federal Physician Payments Sunshine Act, which 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 Covered Recipients, as defined at 42 CFR Part 403, Subpart I;

- HIPAA which prohibits 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, and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information and certain notification requirements and criminal and civil penalties for failure to comply with those requirements;

- the FDCA which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including administrative, civil, and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Healthcare reform in the United States has been implemented in the past, and we expect further changes to be proposed in the future, leading to potential uncertainty in the healthcare industry. Violations of healthcare laws can have an adverse impact on our ability to advance ENTADFI and our operating results.

In the United States, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect the future results of pharmaceutical manufactures' operations. In particular, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. For example, the Affordable Care Act, or the ACA, which was originally enacted in March 2010 and subsequently amended, includes measures to significantly change the way healthcare is financed by both governmental and private insurers.

In August 2022, President Biden signed the Inflation Reduction Act, which extended enhanced subsidies, passed as part of the American Rescue Plan Act in 2021, and prevented insurance companies from imposing significant increases in healthcare premiums for low-income exchange customers through 2025. In addition, under this legislation, Medicare will have the ability to negotiate drug prices for a select list of pharmaceuticals in Medicare Part D drugs, with the list of included drugs expected to increase over the coming years and incorporate drugs in Medicare Parts B and D.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and integrity oversight and reporting obligations.

We may rely on government funding and collaboration with government entities for our product development, which adds uncertainty to our research and development efforts and may impose requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs.

Because we anticipate the resources necessary to develop our products and/or product candidates will be substantial, we may explore funding and development collaboration opportunities with the U.S. government and its agencies. For example, we may apply for certain grant funding from BARDA, the NIH or other government agencies to further the research, development, manufacture, testing, and regulatory approval of our products and/or product candidates. We have no control or input over whether an application for BARDA grant funding or any other funding will be accepted or approved, in full or in part, and we cannot provide investors with any assurances that we will receive such funding.

Contracts and grants funded by the U.S. government and its agencies, contain provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including Intellectual Property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations.
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act, and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

If we received such grants or agreements, we may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third parties, including our competitors, from using those technologies in providing products and services to the U.S. government. Further, under such agreements we could be subject to obligations to and the rights of the U.S. government set forth in the Bayh-Dole Act of 1980, meaning the U.S. government may have rights in certain inventions developed under these government-funded agreements, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government could have the right to require us to grant exclusive, partially exclusive, or nonexclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as "march-in rights." Although the U.S. government's historic restraint with respect to these rights indicates they are unlikely to be used, any exercise of the march-in rights could harm our competitive position, business, financial condition, results of operations and prospects. In the event we would be subject to the U.S. government's exercise such march-in rights, we may receive compensation that is deemed reasonable by the U.S. government in its sole discretion, which may be less than what we might be able to obtain in the open market.

Additionally, the U.S. government requires that any products embodying any invention generated through the use of U.S. government funding be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. manufacturers for products covered by such intellectual property.

Although we may need to comply with some of these obligations, not all of the aforementioned obligations may be applicable to us unless and only to the extent that we receive a government grant, contract or other agreement. However, as an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we were to fail to maintain compliance with those obligations, we may be subject to potential liability and to termination of our contracts, which may have a materially adverse effect on our ability to develop our products and/or product candidates.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Owning our Common Stock

The market price of our common stock has been extremely volatile and may continue to be highly volatile due to numerous circumstances beyond our control, and stockholders could lose all or part of their investment.

The market price of our common stock may be highly volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include:

- whether we achieve our anticipated corporate objectives;
- actual or anticipated fluctuations in our financial condition and operating results;
- changes in financial or operational estimates or projections;
- our execution of our sales and marketing, manufacturing and other aspects of our business plan;
- performance of third parties on whom we rely to manufacture our products and product components, including their ability to comply with regulatory requirements;
- results of operations that vary from those of our competitors and the expectations of securities analysts and investors;
- changes in expectations as to our future financial performance, including financial estimates by securities analysts and investors;
- our announcement of significant contracts, acquisitions, or capital commitments;
- announcements by our competitors of competing products or other initiatives;
- announcements by third parties of significant claims or proceedings against us;
- regulatory and reimbursement developments in the United States and abroad;
- future sales of our common stock;
- product liability claims;
- healthcare reform measures in the United States;
- additions or departures of key personnel; and
- general economic or political conditions in the United States or elsewhere.

In addition, the stock market in general, and the stock of medical biotechnology companies like ours, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the issuer. For example, on February 14, 2023 and December 21, 2023, the closing price of our common stock on Nasdaq was $1.56 and $0.18, respectively, and daily trading volume on these days was approximately 90,326,500 and 534,300 shares, respectively. These broad market fluctuations may adversely affect the trading price of our common stock. In particular, a proportion of our common stock may be traded by short sellers which may put pressure on the supply and demand for our common stock, further influencing volatility in its market price. Additionally, these and other external factors have caused and may continue to cause the market price and demand for our common stock to fluctuate, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. While the market price of our common stock may respond to developments regarding operating performance and prospects, expansion plans, developments regarding our participation in direct contracting, and developments regarding our industry, we believe that the extreme volatility we experienced in recent periods reflects market and trading dynamics unrelated to our underlying business, our actual or expected operating performance, our financial condition, or macro or industry fundamentals, and we do not know if these dynamics will continue or how long they will last. Under these circumstances, we caution you against investing in our common stock, unless you are prepared to incur the risk of losing all or a substantial portion of your investment.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

The market price of our securities may be volatile, and in the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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. Specifically, after a review completed by the Audit Committee, it was determined that our former CEO and an accounting employee charged certain personal expenses on their corporate credit cards that were not recorded as related party receivables. The aggregate amount of such unauthorized charges ranged from approximately (i) $257,000 to $405,000 for all of 2022, (ii) $86,000 to $122,000 for the quarter ended March 31, 2023 and (iii) $79,000 to $150,000 for the quarter ended June 30, 2023. The accounting employee was also the CEO's assistant and had roles in the Company's system of internal control over financial reporting, including controls relating to the Company's corporate credit cards. 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.

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 do not have an effective risk assessment process or effective monitoring of compliance with established accounting policies and procedures, and do not demonstrate a sufficient level of precision in the application of our controls.

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

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

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

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

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.

Our Amended and Restated Certificate of Incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers, other employees or stockholders for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, which may have the effect of discouraging lawsuits against our directors, officers, other employees or stockholders.

Our Amended and Restated Certificate of Incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers, other employees or stockholders for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel except any action (A) as to which the Court of Chancery in the State of Delaware determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), (B) which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, (C) for which the Court of Chancery does not have subject matter jurisdiction, or (D) any action arising under the Securities Act, as to which the Court of Chancery and the federal district court for the District of Delaware shall have concurrent jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our Amended and Restated Certificate of Incorporation. This choice of forum provision may make it more costly for a stockholder to bring a claim, and it may also limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders cannot waive our compliance with federal securities laws and the rules and regulations thereunder. Alternatively, if a court were to find the choice of forum provision contained in our Amended and Restated Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

Our Amended and Restated Certificate of Incorporation provides that the exclusive forum provision will be applicable to the fullest extent permitted by applicable law. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, our Amended and Restated Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, or the rules and regulations promulgated thereunder. We note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

An active trading market for our common stock may not develop or be sustained.

Prior to the commencement of trading of our common stock on February 18, 2022, no public market for our common stock existed. Although our common stock is listed on The Nasdaq Capital Market, an active trading market for our common stock may not develop, or if developed, be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair value of your shares.

Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

Our principal stockholders and management own a significant percentage of our capital stock and will be able to exert a controlling influence over our business affairs and matters submitted to stockholders for approval.

As of April 5, 2024, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own or control 5,766,959 shares of our common stock, which in the aggregate represents approximately 26.0% of the outstanding shares of our common stock. As a result, if some of these persons or entities act together, they will have the ability to exercise significant influence over matters submitted to our stockholders for approval, including the election and removal of directors, amendments to our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, the approval of any business combination and any other significant corporate transaction. These actions may be taken even if they are opposed by other stockholders. This concentration of ownership may also have the effect of delaying or preventing a change of control of our company or discouraging others from making tender offers for our shares, which could prevent our stockholders from receiving a premium for their shares. Some of these persons or entities who make up our principal stockholders may have interests different from yours.

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. On March 13, 2024, we submitted a plan of compliance to Nasdaq to discuss our plans to evidence compliance with the Bid Price Rule and we received an additional 180-day period, or until September 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.

If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on Nasdaq and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

Future sales of our shares by existing stockholders could cause our stock price to decline.

If we or our existing stockholders, directors and officers sell, or indicate an intent to sell, substantial amounts of our common stock or securities convertible into our common stock in the public market after contractual lock-up and other legal restrictions on resale lapse, the trading price of our common stock could decline significantly and could decline below the initial public offering price. We have outstanding 22,324,576 shares of common stock as of the date hereof, assuming no exercise of outstanding options or warrants, are or will be freely tradable, without restriction, in the public market. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business. We have previously registered 2,330,640 shares of common stock under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and lock-up agreements.

Upon issuance, the 1,322,504 shares subject to outstanding options under our stock option plan and the shares reserved for future issuance under our stock option plan will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

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.

CFIUS may delay, prevent or impose conditions on the Conversion.

CFIUS has authority to review certain direct or indirect foreign investments in U.S. businesses for national security considerations. Among other things, CFIUS is authorized to require mandatory filings for certain foreign investments in the United States and to self-initiate national security reviews of certain foreign direct and indirect investments in U.S. businesses if the parties to such investments choose not to file voluntarily. With respect to transactions that CFIUS determines present unresolved national security concerns, CFIUS has the power to suspend transactions, impose mitigation measures or recommend that the President of the United States block pending transactions or order divestitures of completed transactions when national security concerns cannot be mitigated. Whether CFIUS has jurisdiction to review an acquisition or investment transaction depends on, among other factors, the nature and structure of the transaction, whether the target company is a U.S. business, the level of beneficial ownership and voting interests acquired by foreign persons, and the nature of any information, control, access or governance rights that the transaction affords foreign persons. For example, any transaction that could result in foreign "control" (as such term is defined in the CFIUS regulations) of a U.S. business is within CFIUS's jurisdiction. In addition, CFIUS has jurisdiction over certain investments that do not result in control of a U.S. business by a foreign person but that afford a foreign person certain access, involvement or governance rights in a "TID U.S. business," that is, a U.S. business that: (1) produces, designs, tests, manufactures, fabricates, or develops one or more "critical technologies;" (2) owns, operates, manufactures, supplies or services certain "critical infrastructure;" or (3) maintains or collects, directly or indirectly, "sensitive personal data" of U.S. citizens.

Certain entities or individuals associated with or otherwise involved in the transaction are, are controlled by or have substantial ties with a non-U.S. person. Specifically, each of Dr. Schiess and Mr. Brühlmann is a "foreign person" (as such term is defined in 31 C.F.R. § 800.224).

CFIUS has broad discretion to interpret its regulations, and we cannot predict whether CFIUS may seek to review the Conversion. If CFIUS reviews the Conversion and identifies an unresolved national security concern as part of such review, CFIUS could recommend that the President of the United States order one or more foreign persons to divest all or a portion of the Common Stock that they acquired without first obtaining CFIUS approval. Moreover, should CFIUS determine that any parties to the Conversion were required to make a filing with CFIUS but failed to do so, CFIUS could impose a civil penalty not to exceed $250,000 or the value of the relevant transaction, whichever is greater, on the parties it determines were subject to a mandatory filing requirement.

Onconetix and Proteomedix will submit to CFIUS a joint declaration or notice with respect to the PMX Transaction upon the request of CFIUS, but Onconetix has determined to not exercise its right to elect to submit such a joint declaration or notice of its own initiative.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud which could subject us to regulatory sanctions, harm our business and operating results and cause the trading price of our stock to decline.

Effective internal controls required under Section 404 of the Sarbanes-Oxley Act are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our business, reputation and operating results could be harmed. We have discovered, and may in the future discover, areas of our internal controls that need improvement. We cannot be certain that the measures we have taken or intend to take will ensure that we maintain adequate controls over our financial processes and reporting in the future. Any failure to implement the required new or improved controls or difficulties encountered in their implementation could subject us to regulatory sanctions, harm our business and operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also harm our reputation and cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We may remain an "emerging growth company" until as late as December 31, 2027 (the fiscal year-end following the fifth anniversary of the completion of our initial public offering, which closed during February 2022), though we may cease to be an "emerging growth company" earlier under certain circumstances, including (1) if the market value of our common stock that is held by nonaffiliates exceeds $700 million as of any June 30, in which case we would cease to be an "emerging growth company" as of the following December 31, or (2) if our gross revenue exceeds $1.235 billion in any fiscal year. "Emerging growth companies" may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors could find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. An "emerging growth company" can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We are subject to increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. The Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Capital Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Emerging growth companies may implement many of these requirements over a longer period of up to five years from the pricing of their initial public offering. We intend to take advantage of these extended transition periods but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd-Frank Act and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

To comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls when we become subject to this requirement could negatively impact the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations made it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs in the future to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Our management team has limited experience managing a public company.

Several members of our management team have limited experience managing a publicly-traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. Our management team may not successfully or efficiently manage our transition to being a public company subject to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, financial condition and operating results.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and our trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. While we currently have certain analyst coverage, if one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price could decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

Our stock repurchase program may adversely affect our liquidity and cause fluctuations in our stock price.

On November 8, 2022, our Board authorized a stock repurchase program pursuant to which the Company may repurchase up to 5 million shares of our common stock, with a maximum price of $1.00 per share, with discretion to management to make purchases subject to market conditions. On November 18, 2022, our Board approved an increase to the maximum price to $2.00 per share.

Potential future stock repurchases under the stock share repurchase program could be funded by operating cash flow or excess cash balances. The maximum number of shares of the Company's common stock that may yet be repurchased under the share repurchase program is 4.5 million. Repurchases under the stock repurchase program may adversely affect our liquidity, which in turn could impact our profitability, financial condition and results of operations. In addition, repurchases under the stock repurchase program will reduce the number of shares of our common stock available for purchase and sale in the public market, which could affect the market price of our common stock. Furthermore, the Inflation Reduction Act of 2022, which was signed into law in August 2022, imposes a non-deductible 1% excise tax on the fair market value of stock repurchases after December 31, 2022, that exceed $1.0 million in a taxable year, which may impact the tax efficiency of our stock repurchase program.

Failure in, or security breaches or incidents impacting, our information technology or storage systems could significantly disrupt our operations and our research and development efforts.

Our ability to execute our business strategy will depend, in part, on the continued and uninterrupted performance of our information technology, or IT, systems, which support our operations, including at our proposed clinical laboratories. We are dependent on our IT systems for many aspects of our business, including our needs to retain and store our confidential and proprietary business information and to receive and process test orders, securely store patient health records and deliver the results of our tests. The integrity and protection of our own data, and that of our customers and employees, is critical to our business. The regulatory environment governing information, security and privacy and data protection laws is increasingly demanding and continues to evolve. IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, cyberattacks (including ransomware attacks) and other malicious human acts from criminal hackers, hacktivists, state-sponsored intrusions and other attacks, industrial espionage and employee malfeasance, breaches and incidents due to employee error or negligence, and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and other malicious code or similar disruptive problems.

Proclarix is comprised of two components: Proclarix Assays and Proclarix Risk Calculator. The Proclarix Risk Calculator is cloud-based software to integrate the results from Proclarix Assays for THBS1 and CTSD together with age, total and free PSA (from third party manufacturers) to calculate the Proclarix Risk Score. When entering the Patient ID, a warning indicates that the Patient ID shall not contain any sensitive personal patient data. After the risk report is generated, the patient data including values for THBS1, CTSD, total and free PSA together with age and Patient ID is stored for six months and is then automatically deleted.

High-profile security breaches and incidents at other companies and in government agencies have increased in recent years, particularly in the healthcare sector, and security industry experts and government officials have warned about the risks of hackers and cyber-attacks targeting businesses such as ours. Cyber-attacks are becoming more sophisticated and frequent, and in some cases have caused significant harm. Computer hackers and others routinely attempt to breach the security of technology products, services, and systems, and to fraudulently induce employees, customers, or others to disclose information or unwittingly provide access to systems or data. Much of our workforce currently works remotely rather than in our offices, and we may be more susceptible to security breaches and incidents as a result. Our service providers also may accommodate remote workers and therefore may be more susceptible to security breaches and other security incidents.

We have experienced and may in the future experience attempted or successful cyber-attacks of our IT systems or networks. To date, we have not experienced any material cyber-attacks. However, any security breach or incident or interruption could compromise our networks and the information stored therein, including algorithms relating to our products, could be accessed by unauthorized parties, publicly disclosed, lost, rendered inaccessible or unavailable, corrupted, or stolen. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, unauthorized access to our systems, or disruptions or other security breaches impacting our IT systems, any unauthorized access to, or, loss, inaccessibility, unavailability, corruption, theft, or disclosure could also disrupt our operations, including our ability to:

- process tests, provide test results, bill patients;
- provide customer assistance services;
- collect, process and prepare company financial information;
- provide information about our tests and other patient and healthcare provider education and outreach efforts through our website; and
- manage the administrative aspects of our business and damage our reputation.

Any such breach, incident, or other compromise of IT systems or data, or the perception that any of these has occurred, could result in liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (collectively, "HIPAA"), similar U.S. state data privacy and security laws and regulations, and other regulations, as well as in legal claims, complaints, regulatory investigations or proceedings, significant fines or other penalties, or the requirement to enter into a multi-year settlement and remediation agreement with federal or state agencies. We also may be required to incur significant costs in an effort to prevent, detect, and remediate security breaches and other security-related incidents. Additionally, information obtained by third parties in connection with past or future cyberattacks, or other security breaches or incidents could be used in ways that adversely affect our company or our stockholders.

Further, third-party service providers who support our operations, and our independent contractors, consultants, collaborators, and service providers also may suffer interruptions and disruptions of systems and other breaches, incidents, or other compromises of their IT systems or data that they process or maintain for us, which may lead to any of the foregoing. We and our third-party service providers may not have the resources or technical sophistication to anticipate or prevent all cyberattacks or other sources of security breaches or incidents, and we or they may face difficulties or delays in identifying and responding to cyberattacks and data security breaches and incidents. In addition, the interpretation and application of consumer or health related data security, privacy and protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux, such as in the area of international transfers of personal data. Complying with these various laws and satisfying healthcare providers' and patients' evolving expectations with respect to data protection, could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

We do not maintain insurance policies for cybersecurity-related matters, data handling or data security liabilities. The successful assertion of one or more large claims against us could have a material adverse effect on our business, including our financial condition, operating results, and reputation.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. Our Amended and Restated Certificate of Incorporation authorizes us to issue up to 10 million shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval;
- place limitations on the removal of directors;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents certain stockholders holding more than 15% of our outstanding capital stock from engaging in certain business combinations without approval of the holders of at least two-thirds of our outstanding common stock not held by such stockholder.

Any provision of our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws or Delaware law that has the effect of delaying, preventing, or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock, and could also affect the price that some investors are willing to pay for our common stock.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future and, as such, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, any future loan arrangements we enter into may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock, which may never occur, will be your sole source of gain for the foreseeable future.

Environmental, social and governance matters may impact our business and reputation.

Increasingly, in addition to the importance of their financial performance, companies are being judged by their performance on a variety of environmental, social and governance ("ESG") matters, which are considered to contribute to the long-term sustainability of companies' performance.

A variety of organizations measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. In addition, investment in funds that specialize in companies that perform well in such assessments are increasingly popular, and major institutional investors have publicly emphasized the importance of such ESG measures to their investment decisions. Topics taken into account in such assessments include, among others, the company's efforts and impacts on climate change and human rights, ethics and compliance with law, and the role of the company's board of directors in supervising various sustainability issues. In addition to the topics typically considered in such assessments, in the healthcare industry, issues of the public's ability to access our medicines are of particular importance.

In light of investors' increased focus on ESG matters, there can be no certainty that we will manage such issues successfully, or that we will successfully meet society's expectations as to our proper role. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

A possible "short squeeze" due to a sudden increase in demand of our common stock that largely exceeds supply may lead to price volatility in our common stock.

Investors may purchase our common stock to hedge existing exposure in our common stock or to speculate on the price of our common stock. Speculation on the price of our common stock may involve long and short exposures. To the extent aggregate short exposure exceeds the number of shares of our common stock available for purchase in the open market, investors with short exposure may have to pay a premium to repurchase our common stock for delivery to lenders of our common stock. Those repurchases may in turn dramatically increase the price of our common stock until investors with short exposure are able to purchase additional common shares to cover their short position. This is often referred to as a "short squeeze." A short squeeze could lead to volatile price movements in our common stock that are not directly correlated to the performance, or prospects of our company and once investors purchase the shares of common stock necessary to cover their short position the price of our common stock may decline.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We, like other companies in our industry, face several cybersecurity risks in connection with our business. Our business strategy, results of operations, and financial condition have not, to date, been materially affected by risks from cybersecurity threats. During the reporting period, we have not experienced any material cyber incidents, nor have we experienced a series of immaterial incidents, which would require disclosure.

We are in the process of implementing our cybersecurity program, which is aimed at safeguarding the confidentiality, integrity, and availability of our essential systems and information, and is designed to detect and mitigate risks from cybersecurity threats to our data and our systems. Central to our cybersecurity efforts is a robust incident response plan designed to address potential cyber incidents swiftly and effectively.

In designing and evaluating our cybersecurity program, we have adopted the National Institute of Standards and Technology Cybersecurity Framework ("NIST CSF 2.0") as a guiding principle. It is important to clarify that our use of the NIST CSF 2.0 is for guidance purposes to frame our risk identification, assessment, and management processes and does not equate to compliance with any specific technical standards or requirements.

The key components of our cybersecurity program will include:

- conducting risk assessments to pinpoint material cybersecurity threats to our critical systems, data, products, services, and overall IT infrastructure;
- a third-party security expert consultant overseeing the risk assessment process, maintenance of security controls, and coordination of responses to cybersecurity incidents;
- engagement with external service providers to evaluate, enhance, or support our security measures;
- an incident response plan outlining specific procedures for managing cybersecurity incidents; and

Cybersecurity Governance

The governance of cybersecurity risks is a critical function of our Board of Directors, with the Audit Committee playing a key role in the oversight of cybersecurity and related technology risks. The Audit Committee is tasked with monitoring the effectiveness of our cybersecurity risk management program as implemented by management.

The Audit Committee will receive regular updates from management on the state of cybersecurity risks facing the Company. This includes briefings on any significant cyber incidents and ongoing risk management efforts. These updates will enable the Audit Committee to provide informed reports on cybersecurity matters to the full Board.

The responsibility for day-to-day management of cybersecurity risks lies with our management team, including the Chief Financial Officer. This team is at the forefront of our cybersecurity initiatives, coordinating both internal and external resources to anticipate, identify, and mitigate cyber threats. Our approach includes regular updates from our third-party security expert consultant, leveraging intelligence from various sources, and utilizing advanced security tools to protect our digital environment. Our third-party security expert consultant has over 30 years of experience with cybersecurity, information technology development and deployment, and information technology risk assessment and management, including information security management.

Item 2. Properties

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. The lease will automatically renew unless terminated. Either party may terminate the lease with 12 months' written notice.

Item 3. 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.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on Nasdaq under the symbol "ONCO."

Holders

As of April 5, 2024, there were approximately 39 holders of record of our common stock. This number does not include stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Recent Sales of Unregistered Securities

None.

Dividend Policy

As of the date of this Annual Report on Form 10-K, we have not paid any cash dividends to stockholders. The declaration of any future cash dividend will be at the discretion of our board of directors and will depend upon our earnings, if any, our capital requirements and financial position, the general economic conditions, and other pertinent conditions. It is our present intention not to pay any cash dividends in the foreseeable future, but rather to reinvest earnings, if any, in our business operations.

Item 6. Reserved.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under Part I. "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We are a commercial stage biotechnology company focused on the research, development, and commercialization of innovative solutions for men's health and oncology. Through our recent acquisition of Proteomedix, we own Proclarix, an in vitro diagnostic test for prostate cancer approved for sale in the European Union under the In Vitro Diagnostic Regulation ("IVDR"), which is planned to be marketed in the U.S. as a lab developed test. We also own ENTADFI, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of BPH, a disorder of the prostate.

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

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

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

Prior to the acquisition of ENTADFI, we managed one distinct business segment, which was research and development. Beginning in the second quarter of 2023, as a result of the acquisition of ENTADFI, for which we 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 acquisition during the fourth quarter of 2023 of Proteomedix and its diagnostic product Proclarix was determined to be within our commercial segment. The research and development segment was our historical business, and was dedicated to the research and development of various vaccines to prevent infectious diseases. The commercial segment was new in the second quarter of 2023 and is dedicated to the commercialization of our products approved for sale, namely ENTADFI in the U.S. and Proclarix in Europe.

ENTADFI has not generated any revenue from product sales, and Proclarix has generated only minimal amounts of development revenue since its acquisition.

In light of (i) the time and resources needed to continue pursuing commercialization of ENTADFI, and (ii) the Company's cash runway and indebtedness, the Company has determined to temporarily pause its commercialization of ENTADFI, as it considers strategic alternatives. The Company expects to appoint a new Chief Executive Officer in early April 2024, after which the new CEO and the Board will reassess its ENTADFI program in light of the foregoing and other relevant factors.

We are currently focusing our efforts on commercializing Proclarix.

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

- commercialize Proclarix and ENTADFI (if we decide to resume its commercialization), and other commercial-stage products
- hire additional personnel; and
- obtain, maintain, expand, and protect our intellectual property portfolio.

To the extent that we resume the commercialization of ENTADFI, we also expect to incur significant commercialization expenses related to marketing, manufacturing and distribution for ENTADFI. 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.

We do not have any products approved for sale, aside from Proclarix, from which we have generated only minimal amounts of development revenue since its acquisition, and ENTADFI, from which we have not generated any revenue from product sales, and for which we have determined to temporarily pause commercialization activities. 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 Proclarix and ENTADFI (if we decide to resume its commercialization), and to fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and to rely on third-party resources for marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches, to support our operations.

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 timing and success of commercialization activities, the timing of clinical trials and manufacturing activities, and our expenditures on other research and development activities. As of December 31, 2023, the Company had a working capital deficit of approximately $11.4 million and an accumulated deficit of approximately $56.8 million. We will need to raise additional capital to sustain operations and meet our contractual commitments and obligations within the one-year period following the issuance of the accompanying consolidated financial statements.

Until we generate revenue sufficient to support self-sustaining cash flows, if ever, we will need to continue 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 consolidated financial statements incorporated by reference in this Report do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

Because of the numerous risks and uncertainties associated with our business, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Additionally, even if we are able to generate revenue from Proclarix, or ENTADFI, 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 andf10. may be forced to reduce our operations.

Certain Significant Relationships

We have entered into grant, license and collaboration arrangements with various third parties as summarized below. For further details regarding these and other agreements, see the section titled “Business - Intellectual Property” and Note 6 to our consolidated financial statements included elsewhere in this Report.

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

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

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

Ology Agreement (which was later acquired by National Resilience, Inc.)

The Company entered into a Master Services Agreement ("Ology MSA"), dated July 19, 2019, with Ology, Inc. ("Ology") to provide services from time to time, including but not limited to technology transfer, process development, analytical method optimization, cGMP manufacture, regulatory affairs, and stability studies of biologic products. Pursuant to the Ology MSA, the Company and Ology shall enter into a Project Addendum for each project to be governed by the terms and conditions of the Ology MSA.

The Company entered into two Project Addendums as of December 31, 2023. The initial Project Addendum was executed on October 18, 2019, and the Company was required to pay Ology an aggregate of approximately $4 million. Due to unforeseen delays associated with COVID-19, the Company and Ology entered into a letter agreement dated January 9, 2020 to stop work on the project, at which point the Company had paid Ology $100,000 for services to be provided. The second Project Addendum was executed on May 21, 2021, and the Company is obligated to pay Ology an aggregate amount of approximately $2.8 million, plus reimbursement for materials and outsourced testing, which will be billed at cost plus 15%. During 2023 and 2022, the Company and Ology entered into contract amendments that resulted in a net decrease in the Company's obligations of approximately $137,000.

For additional details regarding our relationship with Ology, see the section entitled "Business - Manufacturing and Supply" and Note 6 to our consolidated financial statements included elsewhere in this Report.

Cincinnati Children's Hospital Medical Center Agreement

On June 1, 2021, we entered into an exclusive, worldwide license agreement with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center, or CHMC, which we refer to as the CHMC Agreement, pursuant to which we obtained the right to develop and commercialize certain CHMC patents and related technology directed at a virus-like particle (VLP) vaccine platform that utilizes nanoparticle delivery technology, which may have potential broad application to develop vaccines for multiple infectious diseases. However, as Onconetix has now deprioritized its infectious disease vaccine programs based on a change in clinical focus, we are exploring ways in which CHMC's VLP platform can be used in therapeutic and diagnostic applications in oncology.

Under the CHMC Agreement, we agreed to pay CHMC certain license fees, deferred license fees, development milestone fees, and running royalties beginning on the first net sale (among others). For additional details regarding our relationship with CHMC, see the section entitled "Business - Intellectual Property - Exclusive License Agreement with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center" and Notes 6 and 10 to our consolidated financial statements included elsewhere in this Report. The CHMC license includes the following patents:

U.S. Patent Application No.	U.S. Patent No.	Granted Claim Type	U.S. Expiration	Foreign Counterparts
12/797,396	8,486,421	Compositions of the vaccine/vaccine platform	1/13/2031	CN107043408B EP2440582B1 JP5894528B2
13/924,906	9,096,644	Method of treatment	9/20/2030	CN107043408B EP2440582B1 JP5894528B2
13/803,057	9,562,077	Compositions of the vaccine platform	4/10/2034	none
16/489,095	pending	pending**	[3/15/2038]*	Pending applications in Canada, China, EU, Hong Kong and Japan
63/149,742 (filed 2/16/2021)	pending	pending**	[February 2042]#	TBD
63/162,369 (filed 3/17/2021)	pending	pending**	[March 2042]#	TBD

* Projected expiration if patent issues: 20 years from earliest non-provisional application filing date.

\# Non-provisional application not yet filed. Expiration projected 21 years from provisional application filing date. Dependent on timely conversion to non-provisional application and issuance of patent.

** This is a pending application. Claim type will be determined after U.S. prosecution is complete. The claim type sought includes compositions of the vaccine and vaccine platform.

AbVacc Co-Development Agreement

On February 1, 2023, the Company entered into a co-development agreement with AbVacc, Inc., for the purpose of conducting research aimed at co-development of specific vaccine candidates, including monkeypox and Marburg virus disease with the potential to expand to others using the Norovirus nanoparticle platform ("Co-Development Project"), and to govern the sharing of materials and information, as defined in the agreement, for the Co-Development Project. Under the agreement, AbVacc and the Company will collaborate, through a joint development committee, to establish and implement a development plan or statement of work for each Co-Development Project targeted product. Under the co-development agreement, either the Company or AbVacc, whichever party is the primary sponsor of any resulting product (as defined in the agreement), will be obligated to compensate the other party for certain milestone payments that would range between $2.1 million and $4.75 million, plus royalties of between 2% to 4%. The term of the agreement is three years from the effective date, unless previously terminated by either party, in accordance with the agreement. However, as Onconetix has now deprioritized its infectious disease vaccine programs, this agreement will have little strategic significance going forward.

Services Agreement

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

Components of Results of Operations

Selling, General and Administrative Expenses

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

We anticipate that our selling, general and administrative expenses will continue to increase when compared to historical levels as a result of our dedication to commercialization of our products approved for sale, which includes. Proclarix in Europe and ENTADFI in the U.S (if we decide to resume its commercialization), costs associated with integration of these assets and commercial operations, as well as expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the applicable stock exchange and the SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Research and Development Expenses

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

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

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

Other Income (Expense)

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

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

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

	Year Ended December 31, 2023	Year Ended December 31, 2022	$ Change	% Change
Revenue	$ 58,465	$ -	$ 58,465	100%
Cost of revenue	1,185,630	-	1,185,630	100%
Gross loss	(1,127,165)	-	(1,127,165)	(100)%
Operating expenses				
Selling, general and administrative	$ 14,770,678	$ 9,351,552	5,419,126	57.9%
Research and development	1,949,406	4,129,688	(2,180,282)	(52.8)%
Impairment of ENTADFI assets	14,687,346	-	14,687,346	100.0%
Impairment of deposit on asset purchase agreement	3,500,000	-	3,500,000	100.0%
Total operating expenses	34,907,430	13,481,240	21,426,190	158.9%
Loss from operations	(36,034,595)	(13,481,240)	(22,553,355)	(167.3)%
Other income (expense)				
Loss on extinguishment of note payable	(490,000)	-	(490,000)	(100)%
Interest expense	(671,625)	-	(671,625)	(100)%
Change in fair value of subscription agreement liability	(134,100)	-	(134,100)	(100)%
Change in fair value of contingent warrant liability	(91,967)	61,410	(153,377)	(249.8)%
Total other income (expense)	(1,387,692)	61,410	(1,449,102)	(2,359.7)%
Loss before income taxes	(37,422,287)	(13,419,830)	(24,002,457)	(178.9)%
Income tax benefit	12,593	-	12,593	100%
Net loss	$ (37,409,694)	$ (13,419,830)	(23,989,864)	(178.8)%

Revenue, Cost of Revenue, and Gross Margin

For the year ended December 31, 2023, the Company had less than $0.1 million of revenue, which was attributable to Proteomedix revenue recorded from the date of acquisition through December 31, 2023. Cost of revenue of approximately $1.2 million, and the resulting negative margin, is attributable to costs incurred on Proteomedix revenue including amortization of the product rights intangible asset of approximately $31,000, and an impairment of inventory related to ENTADFI of approximately $1.2 million. The Company did not have any revenue during the year ended December 31, 2022.

Selling, General and Administrative Expenses

For the year ended December 31, 2023, selling, general and administrative expenses increased by approximately $5.4 million compared to 2022. The increase was mainly due to approximately $4.7 million in expenses incurred related to commercialization activities and an increase in professional services of approximately $1.7 million, which is comprised primarily of audit, accounting, and legal services, a significant portion of which were in support of the Company's acquisition activities. In addition, the Company incurred approximately $1.7 million related to the acquisition of Proteomedix, which consists primarily of transaction costs and Proteomedix's selling, general and administrative expenses since the acquisition date. The Company also recorded an impairment of long-lived assets of $0.3 million during 2023. These increases were offset by a decrease in employee and director compensation and benefits of approximately $1.0 million, primarily due to a decrease in stock-based compensation expense. Also, the Company recorded approximately $1.3 million of expense in 2022 related to the settlement agreement with Boustead and approximately $0.3 million for a non-recurring termination fee to the Company's former underwriter, for early termination of the agreement with that underwriter, with no related expenses in 2023. The remaining decrease is due to a decrease in various business activities that occurred during the last half of the year related to the Company's change in business strategy, including decreases in business advisory services, patent costs, travel related expenses, and rent expense, totaling $0.4 million.

Research and Development Expenses

For the year ended December 31, 2023, research and development expenses decreased by approximately $2.2 million compared to 2022. The decrease was primarily due to the Company's decision to deprioritize its vaccine programs and focus on commercialization activities, which occurred during the third quarter of 2023. This change in business strategy led to a pause on the Company's clinical and other research activities, and a resulting decrease of approximately $2.3 million due to decreased costs for related outside services and reduced compensation expense. This was slightly offset by an increase related to Proteomedix's research and development activities since the acquisition date, of approximately $0.1 million.

Impairments

The Company recorded an impairment charge of $14.7 million on the assets acquired as part of the ENTADFI acquisition during the fourth quarter of 2023. In addition, the Company recorded an impairment charge of $3.5 million on a deposit that was made as part of the WraSer APA. No such impairments were recorded during 2022.

Other Income (Expense)

Other expense incurred during the year ended December 31, 2023 increased by approximately $1.4 million compared to 2022 and relates to the change in fair value of the subscription agreement liability of approximately $0.1 million, $0.7 million of interest expense, primarily incurred on notes payable issued in April 2023 related to the acquisition of ENTADFI, a loss on extinguishment of a note payable of $0.5 million in connection with the Veru APA Amendment, and the change in fair value of the contingent warrant liability of approximately $0.1 million. Other income recorded during the year ended December 31, 2022, relates to the change in fair value of the contingent warrant liability.

Income Tax Benefit

The Company recorded an income tax benefit of approximately $13,000 during the year ended December 31, 2023, in connection with the acquisition accounting for the Proteomedix transaction. There was no income tax benefit or expense recorded during the year ended December 31, 2022.

Liquidity and Capital Resources

The Company's operating activities to date have been primarily devoted to seeking licenses, engaging in research and development activities, potential asset and business acquisitions, and expenditures associated with the commercial launch of ENTADFI. The Company has financed its operations since inception primarily using proceeds received from seed investors and proceeds received from its IPO and subsequent debt and equity offerings. During the year ended December 31, 2022, the Company received an aggregate of approximately $33.1 million in net cash proceeds from its IPO and two private placements, and during the year ended December 31, 2023, the Company received net proceeds of approximately $2.3 million in connection with the exercise by an investor of preferred investment options (see Note 9). In addition, on January 23, 2024, the Company received net cash proceeds of $4.6 million in exchange for the issuance of a debenture. The debenture is repayable in full upon the earlier of (i) the closing of a subscription agreement, which was entered into in connection with the acquisition of Proteomedix, and (ii) June 30, 2024 (see Note 13).

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of December 31, 2023, the Company had cash of approximately $4.6 million, a working capital deficit of approximately $11.4 million and an accumulated deficit of approximately $56.8 million.

These factors, along with the Company's forecasted future cash flows, indicate that the Company will be unable to meet its contractual commitments and obligations as they come due in the ordinary course of business, within one year following the issuance of these consolidated financial statements. The Company will require significant additional capital in the short-term to fund its continuing operations, satisfy existing and future obligations and liabilities, including the remaining payments due for the acquisition of the ENTADFI assets, payment due on the Debenture, in addition to funds needed to support the Company's working capital needs and business activities. These business activities include the commercialization of Proclarix and ENTADFI (if we decide to resume its commercialization), and the development and commercialization of the Company's future product candidates. In addition, as discussed more fully in Note 5, if stockholder approval is not obtained by January 1, 2025 with respect to the Series B Convertible Redeemable Preferred Stock issued in connection with the acquisition of Proteomedix, these shares become redeemable for cash, and the Company currently does not have sufficient cash to redeem such shares. Based on the closing price of $0.166 for the Company's stock as of April 5, 2024, the Series B Preferred Stock would be redeemable for approximately $44.8 million.

Management's plans for funding the Company's operations include generating product revenue from sales of Proclarix, which may still be subject to further successful commercialization activities within certain jurisdictions, and ENTADFI, which is subject to further successful commercialization activities which we have temporarily paused as discussed above. 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, and 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. This creates significant uncertainty that the Company will have the funds available to be able to successfully launch ENTADFI and expand commercialization of Proclarix. If the Company is unable to secure additional capital, it may be required to curtail any future clinical trials, development and/or commercialization of 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.

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

Future Funding Requirements

Our primary uses of cash to date have been to fund our operations, which consist primarily of research and development expenditures related to our programs, costs related to acquisitions and potential acquisitions, commercializing ENTADFI and other selling, general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to commercialize Proclarix and ENTADFI, if we proceed with its commercialization, and expand our corporate infrastructure, including the costs associated with being a public company. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

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

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

- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties, and distribution, for Proclarix and ENTADFI (if we decide to resume its commercialization), and other products for which we may receive marketing approval;
- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical and non-clinical studies and clinical trials;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the revenue, if any, received from commercial sales of Proclarix or ENTADFI (if we decide to resume its commercialization), or other products for which we may have received or will receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights; and
- the costs of operating as a public company.

Cash Flows

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

	Year Ended December 31, 2023	Year Ended December 31, 2022
Net cash used in operating activities	$ (13,581,018)	$ (8,675,534)
Net cash used in investing activities	(8,649,035)	(32,665)
Net cash provided by financing activities	1,035,060	32,532,384
Effect of exchange rate changes on cash	(3,331)	-
Net increase (decrease) in cash	$ (21,198,324)	$ 23,824,185

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was $13.6 million, which primarily resulted from a net loss of $37.4 million. This was offset by impairment losses of $19.3 million related to the ENTADFI assets and the WraSer APA, the fair value of the subscription liability agreement of $0.7 million, non-cash interest expense of $0.7 million, a loss on the extinguishment of a note payable of $0.5 million, noncash stock-based compensation expense of $0.3 million, a $0.3 million loss on impairment of long-lived assets, other non-cash items of $0.4 million, and a net change in our operating assets and liabilities of $1.6 million.

Net cash used in operating activities for the year ended December 31, 2022, was $8.7 million, which primarily resulted from a net loss of $13.4 million, which was partially offset by noncash stock-based compensation of approximately $2.0 million, the fair value of restricted common stock that was issued of approximately $0.3 million, and a net change in our operating assets and liabilities of $2.4 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2023 was approximately $8.6 million, of which approximately $6.1 million was used for the acquisition of ENTADFI, $3.5 million was used for the deposit in connection with the potential WraSer APA, and $0.1 million is the net change in the receivable from related parties and purchases of long-lived assets. This was offset by approximately $1.1 million in cash acquired in connection with the acquisition of Proteomedix.

Net cash used in investing activities for the year ended December 31, 2022, was approximately $33,000, which resulted from purchases of property and equipment and the net change in the receivable from related parties.

Cash Flows from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was approximately $1.0 million, and resulted from net proceeds from the exercise of preferred investment options in connection with the warrant inducement transaction of $2.3 million offset by $1.0 million in principal payments on a note payable, $59,000 in purchases of treasury shares, and $205,000 of payment in deferred offering costs.

Net cash provided by financing activities for the year ended December 31, 2022, was approximately $32.5 million, and resulted primarily from the close of our IPO and the Private Placements, which resulted in net proceeds of approximately $33.1 million, offset by approximately $0.6 million in treasury share repurchases.

Legal Contingencies

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

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements Not Yet Adopted

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

Critical Accounting Policies and Estimates

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

While our significant accounting policies are described in more detail in Note 3 to our consolidated financial statements included elsewhere in this Report, we believe the following accounting policies and estimates to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Acquisitions

The Company evaluates acquisitions to first determine whether a set of assets acquired constitutes a business and should be accounted for as a business combination. If the assets acquired are not a business, the transaction is accounted as an asset acquisition in accordance with Accounting Standards Codification ("ASC") 805-50, *Asset Acquisitions* ("ASC 805-50"), which requires the acquiring entity to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, except for non-qualifying assets including financial assets such as inventory. Further, the cost of the acquisition includes the fair value of consideration transferred and direct transaction costs attributable to the acquisition. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values. Contingent consideration payments in asset acquisitions are recognized when the contingency is determined to be probable and reasonably estimable. If the assets acquired are a business, the Company accounts for the transaction as a business combination. Business combinations are accounted for by using the acquisition method of accounting. Under the acquisition method, assets acquired, and liabilities assumed are recorded at their respective fair values. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Acquisition related expenses are expensed as incurred, and are included in selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Goodwill and Other Intangible Assets

Goodwill represents the excess of the cost of a business combination over the fair value of the net assets acquired. Goodwill and intangible assets deemed to have indefinite lives are not amortized but are subject to impairment tests on an annual basis, and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Goodwill is allocated to the reporting unit from which it was created. A reporting unit is an operating segment or sub-segment to which goodwill is assigned when initially recorded. The Company tests indefinite lived intangible assets for impairment, on an annual basis in the fourth quarter, or more frequently if an event occurs or circumstances indicate that the indefinite lived assets may be impaired. The Company may perform a qualitative assessment to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount. If the Company determines this is the case, the Company then performs further quantitative analysis to identify and measure the amount of goodwill impairment loss to be recognized, if any. To perform its quantitative test, the Company compares the fair value of the reporting unit to its carrying value. If the fair value of the reporting unit exceeds the carrying value of its net assets, goodwill is not impaired, and no further testing is required. If the fair value of the reporting unit is less than the carrying value, the Company measures the amount of impairment loss, if any, as the excess of the carrying value over the fair value of the reporting unit. The Company did not test its goodwill or indefinite lived assets for impairment during the year ended December 31, 2023, given that the acquisition date occurred after the annual testing date, and given that there were no impairment indicators from the date of acquisition through the end of the reporting period. The Company has determined that no impairment of its goodwill or indefinite lived intangible assets occurred as of December 31, 2023.

Intangible assets with finite lives are reported at cost, less accumulated amortization, and are amortized over their estimated useful lives, starting when sales for the related product begin. Amortization is calculated using the straight-line method, and recorded within selling, general, and administrative expenses, or cost of revenue, depending on the nature and use of the asset.

During the ordinary course of business, the Company has entered into certain license and asset purchase agreements. Potential milestone payments for development, regulatory, and commercial milestones are recorded when the milestone is probable of achievement. Upon a milestone being achieved, the associated milestone payment is capitalized and amortized over the remaining useful life for approved products, or expensed as research and development expense for milestones relating to products whose FDA approval has not yet been obtained.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including intangible assets with finite useful lives, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable (a "triggering event"). Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the long-lived asset in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value. During the fourth quarter of 2023, the Company determined that there were certain triggering events that indicated that the carrying amount of the assets recorded in connection with the ENTADFI acquisition may not be fully recoverable. A related impairment loss of $14.7 million was recorded during the year ended December 31, 2023. The Company also recorded an impairment loss of approximately $267,000 during the year ended December 31, 2023, related to implementation costs incurred under cloud computing hosting arrangements that were capitalized during the year. There were no other impairment losses on long-lived assets for the years ended December 31, 2023 and 2022.

Accrued Research and Development Expenses

We have entered into various agreements with CMOs and may enter into contracts with CROs in the future. As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and third parties to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued research and development expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We accrue for costs related to research and development activities based on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors, including CMOs, that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received. We make significant judgments and estimates in determining accrued research and development liabilities as of each reporting period based on the estimated time period over which services will be performed and the level of effort to be expended. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Financial instruments

The Company determines the accounting classification of financial instruments that are issued, including its warrants and a subscription agreement, as either liability or equity, by first assessing whether the financial instruments are freestanding financial instruments, and if they meet liability classification in accordance with ASC 480, *Distinguishing Liabilities from Equity*, ("ASC 480"), and then in accordance with ASC 815-40, *Derivatives and Hedging – Contracts in Entity's Own Equity* ("ASC 815-40"). Under ASC 480-10, financial instruments are considered liability-classified if the instruments are mandatorily redeemable, obligate the issuer to settle the instruments or the underlying shares by paying cash or other assets, or must or may require settlement by issuing a variable number of shares.

If the instruments do not meet liability classification under ASC 480, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the financial instruments do not require liability classification under ASC 815-40, in order to conclude equity classification, the Company assesses whether the instruments are indexed to the Company's common stock and whether the instruments are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments are made, the Company concludes whether the instruments are classified as liability or equity. Liability-classified instruments are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. Equity-classified instruments are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Preferred Stock

The Company applies the guidance enumerated in ASC 480, when determining the classification and measurement of preferred stock. Preferred stock subject to mandatory redemption, if any, is classified as a liability and is measured at fair value. The Company classifies conditionally redeemable preferred stock, which includes preferred stock that features redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. At all other times, the Company classifies its preferred stock in stockholders' equity.

Stock-Based Compensation

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards to employees with graded-vesting schedules are recognized, using the accelerated attribution method, on a straight-line basis over the requisite service period for each separately vesting portion of the award.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Expected Term — The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term. The simplified method is used as the Company has insufficient historical information to provide a basis for an estimate of the expected term.

Expected Volatility — Volatility is a measure of the amount by which the Company's share price has historically fluctuated or is expected to fluctuate (i.e., expected volatility) during a period. Due to the lack of an adequate history of a public market for the trading of the Company's common stock and a lack of adequate company-specific historical and implied volatility data, the Company computes stock price volatility over expected terms based on comparable companies' historical common stock trading prices. For these analyses, the Company has selected companies with comparable characteristics, including enterprise value, risk profiles, and position within the industry.

Common Stock Fair Value — The fair value of the common stock underlying the Company's stock options is based on the closing price of the Company's common stock, as reported by the Nasdaq Capital Market, on the grant date of the award.

Risk-Free Interest Rate — The Company bases the risk-free interest rate on the implied yield available on U.S. Treasury securities with a remaining term commensurate with the estimated expected term.

Expected Dividend — The Company has never declared or paid any cash dividends on its shares of common stock and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

The Company recognizes forfeitures of equity awards as they occur.

Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

JOBS Act

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

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

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

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Item 8. Financial Statements and Supplementary Data.

Reference is made to pages F-1 through F-51 comprising a portion of this report, which are incorporated herein by reference.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

On June 29, 2023, Mayer Hoffman McCann P.C. ("MHM"), the Company's registered public accounting firm, informed the Company that it resigned, effective June 29, 2023.

MHM audited the Company's financial statements as of and for the years ended December 31, 2022 and 2021. MHM's audit reports on the Company's financial statements as of, and for the fiscal years ended December 31, 2022 and 2021, dated March 8, 2023, did not contain any adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During the Company's fiscal years ended December 31, 2022 and 2021, and the subsequent interim period through July 6, 2023, there were no disagreements between the Company and MHM on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of MHM, would have caused MHM to make reference to the subject matter of the disagreements in connection with its audit reports on the Company's financial statements for such periods.

During the Company's fiscal years ended December 31, 2022 and 2021, and the subsequent interim period through July 6, 2023, there were no "reportable events", as defined in Regulation S-K Item 304(a)(1)(v), except as previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022. MHM identified a material weakness in internal controls in connection with a lack of staff (a) to maintain optimal segregation of duties 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 and (b) to timely identify, approve or report related party transactions. The Company is taking steps to remediate that material weakness.

On July 6, 2023, the Audit Committee appointed EisnerAmper LLP ("EisnerAmper") to serve as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2023, and related interim periods. The decision to engage EisnerAmper was approved by the Company's Audit Committee of the Board of Directors. During the Company's two most recent fiscal years and the subsequent interim period through July 6, 2023, the Company did not consult EisnerAmper with respect to any of the matters or events listed in Regulation S-K Item 304(a)(2).

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the appropriate time periods, and that such information is accumulated and communicated to the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer has evaluated the effectiveness of our disclosure controls and procedures. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2023, as a result of the material weaknesses described below.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework (2013 framework).

Based on our assessment under the framework in Internal Control-Integrated Framework (2013 framework), our management concluded that our internal control over financial reporting was not effective as of December 31, 2023, due to the existence of the material weaknesses described below.

A material weakness in internal control is a deficiency in internal control, or combination of control deficiencies, that adversely affects the Company's ability to initiate, authorize, record, process, or report external financial data reliably in accordance with GAAP such that there is more than a remote likelihood that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected.

Material Weaknesses in Internal Control Over Financial Reporting

In September 2023, after a review completed by the Audit Committee, it was determined that our former CEO and an accounting employee charged certain personal expenses on their corporate credit cards that were not recorded as related party receivables. The aggregate amount of such unauthorized charges ranged from approximately (i) $257,000 to $405,000 for all of 2022, (ii) $86,000 to $122,000 for the quarter ended March 31, 2023, and (iii) $79,000 to $150,000 for the quarter ended June 30, 2023. These unauthorized charges, in addition to personal charges that were identified as such in previous reporting periods, may have constituted personal loans that are not permissible under Section 402 of the Sarbanes-Oxley Act of 2002. The accounting employee was also the CEO's assistant and had roles in the Company's system of internal control over financial reporting, including controls relating to the Company's corporate credit cards. We determined that this credit card misuse arose from the following control deficiencies, which we have determined to be material weaknesses as of December 31, 2023:

- We did not maintain an effective control environment as there was an inadequate segregation of duties with respect to certain cash disbursements. The processing and the approval for payment of credit card transactions and certain bank wires were being handled by the CEO and an accounting employee, and the accounting employee was responsible for the reconciliation of credit card statements and bank statements. This allowed these individuals to submit unauthorized payments to unauthorized third parties.
- We do not have an effective risk assessment process and effective monitoring of compliance with established accounting policies and procedures, and do not demonstrate a sufficient level of precision in the application of our controls.
- Our controls over the approval and reporting of expenses paid with the Company's credit cards and certain bank wires were not designed and maintained to achieve the Company's objectives.
- We have insufficient accounting resources to maintain adequate segregation of duties, maintain adequate controls over the approval and posting of journal entries, and to provide optimal levels of oversight in order to process financial information in a timely manner, analyze and account for complex, non-routine transactions, and prepare financial statements.
- We do not yet have adequate internal controls in place for the timely identification, approval or reporting of related party transactions.
- The Company did not design, implement and maintain effective controls to ensure information technology ("IT") policies and procedures set the tone at the top, to mitigate the risks to the achievement of IT objectives and ITGCs in the change management, logical security and computer operations domains. Specifically, the design and implementation of user authentication, user access privileges, data backup and data recovery controls as well as the monitoring controls of excessive user access and elevated privileged access to financial applications and data were not appropriately designed and maintained. In addition, these inadequate ITGC controls combined with the use of personal devices to conduct business, can lead to an IT control environment vulnerable to breaches and social engineering persuasion.

  Individually, these deficiencies were evaluated as representing a more than remote likelihood that a misstatement that is more than inconsequential, but, less than material, could occur. However, each of these deficiencies affects the same set of accounts. Taken together, these deficiencies represent a more than remote likelihood that a material misstatement could occur and not be prevented or detected. Therefore, in combination and on the aggregate, these deficiencies represent a material weakness.

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

Remediation of Material Weaknesses

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

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

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

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

Inherent Limitation on the Effectiveness of Internal Control Processes

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

Management's Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Our auditors will not be required to formally opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2023, the Company implemented enhanced approval controls over cash disbursements and journal entries. There were no other changes in our internal control over financial reporting during the year ended December 31, 2023, that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

Directors and Executive Officers

The following table provides information regarding our executive officers and directors as of April 5, 2024:

Name	Age	Position(s)
Executive Officers and Directors		
Ralph Schiess	45	Interim Chief Executive Officer and Chief Science Officer
Bruce Harmon	65	Chief Financial Officer
Christian Brühlmann	47	Chief Strategy Officer
Non-Employee Directors		
James Sapirstein	62	Lead Independent Director
Simon Tarsh	62	Director
Timothy Ramdeen	32	Director
Thomas Meier	61	Director
Ajit Singh	60	Director

Executive Officers and Directors

Executive Officers and Directors

Ralph Schiess

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 of Proteomedix in June 2023 and upon consummation of the Share Exchange between the Company and Proteomedix became the Chief Science Officer of the Company. Dr. Schiess was appointed Interim Chief Executive Officer of the Company by the Board of Directors on January 12, 2024.

Bruce Harmon

Mr. Harmon has more than 40 years of experience in financial positions with life sciences companies and various other industries. Mr. Harmon has served in a variety of roles, including chief financial officer, controller, chief executive officer, and audit committee chairman. He has been an independent consultant since 2008 through his business, Lakeport Business Services, Inc., and served in the outsourced CFO capacity for multiple publicly traded companies. During this time, Mr. Harmon was CFO of Marizyme Inc. from 2020 to 2021, CFO of bioAffinity Technologies Inc. in 2022, a director of Dale Biotech LLC since 2017, and a director of Patriax Industries since 2023. He has extensive experience with fundraising, public offerings, mergers and acquisitions, and turnarounds. Earlier in his career, he was a member of a team that, at the invitation of the Environmental Programmé, presented a green building product to delegates at the United Nations. He earned a Bachelor of Science degree in accounting from Missouri State University.

Christian Brühlmann

Mr. Brühlmann has been Chief Strategy Officer since December 2023. He was Chief Business Officer and co-founder of Proteomedix, which was acquired by the Company in December 2023. 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. Mr. Brühlmann gained 20 years of experience in public and private companies in the life sciences, information and communications and financial industries. Being responsible for product management, business development, operations and finance, he was instrumental in Proteomedix's development from inception to the market introduction of Proclarix. Previously, he worked for Swisscom, Switzerland's telecom market leader in several strategic and leadership roles in the area of digitalization. Mr. Brühlmann received his Bachelor and Master's in Business Administration from University of Zurich, Switzerland and completed executive professional trainings at the Babson College, USA and at the University of St. Gallen, Switzerland.

Non-Executive Directors

James Sapirstein, one of our directors since February 2022 and our Lead Independent Director since October 2023, has over 35 years of experience leading, founding, growing, and selling healthcare companies, specifically in the pharmaceutical space. Mr. Sapirstein is currently the President, CEO and Chairman of First Wave BioPharma, Inc. (Nasdaq: FWBI), where he has been since October 2019. His career began in sales at Eli Lilly, eventually rising to Director of International Marketing at Bristol Myers Squibb from July 1996 to June 2000, and later led the launch of Viread (tenofovir) at Gilead Sciences, Inc. (Nasdaq: GILD), where he served as Global Marketing Lead from June 2020 to June 2002. From November 2006 to January 2011, he served as founding CEO of Tobira Therapeutics (Nasdaq: TBRA), then a private company, and later acquired by Allergan (NYSE: AGN). Since then, he has served as CEO of Alliqua Biomedical (Nasdaq: ALQA) from September 2012 to February 2014 and CEO of Contravir Pharmaceuticals (Nasdaq: CTRV) from March 2014 to October 2018. He has been part of almost two dozen drug product launches and specifically either led or has been a key member of several HIV product launches into different new classes of therapeutics at the time. Additionally, Mr. Sapirstein has held board positions on ZyVersa Therapeutics, Inc. (Nasdaq: ZVSA) since January 2023 and Enochian Biosciences (Nasdaq: ENOB) since April 2018. He previously served as a director of Marizyme, Inc. (OTCMKTS:MRZM) (Executive Chairman) from December 2018 to June 2021, Leading Biosciences from 2016 to 2021, BioNJ, an association of biopharma industries in New Jersey, from February 2017 to February 2019, RespireRX (OTCBB:RSPI) from April 2014 to January 2020, NanoViricides Inc. (NYSE: NNVC) from November 2018 to January 2020, and BWAC from December 2020 until its business combination with Clarus in September 2021. He is also a Board Director for BIO, the leading Biopharma Industries Organization promoting public policy and networking in the healthcare space, where he sits on both the Health Section and Emerging Companies Section Governing Boards. Mr. Sapirstein received a B.S. in Pharmacy from Rutgers University and his MBA from Fairleigh Dickinson University. He is well qualified to serve on our Board due to his extensive network from decades in the healthcare industry. Mr. Sapirstein brings to our Board a significant depth of experience in the pharmaceutical and biotechnology industries that will be invaluable to the Company as we continue to develop biotechnology assets.

Simon Tarsh, one of our directors since August 2022, has more than 40 years of financial experience, working in both the UK and the U.S. He has recently retired from Deloitte Consulting LLP, where he was a Senior Managing Director in the Finance and Enterprise Performance Practice, where he had served global clients since 2007. He led a growing global practice focused around Operational Transformation, including supporting Carve Out transactions, joint ventures and hybrid structures, both in the US and in international locations, such as India, China, Eastern Europe and Latin America. He supported high growth companies with their finance operations as they globalized, and was able to advise them on their expansion, while balancing growth with appropriate controls. Prior to moving to the United States in 2007, Mr. Tarsh's consulting career began with PA Consulting Group, London in 1988, where he was elected as a Partner in 1997, and he built ISG's business process outsourcing advisory practice in Europe between 2001 and 2006. Mr. Tarsh's early career was in finance, working with Marathon Oil and Dow Chemical, and during this period, he qualified as a Chartered Accountant. Mr. Tarsh received a Bachelor of Science undergraduate degree in Business and Administration from the University of Salford, Manchester, UK in 1981, and an MBA from City University Business School, London, UK in 1988. He is a Fellow of the Chartered Institute of Management Accountants (1984), which is considered as a CPA equivalent. Mr. Tarsh's deep financial experience at Deloitte Consulting LLP for fifteen years offers valuable insights to our Board, particularly given the enhanced accounting rules and regulations affecting public companies.

Timothy Ramdeen, one of our directors since January 2023, has nearly a decade of experience in private equity and hedge fund investing, capital markets, and company formation. Since June 2022, Mr. Ramdeen has been founder and managing partner of Dharma Capital Advisors, an investment and advisory firm focused on early-stage private and public companies. From March 2021 to March 2022, Mr. Ramdeen was co-founder, chief investment officer, and portfolio manager at Sixth Borough Capital Management, a multi-stage, event-driven hedge fund focused on both private and public equities. Since 2022, Mr. Ramdeen has been the co-founder of Amplexd Therapeutics, which is a women's health/biotechnology company focused on providing low-cost, effective, safe and accessible treatments for early cervical and HPV-related cancers worldwide. Mr. Ramdeen also serves as a corporate advisor/board member to multiple early-stage companies and investment funds. Previously, Mr. Ramdeen was the fifth hire at Altium Capital Management ("Altium"), a healthcare-focused investment firm, where from July 2019 to March 2021 he served as the sole investment analyst on the private capital markets/special situations desk (privately-negotiated financings, direct investments, event-driven long/short, and private to public investments in micro and small-cap companies). During his tenure at Altium, Mr. Ramdeen was instrumental in co-creating the firm's SPAC and reverse merger investment efforts and establishing extensive relationships with sell-side constituents, buy-side counterparts, and hundreds of private and publicly traded companies across biotechnology, therapeutics, healthcare services, medical devices and medtech. From 2017 to 2018, Mr. Ramdeen worked for Brio Capital Management, an event-driven hedge fund focused on small and micro cap equities. Mr. Ramdeen received his B.S. in Biology from Temple University, where he conducted scientific research across neurology, oncology, and developmental biology. In addition, Mr. Ramdeen earned his MBA in Finance from NYU Stern School of Business. Mr. Ramdeen brings to our Board extensive experience in capital advisement and company development, specifically within the life science industry and for publicly traded companies.

Thomas Meier, one of our directors since February 1, 2024, has close to 25 years' experience as a life-science and biotech entrepreneur, executive manager, and board member. Since June 2022, Dr. Meier has served as Chairman of, and member of the Audit and Compensation Committees of, Santhera Pharmaceuticals Holding AG (SIX: SANN), a publicly listed Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular and pulmonary diseases. Dr. Meier has served on the board of Santhera since 2017 and stepped down as the company's CEO in November 2019 after having served 15 years as executive manager, the last 8 years as CEO. In 2020, Dr. Meier became managing partner of Viopas Venture Consulting GmbH, a Swiss consultancy and advisory firm for the healthcare industry. Since 2020, Dr. Meier has served as a board member of Novaremed AG, a privately held Swiss company developing innovative treatment options for the management of chronic pain and alternatives to opioids. Dr. Meier has served on Novaremed's Audit Committee since October 2021 and became Executive Chairman of the company in January 2024. Since January 2022, Dr. Meier also serves on the board of Visgenx Inc. (USA). In September 2021, he co-founded SEAL Therapeutics AG, a privately owned Swiss gene therapy company for which he also serves as Chairman. Between July 2020 and November 2021, he served as Chairman of privately held Pharmabiome AG (Switzerland). Dr. Meier has a PhD in Biology and qualified as lecturer in neurosciences at the Biozentrum, University of Basel (Switzerland). Dr. Meier brings to our board experience as an internationally recognized scientist with track record in clinical research of orphan diseases.

Ajit Singh, one of our directors since February 7, 2024, is a Partner at Silicon Valley based Artiman Ventures, focused on early-stage technology and life science investments, with over $1 billion in assets under management. Besides serving on the board of directors of Artiman portfolio companies, he has served on the boards of Sofie Biosciences, a PET radiopharmaceuticals company focused on Oncology and Neurology, Leo Cancer Care, focused on radiation oncology since 2013, Artidis, an oncology diagnostics company with nanomechanical biomarkers for cancer, and Chronus Health, in the area of Point-of-Care diagnostics since 2023. He also serves on the Board of Trustees of American Association for Cancer Research (AACR) Foundation, the oldest and the largest cancer research organization globally. Dr. Singh is an Adjunct Professor in the School of Medicine at Stanford where he teaches clinical diagnostics and entrepreneurship. In the past, Dr. Singh has served as a Lead Director on the Board of Directors of Max Healthcare, and as a Senior Advisor to the Tata Trusts Cancer program, which developed a "plan centrally, deliver locally" platform for cancer care, and delivered it via comprehensive cancer centers built bespoke with funding from the Tata Group. Until 2023, he also served on the board of directors of Cadila Pharmaceuticals. Prior to joining Artiman, Dr. Singh was the President and CEO of BioImagene, a company specializing in AI-based Cancer Diagnostics, based in California. BioImagene was acquired by Roche Pharmaceuticals in September 2010. Before BioImagene, Dr. Singh spent nearly twenty years at Siemens in various roles, in the United States and Germany, most recently as the global CEO of Siemens Oncology, and Siemens Digital Imaging Systems. Before transitioning to these executive responsibilities, Dr. Singh spent several years in R&D at Siemens Research in Princeton, responsible for research in the areas of artificial intelligence and robotics. During this time, he concurrently served as an adjunct faculty at Princeton University. Dr. Singh has a Ph.D. in Computer Science from Columbia University, a Master's degree in Computer Engineering from Syracuse University, and a Bachelor's in Electrical Engineering from Indian Institute of Technology (IIT) in Varanasi, India. He has published two books and numerous refereed articles and holds five patents. His Top-10 Book Review is carried by various blogs and reading journals in December every year. Mr. Singh brings to our board significant experience in the biotech industry and diagnostic field, particularly in a commercial execution capacity.

Board of Directors and Corporate Governance

General

Our business and affairs are organized under the direction of our board of directors ("**Board**"), which currently consists of five members. Our Board is divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. Our directors are divided among the three classes as follows:

- the Class I directors are Simon Tarsh and Thomas Meier, and their term will expire at our 2025 annual meeting of stockholders;
- the Class II director is James Sapirstein, and his term will expire at our 2026 annual meeting of stockholders; and
- the Class III directors are Timothy Ramdeen and Ajit Singh, and their term will expire at our 2024 annual meeting of stockholders.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws provide that the authorized number of directors may be changed only by resolution of the Board. Our directors hold office until the earlier of their death, resignation, removal, or disqualification, or until their successors have been elected and qualified. Our board of directors does not have a formal policy on whether the roles of Chief Executive Officer and Chairman of our Board should be separate. The primary responsibilities of our Board are to provide oversight, strategic guidance, counselling, and direction to our management.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Directors and Executive Officers Qualifications

We believe that the collective skills, experiences, and qualifications of our directors provide our Board with the expertise and experience necessary to advance the interests of our stockholders. In selecting directors, the Board considers candidates that possess qualifications and expertise that will enhance the composition of the Board. Nominees for director will be selected on the basis of, among other things, leadership experience, knowledge, skills, expertise, integrity, diversity, ability to make independent analytical inquiries, understanding of the Company's business environment and willingness to devote adequate time and effort to Board responsibilities. The Nominating & Corporate Governance Committee may require certain skills or attributes, such as financial or accounting experience, to meet specific board needs that arise from time to time and will also consider the overall experience and makeup of its members to obtain a broad and diverse mix of board members. We believe that our directors should have the highest professional and personal ethics and values, consistent with our longstanding values and standards. They should have broad experience at the policy-making level in business, exhibit commitment to enhancing stockholder value and have sufficient time to carry out their duties and to provide insight and practical wisdom based on their past experience.

Committees of the Board

Our Board has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that has been adopted by our Board. Copies of each committee's charter are posted on the "Investor Relations" section of our website, which is located at *https://onconetix.com/corporate-governance/governance-overview*. Each committee has the composition and responsibilities described below. Our Board may from time to time establish other committees.

Audit Committee

Our audit committee ("**Audit Committee**") consists of Simon Tarsh, who is the chair of the committee, Timothy Ramdeen, and James Sapirstein. Our Board has determined that each of the members of our Audit Committee satisfies the Nasdaq Marketplace Rules and SEC independence requirements. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy, and effectiveness of our financial controls;
- reviewing and approving, in accordance with the Company's policies, any related party transaction as defined by applicable rules and regulations
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented; and
- reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

The Board has determined that Simon Tarsh qualifies as an "audit committee financial expert" within the meaning of applicable SEC regulations and meets the financial sophistication requirements of the Nasdaq Marketplace Rules. In making this determination, the Board has considered Mr. Tarsh's extensive financial experience and business background. Both our independent registered public accounting firm and management periodically meet privately with our Audit Committee.

Compensation Committee

Our compensation committee ("**Compensation Committee**") consists of James Sapirstein, who is the chair of the committee, Simon Tarsh, and Timothy Ramdeen. Our board of directors has determined that each of the members of our Compensation Committee is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, and satisfies the Nasdaq Marketplace Rules independence requirements. The functions of this committee include, among other things:

- reviewing, modifying, and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and approving the compensation, the performance goals, and objectives relevant to the compensation, and other terms of employment of our executive officers;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending, or terminating existing plans and programs;
- reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC; and
- preparing the report that the SEC requires in our annual proxy statement.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee ("**Nominating Committee**") consists of Timothy Ramdeen, who is the chair of the committee, James Sapirstein and Simon Tarsh. Our Board has determined that each of the members of this committee satisfies the Nasdaq Marketplace Rules independence requirements. The functions of this committee include, among other things:

- identifying, reviewing, and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating, and recommending individuals for membership on our board of directors; and
- evaluating nominations by stockholders of candidates for election to our board of directors.

Board Leadership Structure

Our board of directors is free to select the Chairman of the board of directors and the Chief Executive Officer in a manner that it considers to be in the best interests of our company at the time of selection. Currently, Ralph Schiess serves as our Interim Chief Executive Officer and James Sapirstein serves as our non-executive Chairman. All five members of our board of directors have been deemed to be "independent" by the board of directors, which we believe provides sufficient independent oversight of our management.

Our board of directors, as a whole and also at the committee level, plays an active role overseeing the overall management of our risks. Our Audit Committee reviews risks related to financial and operational items with our management and our independent registered public accounting firm. Our board of directors is in regular contact with our Chief Executive Officer, who reports directly to the board of directors and supervises day-to-day risk management.

Role of Board in Risk Oversight Process

We face a number of risks, including those described under the caption "Risk Factors" contained elsewhere in this Report. Our board of directors believes that risk management is an important part of establishing, updating, and executing our business strategy. Our board of directors has oversight responsibility relating to risks that could affect the corporate strategy, business objectives, compliance, operations, and the financial condition and performance of our Company. Our board of directors focuses its oversight on the most significant risks facing us and, on our processes to identify, prioritize, assess, manage, and mitigate those risks. Our board of directors receives regular reports from members of our senior management on areas of material risk to us, including strategic, operational, financial, legal and regulatory risks. While our board of directors has an oversight role, management is principally tasked with direct responsibility for management and assessment of risks and the implementation of processes and controls to mitigate their effects on us.

Our board is generally responsible for the oversight of corporate risk in its review and deliberations relating to our activities. Our principal source of risk falls into two categories, financial and product commercialization. Our Audit Committee oversees management of financial risks; our board regularly reviews information regarding our cash position, liquidity, and operations, as well as the risks associated with each. The board regularly reviews plans, results and potential risks related to our product offerings, growth and strategies. Our Compensation Committee oversees risk management as it relates to our compensation plans, policies and practices for all employees including executives and directors, particularly whether our compensation programs may create incentives for our employees to take excessive or inappropriate risks which could have a material adverse effect on our company.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The code of business conduct and ethics is posted on our website at *www.onconetix.com*. We expect that any amendments or waivers to the code that are required by law or Nasdaq Marketplace Rules will be disclosed on our website.

Insider Trading Policy

On December 1, 2023, we adopted insider trading policies and procedures governing the purchase, sale, and/or other dispositions of our securities by directors, officers, and employees, which are reasonably designed to promote compliance with insider trading laws, rules and regulations, and applicable Nasdaq listing standards (the "**Insider Trading Policy**").

The foregoing description of the Insider Trading Policy does not purport to be complete and is qualified in its entirety by the terms and conditions of the Insider Trading Policy, a copy of which is attached hereto as Exhibit 19 and is incorporated herein by reference.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires the Company's directors, executive officers, and persons who own more than 10% of a registered class of the Company's equity securities, to file with the SEC reports of beneficial ownership and reports of changes in beneficial ownership in the Company's securities. Based solely upon a review of Forms 3, 4 and 5, and amendments thereto, filed electronically with the SEC during the year ended December 31, 2023, the Company believes that all Section 16(a) filings applicable to its directors, officers, and 10% stockholders were filed on a timely basis during the year ended December 31, 2023, except that Ralph Schiess filed one late Form 3.

Item 11. Executive Compensation.

Summary Compensation Table

The following table sets forth total compensation paid to our named executive officers for the years ended December 31, 2023 and 2022. Individuals we refer to as our "named executive officers" include (i) all individuals serving as our Chief Executive Officer during the fiscal year ended December 31, 2023; (ii) our two most highly compensated executive officers other than our Chief Executive Officer who were serving as executive officers at the end of the fiscal year ended December 31, 2023, whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2023 and (iii) up to two of our most highly compensated executive officers other than our Chief Executive Officer who served as executive officers during the fiscal year ended December 31, 2023 but not at the end of the fiscal year ended December 31, 2023 whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2023.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)[1]	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Joseph Hernandez[2]	2023	371,875	-	153,750	-	-	525,625
Former Chief Executive Officer	2022	569,138	437,500	-	696,738	-	1,703,376
Neil Campbell[3]	2023	114,792	75,000	-	186,377	-	376,169
Former Chief Executive Officer	2022	-	-	-	-	-	-
Jon Garfield[4]	2023	343,167	-	76,875	-	72,500	492,542
Former Chief Financial Officer	2022	369,750	174,000	-	359,309	-	903,059
Bruce Harmon [6]	2023	78,542	24,375	-	62,126	-	165,043
Chief Financial Officer	2022	-	-	-	-	-	-
Erin Henderson [5]	2023	315,972	-	153,750	-	81,250	550,972
Former Chief Business Officer and Corporate Secretary	2022	296,905	230,000	-	706,449	-	1,233,354

(1) This figure represents the aggregate grant date fair value of stock-based awards granted in the fiscal year, computed in accordance with the provisions of FASB ASC 718. Assumptions used in the calculation of these amounts are included in the notes to our consolidated financial statements included elsewhere in this Report.
(2) Mr. Hernandez resigned as Chief Executive Officer on August 16, 2023.
(3) Mr. Campbell was appointed by the Board to serve as Chief Executive Officer on October 4, 2023, and resigned on January 10, 2024. Mr. Campbell received a sign-on bonus of $75,000.
(4) Mr. Garfield resigned as Chief Financial Officer on October 4, 2023. Mr. Garfield received severance of $72,500 upon his resignation.
(5) Ms. Henderson resigned as Chief Business Officer on December 21, 2023.
(6) Mr. Harmon was appointed by the Board to serve as Chief Financial Officer on October 4, 2023

Employment Agreements of Executive Officers

Set forth below is a summary of many of the material provisions of the employment agreements with our named executive officers and other executive officers, which summaries do not purport to contain all of the material terms and conditions of each such agreement.

Joseph Hernandez

Effective upon the closing of our initial public offering, we entered into an employment agreement with Mr. Hernandez (the "Hernandez Employment Agreement"), pursuant to which he was employed as the Chief Executive Officer of the Company, which superseded Mr. Hernandez's prior consulting agreement with the Company. The Hernandez Employment Agreement provided for an annual base salary, subject to annual increases in the discretion of our compensation committee, the Company, and an annual performance bonus. Pursuant to the Hernandez Employment Agreement, following the completion of our initial public offering, Mr. Hernandez's base salary was $595,000. The annual performance bonus was up to 50% of annual base salary (the "Target Annual Bonus"), with the actual bonus being based upon the level of achievement of annual Company and individual performance objectives for such fiscal year, as determined by our compensation committee.

In the event that Mr. Hernandez's employment was terminated by the Company without cause (as defined in the Hernandez Employment Agreement), or if Mr. Hernandez terminated his employment for "Good Reason" (as defined in the Hernandez Employment Agreement), in addition to accrued unpaid salary, reimbursements and vacation days, he would be entitled to certain severance payments and benefits, including: (i) any unpaid annual bonus in respect of any completed fiscal year that has ended prior to the date of such termination; (ii) subject to certain conditions set forth in the Hernandez Employment Agreement, an amount equal to (A) the Target Annual Bonus otherwise for the fiscal year in which such termination occurred, assuming Mr. Hernandez had remained employed through the applicable payment date, multiplied by (B) a fraction, the numerator of which is the number of days elapsed from the commencement of such fiscal year through the date of such termination and the denominator of which is 365 (or 366, as applicable); (iii) a payment equal to twelve (12) months of his base salary; and (iv) payment of an amount equal to the difference between the monthly COBRA premium cost and the monthly contribution paid by active employees for the same coverage for eighteen months following his termination. The Hernandez Employment Agreement also provides that if a change in control (as defined in the Hernandez Employment Agreement) occurs, and during the period commencing three months prior to a change in control and ending on the eighteen (18) -month anniversary of the change in control, Mr. Hernandez is terminated without cause or he resigns for good reason, Mr. Hernandez is entitled to (i) any unpaid annual bonus in respect of any completed fiscal year that has ended prior to the date of such termination; (ii) subject to certain conditions set forth in the Hernandez Employment Agreement, an amount equal to (A) the Target Annual Bonus otherwise for the fiscal year in which such termination occurred, assuming Mr. Hernandez had remained employed through the applicable payment date, multiplied by (B) a fraction, the numerator of which is the number of days elapsed from the commencement of such fiscal year through the date of such termination and the denominator of which is 365 (or 366, as applicable); (iii) severance of 18 months' salary; and (iv) payment of an amount equal to the difference between the monthly COBRA premium cost and the monthly contribution paid by active employees for the same coverage for eighteen months following his termination. Additionally, any unvested portion of the equity awards held subject to time-vesting held by Mr. Hernandez would automatically vest.

The Hernandez Employment Agreement is governed by the laws of the State of Ohio and contains non-solicitation and non-competition covenants (each of which remains in effect during the term of employment and for six months following termination of employment) and confidentiality, trade secrets and assignment of intellectual property clauses.

Pursuant to the non-solicitation and non-competition covenants, Mr. Hernandez agreed to not directly or indirectly solicit any comparable business from a broad category of customers, request or advise customers to curtail, cancel, or withdraw its business from Blue Water Vaccines Inc., aid any other entity in obtaining business from customers that is comparable or similar to any products or services provided by the Company or otherwise interfere with any transaction, agreement, business relationship, and/or business opportunity between the Company and any customer or potential customer of the Company.

During the term of employment and for a period of six months after termination ("the Post-Termination Restricted Period"), Mr. Hernandez is prohibited from recruiting, encouraging, soliciting, or inducing, or in any manner attempting to recruit, encourage, solicit, or induce, any person employed by or engaged by the Company or its subsidiaries to terminate such person's employment or services (or in the case of a consultant, materially reducing such services) with the Company or its subsidiaries, hiring, or engaging any individual who was employed by or providing services to Blue Water Vaccines Inc. or its subsidiaries within the six (6) month period prior to the date of such hiring or engagement, or encouraging, soliciting, or inducing, or in any manner attempting to encourage, solicit, or induce, any current or prospective client, customer, licensee, supplier, or other business relation of the Company or its subsidiaries, or any such relation that was a client, customer, licensee or other business relationship within the prior six (6) month period to cease doing business with or reduce the amount of business conducted with the Company or its subsidiaries, or in any way interfering with the relationship between any such party and the Company or its subsidiaries.

Neil Campbell

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 served 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. In addition, Dr. Campbell was entitled to receive, subject to employment by the Company on the applicable date of bonus payout, an annual target discretionary bonus of up to 50% of his annual base salary, payable at the discretion of the Compensation Committee of the Board. Dr. Campbell was 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 Campbell Employment Agreement, Dr. Campbell was granted a long-term equity incentive grant in the form of an option to purchase 3% of the total outstanding shares of the Company's common stock as of the Effective Date. Such award vests in quarterly increments over a period of three years from the Effective Date, 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.

Pursuant to the Campbell Employment Agreement, Dr. Campbell agreed to be bound by certain non-compete and non-solicitation covenants contained therein.

Effective as of January 10, 2024, Dr. Campbell resigned as President and Chief Executive Officer and a member of the Board. 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.

Jon Garfield

Effective upon the closing of our initial public offering, we entered into an employment agreement with Mr. Garfield (the "Garfield Employment Agreement"), pursuant to which he was employed as the Chief Financial Officer of the Company. The Garfield Employment Agreement provided for an annual base salary, subject to annual increases in the discretion of our compensation committee, the Company, and an annual performance bonus. Pursuant to the Garfield Employment Agreement, following the completion of our initial public offering, Mr. Garfield's base salary was $435,000. The annual performance bonus was up to 50% of annual base salary (the "Target Annual Bonus"), with the actual bonus being based upon the level of achievement of annual Company and individual performance objectives for such fiscal year, as determined by our compensation committee.

Effective as of October 4, 2023, Mr. Garfield resigned as Chief Financial Officer of the Company. The Company and Mr. Garfield entered into a Separation Agreement, which provides for two months of severance payment.

Bruce Harmon

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 1% of the total outstanding shares of the Company's common stock as of the Effective Date. Such award vests in quarterly increments over a period of three years from the Effective Date, 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 the Nasdaq Stock Market on the grant date.

Pursuant to the Harmon Employment Agreement, Mr. Harmon agreed to be bound by certain non-compete and non-solicitation covenants contained therein.

Erin Henderson

Effective upon the closing of our initial public offering, we entered into an employment agreement with Ms. Henderson (the "Henderson Employment Agreement"), pursuant to which she was employed as the Chief Business Officer of the Company. The Henderson Employment Agreement provided for an annual base salary, subject to annual increases in the discretion of our compensation committee, the Company, and an annual performance bonus. Pursuant to the Henderson Employment Agreement, following the completion of our initial public offering, Ms. Henderson's base salary was $325,000. The annual performance bonus will be up to 40% of annual base salary (the "Target Annual Bonus"), with the actual bonus being based upon the level of achievement of annual Company and individual performance objectives for such fiscal year, as determined by our compensation committee.

Ms. Henderson resigned as Chief Business Officer of the Company, effective as of December 21, 2023. 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.

Christian Brühlmann

In November 2011, Christian Brühlmann entered into an employment agreement with Proteomedix (as amended, the "Brühlmann Employment Agreement"), pursuant to which Mr. Brühlmann serves as Chief Financial Officer of Proteomedix and was paid a base salary of 233,100 Swiss francs ("CHF") in the fiscal year ended December 31, 2023. Mr. Brühlmann is also eligible to participate in the stock option plan sponsored by Proteomedix (the "PMX Option Plan") and to receive accident insurance, sick pay insurance, a pension plan, and certain government-mandated child allowance benefits.

Pursuant to the Brühlmann Employment Agreement, Mr. Brühlmann agreed to be bound by certain non-compete and non-solicitation covenants contained therein.

The Brühlmann Employment Agreement may be terminated with notice in writing by either Proteomedix or Mr. Brühlmann. In the event of a change of control, either party must give twelve months' notice, but for a period starting six months prior to and two years after a change of control becomes effective, Proteomedix must, upon request of Mr. Brühlmann, release him from his working obligations ("Garden Leave") within 30 days after receipt of such request. During the Garden Leave, Mr. Brühlmann may enter into consulting arrangements and accept board positions, provided that Mr. Brühlmann' statutory and contractual confidentiality, non-competition and non-solicitation obligations remain unchanged and in effect. If the termination of the Brühlmann Employment Agreement is for any other reason than a change of control, then either party must give five months' notice.

Ralph Schiess

In November 2011, Ralph Schiess entered into an employment agreement with Proteomedix (as amended, the "Schiess Employment Agreement"), pursuant to which Dr. Schiess serves as Chief Executive Officer of Proteomedix and was paid a base salary of CHF 233,100 in the fiscal year ended December 31, 2023. Dr. Schiess is also eligible to participate in the PMX Option Plan and to receive accident insurance, sick pay insurance, a pension plan, and certain government-mandated child allowance benefits.

Pursuant to the Schiess Employment Agreement, Dr. Schiess agreed to be bound by certain non-compete and non-solicitation covenants contained therein.

The Schiess Employment Agreement may be terminated with notice in writing by either Proteomedix or Dr. Schiess. In the event of a change of control, either party must give twelve months' notice, but for a period starting six months prior to and two years after a change of control becomes effective, Proteomedix must, upon request of Dr. Schiess, must provide Garden Leave within 30 days after receipt of such request. During the Garden Leave, Dr. Schiess may enter into consulting arrangements and accept board positions, provided that Dr. Schiess' statutory and contractual confidentiality, non-competition and non-solicitation obligations remain unchanged and in effect. If the termination of the Schiess Employment Agreement is for any other reason than a change of control, then either party must give five months' notice.

Potential Payments Upon Termination or Change-in-Control

See "Employment Agreements of Named Executive Officers" above.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2023. Each of the awards set forth in the table below was granted under our 2022 Equity Incentive Plan.

	Option Awards					Stock Awards			
Name (a)	Number of securities underlying unexercised options (#) exercisable (b)	Number of securities underlying unexercised options (#) unexercisable (c)	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#) (d)	Option exercise price ($) (e)	Option expiration date (f)	Number of shares or units of stock that have not vested (#) (g)	Market value of shares or units of stock that have not vested ($) (h)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#) (i)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($) (j)
Neil Campbell	-	-	532,326	$ 0.43	10/4/33	-	-	-	-
Bruce Harmon	-	-	177,442	$ 0.43	10/4/33	-	-	-	-
Joseph Hernandez	-	-	-	-	-	-	-	-	-
Jon Garfield	-	-	-	-	-	-	-	-	-
Erin Henderson	16,276	-	-	0.01	4/2/30	150,000	29,700	150,000	29,700
	153,920	46,080	46,080	6.45	5/4/32	-	-	-	-

(1) As of December 31, 2023, these incentive options, which were granted on October 4, 2023, vest and become exercisable as follows: 44,361 options vest quarterly beginning on January 4, 2024 through October 4, 2026. All but 44,361 of these options were forfeited subsequent to December 31, 2023, in connection with Dr. Campbell's resignation.

(2) These incentive options, which were granted on October 4, 2023, vest and become exercisable as follows: 14,787 options vest quarterly beginning on January 4, 2024 through October 4, 2026.

Director Compensation

Prior to April 2022, our directors have not received cash compensation for their service except for option grants. However, in April 2022, after a review of non-employee director compensation at comparable companies, the Board approved cash and equity compensation of directors, such that we will pay each of our non-employee directors an annual cash retainer for service on the Board and for service on each committee on which the director is a member. The chair of each committee receives an additional annual retainer for such service. All retainers are payable in arrears in four equal quarterly installments. The retainers paid to non-employee directors for service on the Board and for service on each committee of the Board on which the director is a member are as follows:

Annual Board Service Retainer	
All non-employee directors	$ 45,000
Annual Committee Member Service Retainer	
Member of the Audit Committee	$ 10,000
Member of the Compensation Committee	$ 7,500
Member of the Nominating and Corporate Governance Committee	$ 5,000
Annual Committee Chair Service Retainer	
(in addition to Committee Member Service Retainer above):	
Chair of the Audit Committee	$ 20,000
Chair of the Compensation Committee	$ 15,000
Chair of the Nominating and Corporate Governance Committee	$ 10,000

Additionally, each non-director will receive an annual grant of nonqualified stock options to purchase 0.04% of the shares of Common Stock outstanding as of the date of the Company's annual meeting, such options vesting monthly over a one-year period and fully vesting upon the director's death or disability or upon a change of control of the Company.

Our Nominating Committee will continue to review and make recommendations to the Board regarding compensation of directors, including equity-based plans. We will reimburse our non-employee directors for reasonable travel expenses incurred in attending board and committee meetings.

Director Compensation Table

The following table sets forth information concerning the compensation of our directors for the year ended December 31, 2023:

Name	Fees Earned or Paid In Cash ($)	Stock Awards ($)[1]	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Simon Tarsh	107,500[2]	5,120[3]	—	-	112,620
James Sapirstein	175,000[4]	5,120[3]	—	2,000[5]	182,120
Vuk Jeremic	43,125[6]	5,120[3]	—	-	48,245
Timothy Ramdeen	75,000[7]	5,120[3]	2,549[8]	-	82,669

(1) This figure represents the aggregate grant date fair value of stock-based awards granted in the fiscal year, computed in accordance with the provisions of FASB ASC 718. Assumptions used in the calculation of these amounts are included in the notes to our consolidated financial statements included elsewhere in this Report.
(2) Represents fees earned by Mr. Tarsh for serving as a member of the Board, Compensation Committee, and Nominating Governance Committee, as well as Chairman of the Audit Committee, totaling $77,500. This figure also includes $30,000 of fees earned by Mr. Tarsh for Special Committee compensation.
(3) These directors were each granted 6,360 shares of restricted stock, which vest on May 31, 2024. All such shares are unvested and remain outstanding as of December 31, 2023, except for the 6,360 shares originally granted to Mr. Jeremic, which forfeited unvested on his resignation date.
(4) Represents fees earned by Mr. Sapirstein, for serving as a member of the Board, Audit Committee, and Nominating Governance Committee, as well as Chairman of the Compensation Committee, totaling $75,000. This figure also includes $100,000 of fees earned by Mr. Sapirstein for his role as Lead Independent Director and non-executive Chairman of the Board.
(5) Represents travel expenses incurred by Mr. Sapirstein and reimbursed by the Company.
(6) Represents pro-rated fees earned by Mr. Jeremic for 2023, through his resignation on September 2, 2023. Such fees were earned for serving as a member of the Board, Compensation Committee, and Nominating Governance Committee.
(7) Represents fees earned by Mr. Ramdeen, for serving as a member of the Board, Audit Committee, and Compensation Committee, as well as Chairman of the Nominating Governance Committee.
(8) Mr. Ramdeen was granted 2,386 stock options during the year ended December 31, 2023, when he joined the Board January 2023. The options vested monthly through May 13, 2023. At December 31, 2023, these options are fully vested and outstanding.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information concerning the ownership of our common stock, with respect to: (i) each person, or group of affiliated persons, known to us to be the beneficial owner of more than five percent of our common stock; (ii) each of our directors; (iii) each of our named executive officers; and (iv) all of our current directors and executive officers as a group.

Applicable percentage ownership is based on 22,186,746 shares of common stock outstanding as of April 5, 2024.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting or investment power with respect to such securities. In addition, pursuant to such rules, we deemed outstanding shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of April 5, 2024. We did not deem such shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the beneficial owners named in the table below have sole voting and investment power with respect to all shares of our common stock that they beneficially own, subject to applicable community property laws.

	Shares of Common Stock Owned	
Name and Address of Beneficial Owner[1]	**Number of Shares**	**Percentage**
Executive Officers and Directors		
Ralph Schiess	269,749[2][11]	1.2%
Bruce Harmon	29,574[3]	*
Christian Brühlmann	236,029[4][11]	1.1%
Simon Tarsh	4,073[5]	*
Timothy Ramdeen	2,386[6]	*
James Sapirstein	30,467[7]	*
Thomas Meier	-	-
Ajit Singh	-	*
All directors and named executive officers as a group (8 persons)	572,278	2.6%
5% Stockholders		
Joseph Hernandez	2,650,351[8]	12.0%
Altos Venture AG	1,103,403[9]	5.0%
American Financial Group, Inc.	1,440,927[10]	6.5%

* Represents beneficial ownership of less than 1%.

(1) Unless otherwise noted, the business address of each of the following entities or individuals is c/o Onconetix, Inc., 201 E. Fifth Street, Suite 1900, Cincinnati, Ohio 45202.
(2) Consists of 269,749 shares of common stock.
(3) Consists of 29,574 shares of common stock underlying options that are currently exercisable within 60 days of April 5, 2024.
(4) Consists of 236,029 shares of common stock.
(5) Consists of 4,073 shares of common stock underlying options that are currently exercisable within 60 days of April 5, 2024.

(6) Consists of 2,386 shares of common stock underlying options that are currently exercisable within 60 days of April 5, 2024.
(7) Consists of 30,467 shares of common stock underlying options that are currently exercisable within 60 days of April 5, 2024.
(8) Based on a Schedule 13G filed with the SEC on February 14, 2023. The principal business address for Mr. Hernandez was c/o Onconetix, Inc., 201 E. Fifth Street, Suite 1900, Cincinnati, Ohio 45202.
(9) Based on a Schedule 13D filed with the SEC on December 28, 2023. The principal business address for Altos Venture AG is Obertorweg 64, CH-4123 Allschwil/Switzerland.
(10) Based on a Schedule 13G/A filed with the SEC on January 26, 2024. The principal business address for American Financial Group, Inc. is 301 East Fourth Street, Cincinnati, Ohio 45202.
(11) Excludes: (i) any options granted to the individual pursuant to the PMX Option Plan, which will be converted into Onconetix securities after the Conversion; and (ii) any shares of Series B Preferred Stock held by the individual, which shares are not convertible into shares of common stock unless and until Stockholder Approval is obtained.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2023, regarding our common stock that may be issued under the Company's 2019 Equity Incentive Plan (the "2019 Plan") and the Company's 2022 Equity Incentive Plan (the "2022 Plan").

Plan category:	Number of Securities to be issued Upon Exercise of Outstanding Options, Warrants, and Rights (a)	Weighted Average Exercise Price of Outstanding Options (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in column (a)) (c)
Equity compensation plans approved by stockholders			
2019 Plan [1]	508,028	$ 0.01	0[1][2]
2022 Plan [3]	1,396,802	$ 2.21	718,402
Total	1,904,830	$ 1.63	718,402

(1) The 2019 Plan permits grants of equity awards to employees, directors, consultants, and other independent contractors. Our board of directors and stockholders have approved a total reserve of 1,400,000 shares for issuance under the 2019 Plan.
(2) Once the 2022 Plan became effective, no further grants were made under the 2019 Plan and all shares that remained available for the issuance of awards under our 2019 Plan as of immediately prior to the time our 2022 Plan became effective were rolled over into the 2022 Plan.
(3) The 2022 Plan permits grants of equity awards to employees, directors, consultants, and other independent contractors. Our board of directors and stockholders have approved a total reserve of 3,150,000 shares for issuance under the 2022 Plan.

The following table provides information as of December 31, 2023, regarding common stock of Proteomedix that may be issued under a stock option plan sponsored by Proteomedix (the "PMX Option Plan").

Plan category:	Number of Securities to be issued Upon Exercise of Outstanding Options (a)	Weighted Average Exercise Price of Outstanding Options (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in column (a)) (c)
Equity compensation plans approved by Proteomedix board of directors			
PMX Option Plan [(1)]	58,172	$ 3.46	n/a(1)(2)
Total	58,172	$ 3.46	

(1) The PMX Option Plan permits grants of equity awards to employees and consultants. The board of directors of Proteomedix approves shares issued under this plan and there is no maximum number of shares that may be issued.
(2) The PMX Option Plan does not have a maximum number of shares that may be issued.

2022 Equity Incentive Plan

Our board of directors adopted, and our stockholders approved, our 2022 Plan effective upon the completion of our initial public offering. Our 2022 Plan is a successor to and continuation of our 2019 Plan. Our 2022 Plan became effective on the date of the completion of our initial public offering. Once the 2022 Plan became effective, no further grants will be made under the 2019 Plan.

Awards. Our 2022 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Internal Revenue Code, or the Code, to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of our affiliates.

Authorized Shares. Initially, the maximum number of shares of our common stock that may be issued under our 2022 Plan was 1,600,000 shares of our common stock, which is the sum of (i) 200,000 new shares, plus (ii) an additional number of shares not to exceed 1,400,000 (calculated after giving effect to the Pre-IPO Stock Split), consisting of (A) shares that remain available for the issuance of awards under our 2019 Plan as of immediately prior to the time our 2022 Plan becomes effective and (B) shares of our common stock subject to outstanding stock options or other stock awards granted under our 2019 Plan that, on or after the 2022 Plan becomes effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time.

On August 22, 2022, at the Company's 2022 annual meeting of stockholders, the Company's stockholders approved an additional 1,000,000 shares of common stock that may be issued under the 2022 Plan. On May 31, 2023, at the Company's 2022 annual meeting of stockholders, the Company's stockholders approved an additional 550,000 shares of common stock that may be issued under the 2022 Plan.

The number of shares of common stock available for issuance under our 2022 Plan will be reduced by: one share for each share of common stock issued pursuant to a stock option or stock appreciation right with respect to which the exercise or strike price is at least 100% of the Fair Market Value of the Common Stock subject to the stock option or appreciation right on the grant date; and (ii) 1.20 shares for each share of common stock issued pursuant to any restricted stock unit or other "full value award." The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2022 Plan is equal to the number of shares reserved under the 2022 Plan at any time.

Shares subject to stock awards granted under our 2022 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares do not reduce the number of shares available for issuance under our 2022 Plan. Shares withheld under a stock award to satisfy the exercise, strike, or purchase price of a stock award or to satisfy a tax withholding obligation do not reduce the number of shares available for issuance under our 2022 Plan. If any shares of our common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us (i) because of a failure to meet a contingency or condition required for the vesting of such shares, (ii) to satisfy the exercise, strike or purchase price of an award or (iii) to satisfy a tax withholding obligation in connection with an award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under the 2022 Plan. Any shares previously issued which are reacquired in satisfaction of tax withholding obligations or as consideration for the exercise or purchase price of a stock award will again become available for issuance under the 2022 Plan. The number of shares available for issuance under our 2022 Plan will increase by 1.20 shares for each share subject to restricted stock units or other full value awards (not including stock options or stock appreciation rights) which are forfeited or reacquired for the reasons described in the preceding two sentences.

Plan Administration. Our Board of Directors has assigned the authority to administer the 2022 Plan to our Compensation Committee, but may, at any time, re-vest in itself some or all of the power delegated to our Compensation Committee. The Compensation Committee may delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards and (ii) determine the number of shares subject to such stock awards. Under our 2022 Plan, our Compensation Committee has the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

Stock Options. ISOs and NSOs are granted under stock option agreements in a form approved by the Compensation Committee. The Compensation Committee determines the exercise price for stock options, within the terms and conditions of the 2022 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2022 Plan vest at the rate specified in the stock option agreement as determined by the Compensation Committee.

The Compensation Committee determines the term of stock options granted under the 2022 Plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement, or other written agreement between us and the recipient approved by the Compensation Committee, provide otherwise, if an option holder's service relationship with us or any of our affiliates ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an option holder's service relationship with us or any of our affiliates ceases due to death, or an option holder dies within a certain period following cessation of service, the option holder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an option holder's service relationship with us or any of our affiliates ceases due to disability, the option holder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the Compensation Committee and may include (i) cash, check, bank draft or money order, (ii) a broker-assisted cashless exercise, (iii) the tender of shares of our common stock previously owned by the option holder, (iv) a net exercise of the option if it is an NSO or (v) other legal consideration approved by the Board of Directors.

Unless the Compensation Committee provides otherwise, options or stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the Compensation Committee or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement or other divorce or separation instrument.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted under restricted stock unit award agreements in a form approved by the Compensation Committee. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the Compensation Committee or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient approved by the Compensation Committee, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements in a form approved by the Compensation Committee. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The Compensation Committee determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements in a form approved by the Compensation Committee. The Compensation Committee determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2022 Plan vests at the rate specified in the stock appreciation right agreement as determined by the Compensation Committee. Stock appreciation rights may be settled in cash or shares of common stock or in any other form of payment as determined by the Board and specified in the stock appreciation right agreement.

The Compensation Committee determines the term of stock appreciation rights granted under the 2022 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2022 Plan permits the grant of performance awards that may be settled in stock, cash, or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by the board of directors or the Compensation Committee. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the board of directors at the time the performance award is granted, the board or Compensation Committee will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring and/or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any portion of our business which is divested achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (xi) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the U.S. Food and Drug Administration or any other regulatory body.

Other Stock Awards. The Compensation Committee may grant other awards based in whole or in part by reference to our common stock. The Compensation Committee will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including awards granted and cash fees paid by us to such non-employee director, will not exceed $150,000 in total value; provided that such amount will increase to $200,000 for the first year for newly appointed or elected non-employee directors.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the 2022 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs and (iv) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. The following applies to stock awards under the 2022 Plan in the event of a corporate transaction (as defined in the 2022 Plan), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the Board of Directors or Compensation Committee at the time of grant.

In the event of a corporate transaction, any stock awards outstanding under the 2022 Plan may be assumed, continued, or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the board of directors may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the per share amount payable to holders of common stock in connection with the corporate transaction over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of common stock.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend or terminate our 2022 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our 2022 Plan. No stock awards may be granted under our 2022 Plan while it is suspended or after it is terminated.

2019 Equity Incentive Plan

Our board of directors adopted, and our stockholders approved our 2019 Equity Incentive Plan (the "2019 Plan") in July 2019 for grants of awards to employees, directors, officers, and consultants of us or any of our subsidiaries. Once the 2022 Plan became effective, no further grants will be made under the 2019 Plan. However, the 2019 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2019 Plan.

Awards. Our 2019 Plan provides for the grant of stock awards (collectively, "Stock Awards") to employees, directors, officers and consultants of us or any of our subsidiaries, consisting of (i) incentive stock options, ("ISOs"), within the meaning of Section 422 of the Internal Revenue Code (the "Code"); (ii) nonstatutory stock options ("NSOs"); (iii) stock appreciation rights; (iv) restricted stock awards; (v) restricted stock unit awards, and (vi) other forms of awards.

Authorized Shares. As of April 5, 2024, stock options covering 508,028 shares, each with an exercise price of $0.01 per share were the only outstanding Stock Awards outstanding under our 2019 Plan. Once the 2022 Plan became effective, no further grants were made under the 2019 Plan and all shares that remained available for the issuance of awards under our 2019 Plan as of immediately prior to the time our 2022 Plan became effective were rolled over into the 2022 Plan.

Plan Administration. The 2019 Plan may be administered by our board of directors, and our board of directors may delegate such administration to a committee of the board of directors (as applicable, the "Administrator"). The Administrator, in its discretion, selects the individuals to whom awards may be granted, the time or times at which such awards are granted and the terms and conditions of such awards.

Stock Options. Stock options entitle the holder to purchase a specified number of shares of common stock at a specified price (the exercise price), subject to the terms and conditions of the stock option grant. Our board of directors may grant either incentive stock options, which must comply with Code Section 422, or nonqualified stock options. ISO's may only be granted to employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Our Administrator sets exercise prices and terms and conditions, except that stock options must be granted with an exercise price not less than 100% of the fair market value of our common stock on the date of grant. Unless our Administrator determines otherwise, fair market value means, as of a given date, the closing price of our common stock. At the time of grant, our board of directors determines the terms and conditions of stock options, including the quantity, exercise price, vesting periods, term (which may not exceed 10 years) and other conditions on exercise. Pursuant to the 2019 Plan, we may only issue 1,400,000 ISO's.

Eligibility. Awards may be granted under the 2019 Plan to officers, employees, directors, officers and of us and our subsidiaries. Incentive stock options may be granted only to employees of us or our subsidiaries.

Restricted Stock, Restricted Stock Units and Other Stock-Based Awards. Our board of directors may grant awards of restricted stock, which are shares of common stock subject to specified restrictions, and restricted stock units, or RSUs, which represent the right to receive shares of our common stock in the future. These awards may be made subject to repurchase, forfeiture or vesting restrictions at the discretion of our board of directors' discretion. The restrictions may be based on continuous service with us or the attainment of specified performance goals, as determined by the board of directors. Stock units may be paid in stock or cash or a combination of stock and cash, as determined by the board of directors. Other stock awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than one hundred percent (100%) of the fair market value of the common stock at the time of grant) may be granted either alone or in addition to stock awards provided for under the 2019 Plan.

Stock Appreciation Rights. Upon exercise, SARs entitle the holder to receive payment per share in stock or cash, or in a combination of stock and cash, equal to the excess of the share's fair market value on the date of exercise over the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date (the "grant price". Exercise of a SAR issued in tandem with a stock option will reduce the number of shares underlying the related stock option to the extent of the SAR exercised. The term of a SAR cannot exceed 10 years.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares subject to the 2019 Plan, (ii) the class and maximum number of shares that may be issued on the exercise of ISOs and (iii) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. The following applies to Stock Awards under the 2019 Plan in the event of a corporate transaction (as defined in the 2019 Plan), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the Board of Directors at the time of grant.

In the event of a corporate transaction, the board of directors may take one of the following actions, contingent on the completion of the corporate transaction: (i) arrange for the surviving or acquiring corporation (or its parent company) to assume, continue or substitute the Stock Award for a similar stock award; (ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of common stock issued pursuant to the Stock Award to the surviving or acquiring corporation (or its parent company); (iii) accelerate the vesting (in whole or in part) of the Stock Award; (iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award; (v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the corporate transaction, in exchange for such cash consideration that the Board of Directors; and (vi) make a payment equal to the excess, if any, of (A) the value of the property the participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the corporate transaction, over (B) any exercise price payable by such holder in connection with such exercise The Board of Directors need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all participants. The Board of Directors may also take different actions with respect to the vested and unvested portions of a Stock Award.

Additionally, under the 2019 Plan, a Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control (as defined in the 2019 Plan) as may be provided in the Grant Agreement for such Stock Award or as may be provided in any other written agreement between the participant and the Company or any of its subsidiaries which may employ the participant, but in the absence of such provision, no such acceleration will occur.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend or terminate our 2019 Plan, subject to certain conditions, including that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2019 Plan.

Proteomedix Stock Option Plan

The PMX Option Plan was approved by Proteomedix's board of directors as of July 1, 2015, and provides for the grant of options to acquire shares in Proteomedix. The terms of the PMX Option Plan are described in more detail below.

The PMX Option Plan is administered by a plan administrator (one or several persons) elected by Proteomedix's board of directors (the "Proteomedix Board") from time to time. The plan administrator acts within the guidelines set and approved by Proteomedix's board of directors or a committee thereof and is authorized to, among others, determine (i) which eligible persons are to receive awards under the PMX Option Plan, (ii) the time or times when such options grants are to be made, (iii) the nature and the number of options covered by each such grant, (iv) the time or times at which each option right is to become exercisable, (v) the vesting conditions applicable to the options, (vi) the maximum term for which the options are to remain outstanding, and (vii) any terms and conditions of the options granted, in each case, subject to the guidelines set and approved by Proteomedix's board of directors or a committee thereof. Persons eligible to participate in the PMX Option Plan are employees, members of Proteomedix's board of directors and consultants of Proteomedix or a subsidiary. The plan administrator determines within the guidelines set and approved by Proteomedix's board of directors or a committee which eligible persons are to receive rights to acquire options under the PMX Option Plan.

The number of shares that may be issued under the PMX Option Plan is determined by the Proteomedix's board of directors. In the event common shares that otherwise would have been issuable under the PMX Option Plan are withheld by Proteomedix in payment of the exercise price or withholding obligations, such shares shall remain available for issuance under the PMX Option Plan. In the event that an outstanding award expires or is cancelled, forfeited or terminated for any reason, the shares allocable to the unexercised or unsettled portion shall remain available for issuance under the PMX Option Plan.

A participant may only exercise an option or stock appreciation right to the extent that the option or stock appreciation right has vested and has not lapsed under the PMX Option Plan. Unless otherwise determined by Proteomedix's board of directors at the grant date or set forth in the grant notice, an option or an award in the form of a restricted stock unit or stock appreciation right granted under the PMX Option Plan typically vests as to 25.0% of the award at the end of the first year following the vesting start date, with the remaining 75.0% of the award vesting monthly over the 3 years after the first year following the vesting start date.

If indicated in the grant notice or otherwise resolved by Proteomedix's board of directors, upon the occurrence of a "Corporate Transaction" (as defined in the PMX Option Plan), all options (i) shall fully vest and (ii) may be immediately exercised, except if such options are canceled by the plan administrator in exchange for compensation equivalent to the economic value of the option under the PMX Option Plan.

Proteomedix has complete and exclusive power and authority to amend or modify the PMX Option Plan in any or all respects. No such amendment or modification shall, without the consent of the grantee, adversely affect his/her rights and obligations under the PMX Option Plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The following is a description of transactions since January 1, 2022 to which we were a party in which (i) the amount involved exceeded or will exceed the lesser of $120,000 of one percent (1%) of our average total assets at year-end for the last two completed fiscal years and (ii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, any of the foregoing persons, who had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other similar arrangements, which are described under "Executive and Director Compensation."

Debenture

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

Related party advances

During the year ended December 31, 2023, the Company's Audit Committee completed a review of the Company's expenses due to certain irregularities identified with regards to the related party balance. Based on the results of the review, it was determined that the Company paid and recorded within selling, general and administrative expenses, personal expenditures of the Company's former CEO and an accounting employee who was also the former CEO's assistant, during 2022 and during the first three quarters of 2023. The Company evaluated the receivable, which aggregated to approximately $522,000 as of September 30, 2023, and which represented the total of the items identified as personal in nature for which the Company did not anticipate recovery from the related party. As the Company concluded that the remaining amounts are not likely to be recovered, this would not cause an adjustment to previously issued financial statements. The Company recorded a corresponding reserve for the full amount, resulting in a net related party receivable balance of $0 and a loss on related party receivable of approximately $266,000, which was recorded in selling, general, and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2023. During the fourth quarter of 2023, the Company recorded a recovery of approximately $159,000 with respect to amounts that the former CEO agreed to repay the Company, through a reduction of amounts that were due to him from the Company under his indemnification rights pursuant to his employment agreement.

Lease Agreement

On February 28, 2022, the Company entered into a short-term lease in Palm Beach, Florida with an unrelated party, with a commencement date of May 1, 2022, for approximately $14,000 per month. The lease, which was personally guaranteed by the Company's former Chief Executive Officer, ended on April 30, 2023. During the years ended December 31, 2023 and 2022, the Company incurred rent expense on this lease of approximately $51,000 and $129,000, respectively, and variable lease expense of approximately $4,000 and $12,000, respectively.

Consulting Agreement

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

Director Independence

The Board has evaluated each of its directors' independence from the Company based on the definition of "independence" established by Nasdaq and has determined that each of Simon Tarsh, Timothy Ramdeen, James Sapirstein and Ajit Singh are independent directors, constituting a majority of the Board. The Board has further determined that each member of our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee is "independent" under applicable Nasdaq rules.

The Board has also determined that each member of our audit committee is "independent" for purposes the Exchange Act.

In its evaluation of each director's or nominee's independence from the Company, the Board reviewed whether any transactions or relationships currently exist or existed during the past year between each director or nominee and the Company and its subsidiaries, affiliates, equity investors, or independent registered public accounting firm, and whether there were any transactions or relationships between each director or nominee and members of the senior management of the Company or their affiliates.

Item 14. Principal Accounting Fees and Services.

Audit and Non-Audit Fees

EisnerAmper served as the independent registered public accounting firm to audit our books and accounts for the fiscal year ended December 31, 2023.

Mayer Hoffman McCann P.C. ("MHM") served as the independent registered public accounting firm to audit our books and accounts for the fiscal year ended December 31, 2022. Substantially all of MHM's personnel, who work under the control of MHM shareholders, are employees of wholly owned subsidiaries of CBIZ, Inc., which provides personnel and various services to MHM in an alternative practice structure.

The table below presents the aggregate fees billed for professional services rendered by EisnerAmper for the year ended December 31, 2023.

Audit fees	$	778,568
Audit-related fees		-
Tax fees		-
All other fees		-
Total fees	$	778,568

In the above table, "audit fees" are fees billed for services provided related to the audit of our annual consolidated financial statements, quarterly reviews of our interim condensed financial statements, and services normally provided by EisnerAmper in connection with regulatory filings or engagements for that fiscal period.

The table below presents the aggregate fees billed for professional services rendered by MHM for the years ended December 31, 2023 and 2022.

		2023		2022
Audit fees	$	208,426	$	633,629
Audit-related fees		-		-
Tax fees	$	11,889		9,975
All other fees		-		-
Total fees	$	220,315	$	643,604

In the above table, "audit fees" are fees billed for services provided related to the audit of our annual financial statements, quarterly reviews of our interim condensed financial statements, and services normally provided by MHM in connection with regulatory filings or engagements for those fiscal periods. "Tax fees" consist of amounts billed by an associated entity of MHM for services in connection with the preparation of our federal and state tax returns.

Pre-Approval Policy

It is the Audit Committee's policy to approve in advance the types and amounts of audit, audit-related, tax, and any other services to be provided by our independent registered public accounting firm. In situations where it is not practicable to obtain full Audit Committee approval, the Audit Committee has delegated authority to the Chair of the Audit Committee to grant pre-approval of audit and permissible non-audit services and any associated fees. Any pre-approved decisions by the Chair are required to be reviewed with the Audit Committee at its next scheduled meeting.

Our Audit Committee was formed upon the consummation of our initial public offering. As a result, the audit committee did not pre-approve all of the foregoing services, although any services rendered prior to the formation of our audit committee were approved by our board of directors. Since the formation of our Audit Committee, and on a going-forward basis, the Audit Committee has and will pre-approve all auditing services and permitted non-audit services to be performed for us by our auditors, including the fees and terms thereof (subject to the de minimis exceptions for non-audit services described in the Exchange Act which are approved by the audit committee prior to the completion of the audit).

PART IV

Item 15. Exhibit and Financial Statement Schedules.

ONCONETIX, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Onconetix, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Onconetix Inc. and Subsidiary (the "Company") as of December 31, 2023, and the related consolidated statements of operations and comprehensive loss, convertible redeemable preferred stock and stockholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2023, and the consolidated results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2023.

EISNERAMPER LLP
Iselin, New Jersey
April 11, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
and Stockholders of **Onconetix, Inc.**

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Onconetix, Inc. (formerly known as Blue Water Vaccines Inc.)(the "Company") as of December 31, 2022, and the related consolidated statements of operations and comprehensive loss, convertible redeemable preferred stock and stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

We served as the Company's auditor from 2021 to 2023.

/s/ Mayer Hoffman McCann P.C.

Los Angeles, California
March 8, 2023

ONCONETIX, INC.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash	$ 4,554,335	$ 25,752,659
Accounts receivable, net	149,731	—
Inventories	364,052	—
Prepaid expenses and other current assets	770,153	469,232
Receivable from related parties, net	—	35,850
Total current assets	5,838,271	26,257,741
Prepaid expenses, long-term	17,423	38,617
Property and equipment, net	60,654	14,089
Deferred offering costs	366,113	—
Operating right of use asset	148,542	—
Intangible assets, net	25,410,887	—
Goodwill	55,676,142	—
Total assets	**$ 87,518,032**	**$ 26,310,447**
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 5,295,114	$ 1,499,296
Accrued expenses	2,199,867	2,409,128
Notes payable, net of debt discount of $381,627	9,618,373	—
Operating lease liability, current	74,252	—
Contingent warrant liability	2,641	14,021
Total current liabilities	17,190,247	3,922,445
Note payable	118,857	—
Subscription agreement liability	864,000	—
Pension benefit obligation	556,296	—
Operating lease liability, net of current portion	74,290	—
Deferred tax liability, net	3,073,781	—
Total liabilities	21,877,471	3,922,445
Commitments and Contingencies (see Note 10)		
Series B Convertible Redeemable Preferred stock, $0.00001 par value, 2,700,000 and 0 shares authorized at December 31, 2023 and 2022, respectively; 2,696,729 and 0 shares issued and outstanding at December 31, 2023 and 2022, respectively	64,236,085	—
Stockholders' equity (deficit)		
Series A Convertible Preferred stock, $0.00001 par value, 10,000 and 0 shares authorized at December 31, 2023 and 2022, respectively; 3,000 and 0 shares issued and outstanding at December 31, 2023 and 2022, respectively; Liquidation preference of $3,000,000 and $0 at December 31, 2023 and 2022, respectively.	—	—
Common stock, $0.00001 par value, 250,000,000 shares authorized at December 31, 2023 and 2022; 22,841,975 and 15,724,957 shares issued at December 31, 2023 and 2022, respectively; 22,324,576 and 15,265,228 shares outstanding at December 31, 2023 and 2022, respectively	228	157
Additional paid-in-capital	49,428,809	42,331,155
Treasury stock, at cost; 517,399 and 459,729 shares of common stock at December 31, 2023 and 2022, respectively	(625,791)	(566,810)
Accumulated deficit	(56,786,194)	(19,376,500)
Accumulated other comprehensive income	2,380,920	—
Total Onconetix stockholders' equity (deficit)	(5,602,028)	22,388,002
Non-controlling interest	7,006,504	—
Total stockholders' equity	1,404,476	22,388,002
Total liabilities, convertible redeemable preferred stock, and stockholders' equity (deficit)	**$ 87,518,032**	**$ 26,310,447**

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

ONCONETIX, INC.
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31, 2023	Year Ended December 31, 2022
Revenue	$ 58,465	$ —
Cost of revenue	1,185,630	—
Gross loss	(1,127,165)	—
Operating expenses		
Selling, general and administrative	14,770,678	9,351,552
Research and development	1,949,406	4,129,688
Impairment of ENTADFI assets	14,687,346	—
Impairment of deposit on asset purchase agreement	3,500,000	—
Total operating expenses	34,907,430	13,481,240
Loss from operations	(36,034,595)	(13,481,240)
Other income (expense)		
Loss on extinguishment of note payable	(490,000)	—
Interest expense	(671,625)	—
Change in fair value of subscription agreement liability	(134,100)	—
Change in fair value of contingent warrant liability	(91,967)	61,410
Total other income (expense)	(1,387,692)	61,410
Loss before income taxes	(37,422,287)	(13,419,830)
Income tax benefit	12,593	—
Net loss	**$ (37,409,694)**	**$ (13,419,830)**
Cumulative preferred stock dividends	—	96,359
Net loss attributable to common stockholders	$ (37,409,694)	$ (13,516,189)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.19)	$ (1.10)
Weighted average number of common shares outstanding, basic and diluted	17,111,374	12,271,449
Other comprehensive loss		
Net loss	$ (37,409,694)	$ (13,419,830)
Foreign currency translation	2,374,957	—
Change in pension benefit obligation	5,963	—
Total comprehensive loss attributable to common stockholders	$ (35,028,774)	$ (13,419,830)

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

ONCONETIX, INC.
Consolidated Statements of Convertible Redeemable Preferred Stock and Stockholders' Equity (Deficit)
For the years ended December 31, 2023 and 2022

	Series B Preferred Stock		Series A Preferred Stock		Series Seed Preferred Stock		Common Stock		Additional Paid-in	Treasury Stock		Accumulated	Other Comprehensive	Total Onconetix	Non-controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Shares	Amount	Deficit	Income	Equity (Deficit)	Interest	Equity (Deficit)
Balance at December 31, 2021	**—**	**$ —**	**—**	**$ —**	**1,146,138**	**$ 11**	**3,200,000**	**$ 32**	**$ 7,403,204**	**—**	**$ —**	**$ (5,956,670)**	**$ —**	**$ 1,446,577**	**$ —**	**$ 1,446,577**
Issuance of common stock in initial public offering, net of $2.9 million of offering costs	—	—	—	—	—	—	2,222,222	22	17,138,818	—	—	—	—	17,138,840	—	17,138,840
Conversion of convertible preferred stock to common stock upon initial public offering	—	—	—	—	(1,146,138)	(11)	5,626,365	56	(45)	—	—	—	—	—	—	—
Issuance of common stock and warrants in April private placement, net of $1.1 million of offering costs	—	—	—	—	—	—	590,406	6	6,858,322	—	—	—	—	6,858,328	—	6,858,328
Issuance of common stock and warrants in August private placement, net of $2.2 million of offering costs	—	—	—	—	—	—	1,350,000	14	8,689,302	—	—	—	—	8,689,316	—	8,689,316
Exercise of stock options	—	—	—	—	—	—	165,452	2	1,653	—	—	—	—	1,655	—	1,655
Exercise of pre-funded warrants	—	—	—	—	—	—	2,277,046	22	1,414	—	—	—	—	1,436	—	1,436
Issuance of restricted common stock	—	—	—	—	—	—	293,466	3	263,921	—	—	—	—	263,924	—	263,924
Stock-based compensation	—	—	—	—	—	—	—	—	1,974,566	—	—	—	—	1,974,566	—	1,974,566
Purchase of treasury shares	—	—	—	—	—	—	—	—	—	(459,729)	(566,810)		—	(566,810)	—	(566,810)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(13,419,830)	—	(13,419,830)	—	(13,419,830)
Balance at December 31, 2022	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**15,724,957**	**$ 157**	**$42,331,155**	**(459,729)**	**$(566,810)**	**$ (19,376,500)**	**$ —**	**$ 22,388,002**	**$ —**	**$ 22,388,002**
Issuance of common stock from exercise of preferred investment options	—	—	—	—	—	—	2,486,214	25	2,272,813	—	—	—	—	2,272,838	—	2,272,838
Issuance of warrants for settlement of contingent warrants	—	—	—	—	—	—	—	—	129,184	—	—	—	—	129,184	—	129,184
Issuance of Series A Preferred Stock	—	—	3,000	—	—	—	—	—	3,490,000	—	—	—	—	3,490,000	—	3,490,000
Issuance of common stock and Series B Preferred Stock in connection with PMX Transaction	2,696,729	64,236,085	—	—	—	—	3,675,414	37	875,447	—	—	—	—	875,484	—	875,484
Assumption of stock-based compensation plan awards in connection with PMX Transaction	—	—	—	—	—	—		—	—	—	—	—	—	—	7,006,504	7,006,504
Exercise of stock options	—	—	—	—	—	—	45,920	—	459	—	—	—	—	459	—	459
Exercise of pre-funded warrants	—	—	—	—	—	—	646,640	7	(7)	—	—	—	—	—	—	—
Issuance of restricted stock	—	—	—	—	—	—	512,940	5	(5)	—	—	—	—	—	—	—
Forfeitures of restricted stock	—	—	—	—	—	—	(250,110)	(3)	3	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	329,760	—	—	—	—	329,760	—	329,760
Purchase of treasury shares	—	—	—	—	—	—	—	—	—	(57,670)	(58,981)	—	—	(58,981)	—	(58,981)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	—	2,374,957	2,374,957	—	2,374,957
Changes in pension benefit obligation	—	—	—	—	—	—	—	—	—	—	—	—	5,963	5,963	—	5,963
Net loss	—	—	—	—	—	—	—	—	—	—	—	(37,409,694)	—	(37,409,694)	—	(37,409,694)
Balance at December 31, 2023	**2,696,729**	**$64,236,085**	**3,000**	**$ —**	**—**	**$ —**	**22,841,975**	**$ 228**	**$49,428,809**	**(517,399)**	**$(625,791)**	**$ (56,786,194)**	**$ 2,380,920**	**$ (5,602,028)**	**$ 7,006,504**	**$ 1,404,476**

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

ONCONETIX, INC.
Consolidated Statements of Cash Flows

	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash flows from operating activities		
Net loss	$ (37,409,694)	$ (13,419,830)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of ENTADFI assets	14,687,346	—
Impairment of deposit on asset purchase agreement	3,500,000	—
Fair value of subscription agreement liability	729,900	—
Amortization of debt discount	671,373	—
Loss on extinguishment of note payable	490,000	—
Stock-based compensation	329,760	1,974,566
Loss on impairment of other long-lived assets	267,019	—
Loss on related party receivable	265,648	—
Recovery of related party receivable	(159,000)	—
Deferred tax benefit	(12,593)	—
Impairment of inventory	1,152,369	—
Depreciation and amortization	43,937	6,752
Change in fair value of contingent warrant liability	91,967	(61,410)
Change in fair value of subscription agreement liability	134,100	—
Net periodic pension benefit	13,875	—
Issuance of restricted common stock	—	263,924
Changes in operating assets and liabilities:		
Accounts receivable	(62,286)	—
Inventories	(315,828)	—
Prepaid expenses and other current assets	(412,601)	(234,681)
Other noncurrent assets	(16,883)	(38,617)
Accounts payable	3,372,648	1,093,913
Accrued expenses	(942,075)	1,739,849
Net cash used in operating activities	(13,581,018)	(8,675,534)
Cash flows from investing activities		
Acquisition of assets, including transaction costs of $79,771	(6,079,771)	—
Deposit made in connection with asset purchase agreement	(3,500,000)	—
Cash acquired through business combination	1,056,578	—
Purchases of other long-lived assets	(51,744)	—
Net advances to related parties	(70,798)	(23,326)
Purchases of property and equipment	(3,300)	(9,339)
Net cash used in investing activities	(8,649,035)	(32,665)
Cash flows from financing activities		
Purchase of treasury shares	(58,981)	(566,810)
Payment of deferred offering costs	(205,093)	—
Principal payment of note payable	(1,000,000)	—
Proceeds from exercise of preferred investment options, net	2,298,675	—
Proceeds from exercise of stock options	459	1,655
Proceeds from issuance of common stock in initial public offering, net of underwriting discount	—	18,400,000
Payments of initial public offering costs	—	(926,972)
Proceeds from issuance of common stock and warrants in private placements, net of placement agent discount	—	16,468,123
Payment of private placement issuance costs		(845,048)
Proceeds from exercise of pre-funded warrants	—	1,436
Net cash provided by financing activities	1,035,060	32,532,384
Effect of exchange rate changes on cash	(3,331)	—
Net increase (decrease) in cash	(21,198,324)	23,824,185
Cash, beginning of period	25,752,659	1,928,474
Cash, end of period	$ 4,554,335	$ 25,752,659
Noncash investing and financing activities:		
Inventory and intangible assets acquired through issuance of notes payable	$ 12,947,000	$ —
Effect of business combination (Note 5)	$ 64,054,991	$ —
Settlement of note payable through issuance of Series A convertible preferred stock	$ 3,490,000	$ —
Incremental fair value of exchanged preferred investment options	$ 2,613,011	$ 860,204
Deferred offering costs included in accounts payable	$ 150,000	$ —
Recognition of contingent warrant liability	$ 25,837	$ 75,431
Warrants issued for settlement of contingent warrants	$ 129,184	$ —
Deferred offering costs previously included in prepaid expenses	$ (11,020)	$ —
Exercise of pre-funded warrants	$ 7	$ 6
Issuance of restricted stock	$ 5	$ —
Restricted stock forfeitures	$ (3)	$ —
Payment of accrued bonus through related party receivable	$ —	$ 140,000
Conversion of Series Seed Preferred Stock to common stock upon initial public offering	$ —	$ 45

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

Note 1 — Organization and Basis of Presentation

Organization and Nature of Operations

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

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

Historically, the Company's focus was on the research and development of transformational vaccines to prevent infectious diseases worldwide, until the third quarter of 2023, at which time the Company deprioritized its efforts on vaccine development activities to focus on commercialization activities for ENTADFI® and pursue other potential acquisitions. In light of (i) the time and resources needed to continue pursuing commercialization of ENTADFI, and (ii) the Company's cash runway and indebtedness, the Company has determined to temporarily pause its commercialization of ENTADFI, as it considers strategic alternatives. The Company expects to appoint a new Chief Executive Officer in the second quarter of 2024, after which the new CEO and the Board will reassess its ENTADFI program in light of the foregoing and other relevant factors.

On April 21, 2023, the Company filed an amendment to its Amended and Restated Certificate of Incorporation with the Secretary of State of Delaware to change its corporate name from "Blue Water Vaccines Inc." to "Blue Water Biotech, Inc." The name change was effective as of April 21, 2023. On December 15, 2023, the Company filed an amendment to its Amended and Restated Certificate of Incorporation with the Secretary of State of Delaware to change its corporate name from "Blue Water Biotech, Inc." to "Onconetix, Inc." In connection with each of the name changes, the Company also amended the Company's bylaws to reflect the new corporate name.

Basis of Presentation and Principles of Consolidation

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

Certain reclassifications have been made to prior year amounts reported in the accompanying consolidated statement of cash flows to conform to the current year presentation. These reclassifications, which resulted in a difference of approximately $23,000 between operating and investing cash flow activity, are not significant and had no impact on the previously reported financial position or results of operations of the Company.

Initial Public Offering

On February 23, 2022, the Company completed its initial public offering ("IPO") in which the Company issued and sold 2,222,222 shares of its common stock, at a price to the public of $9.00 per share. Proceeds from the IPO, net of underwriting discounts, commissions, and offering costs of $2.9 million, were $17.1 million. In connection with the completion of the IPO, all outstanding shares of convertible preferred stock were converted into 5,626,365 shares of common stock (see Note 9).

Note 2 — Going Concern and Management's Plans

The Company's operating activities to date have been devoted to seeking licenses, engaging in research and development activities, potential asset and business acquisitions, and expenditures associated with the commercial launch of ENTADFI®. The Company has financed its operations since inception primarily using proceeds received from seed investors and proceeds received from its IPO and subsequent debt and equity offerings. During the year ended December 31, 2022, the Company received an aggregate of approximately $33.1 million in net cash proceeds from its IPO and two private placements, and during the year ended December 31, 2023, the Company received net proceeds of approximately $2.3 million in connection with the exercise by an investor of preferred investment options (see Note 9). In addition, on January 23, 2024, the Company received net cash proceeds of $4.6 million in exchange for the issuance of a debenture. The debenture is repayable in full upon the earlier of (i) the closing of a subscription agreement, which was entered into in connection with the acquisition of Proteomedix, and (ii) June 30, 2024 (see Note 14).

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of December 31, 2023, the Company had cash of approximately $4.6 million, a working capital deficit of approximately $11.4 million and an accumulated deficit of approximately $56.8 million.

Note 2 — Going Concern and Management's Plans (cont.)

These factors, along with the Company's forecasted future cash flows, indicate that the Company will be unable to meet its contractual commitments and obligations as they come due in the ordinary course of business, within one year following the issuance of these consolidated financial statements. The Company will require significant additional capital in the short-term to fund its continuing operations, satisfy existing and future obligations and liabilities, including the remaining payments due for the acquisition of the ENTADFI® assets, payment due on the debenture, in addition to funds needed to support the Company's working capital needs and business activities. These business activities include the commercialization of ENTADFI®, which we have temporarily paused as discussed above, and Proclarix, and the development and commercialization of the Company's current product candidates and future product candidates. In addition, as discussed more fully in Note 5, if stockholder approval is not obtained by January 1, 2025 with respect to the Series B Convertible Redeemable Preferred Stock issued in connection with the acquisition of Proteomedix, these shares become redeemable for cash at the option of the holders, and the Company currently does not have sufficient cash to redeem such shares.

Management's plans for funding the Company's operations include generating product revenue from sales of Proclarix, which may still be subject to further successful commercialization activities within certain jurisdictions, and ENTADFI, which is subject to further successful commercialization activities which we have temporarily paused as discussed above. 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, and 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. This creates significant uncertainty that the Company will have the funds available to be able to successfully launch ENTADFI® and expand commercialization of Proclarix. If the Company is unable to secure additional capital, it may be required to curtail any future clinical trials, development and/or commercialization of 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.

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

Note 3 — Summary of Significant Accounting Policies

Use of Estimates

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

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash accounts in financial institutions, which, at times, exceed the Federal Depository Insurance Coverage limit for those maintained in the United States and exceed the Swiss Financial Market Supervisory Authority for those maintained in Switzerland. As of December 31, 2023 and 2022, the Company has not experienced losses on these accounts and management believes the Company is not exposed to significant risks on such accounts.

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

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. Prior to the acquisition of ENTADFI® during the quarter ended June 30, 2023, the Company managed one distinct business segment, which was vaccine discovery and development. During the second quarter of 2023, as a result of the acquisition of ENTADFI®, for which the Company is working towards commercial launch, the Company operated in two business segments: research and development and commercial. During the third quarter of 2023, the Company deprioritized its vaccine discovery and development programs, and accordingly, as of December 31, 2023, the Company was operating in one segment: commercial. Management's determination of its operating segments is consistent with the financial information regularly reviewed by the CODM for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods.

The distribution of revenue by geographical area was as follows:

	Years Ended December 31,	
	2023	**2022**
United States	$ —	$ —
Switzerland	58,465	—
Total	**$ 58,465**	$ —

The distribution of long-lived assets by geographical area, which includes property and equipment and the Company's right of use asset, was as follows:

	Years Ended December 31,	
	2023	**2022**
United States	$ 10,956	$ 14,089
Switzerland	198,240	—
Total	**$ 209,196**	**$ 14,089**

Foreign Currency Translation

The financial statements of Proteomedix, the Company's foreign subsidiary, are measured using the local currency, which is the Swiss Franc, as the functional currency. Assets and liabilities of this subsidiary are translated into U.S. dollars at exchange rates as of the consolidated balance sheet date. Equity is translated at historical exchange rates. Revenues and expenses are translated into U.S. dollars at average rates of exchange in effect during the period. The resulting cumulative translation adjustments have been recorded as a separate component of stockholders' equity, as accumulated other comprehensive income or loss. Foreign currency transaction gains and losses are included in the results of operations, and were not significant for the years ended December 31, 2023, or 2022.

Accounts receivable

The Company performs periodic credit evaluations of its customers' financial condition and extends credit to virtually all of its customers on an uncollateralized basis. Credit losses to date have been insignificant and within management's expectations. The Company provides an allowance for doubtful accounts that is based upon a review of outstanding receivables, historical collection information, expected future losses, and existing economic conditions. As of December 31, 2023, there was no allowance for doubtful accounts. As of December 31, 2023, substantially all of the Company's accounts receivable are due from a single customer.

Inventories

Inventories consist of product acquired in the ENTADFI and Proteomedix transactions. Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis, aside from inventories acquired in an asset acquisition or business combination, which are recorded at fair value. The Company periodically reviews the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise non-saleable items taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand. If non-saleable items are observed and there are no alternate uses for the inventory, the Company records a write-down to net realizable value in the period that the decline in value is first recognized. The Company recorded an impairment of inventory in the amount of approximately $1.2 million during the year ended December 31, 2023, as a result of the delay in launching ENTADFI and the Company's decision to pause related commercialization activities.

Property and Equipment

Property and equipment consists of laboratory equipment, computers, and office furniture and fixtures, all of which are recorded at cost. Depreciation is recorded using the straight-line method over the respective useful lives of the assets ranging from two to ten years. Depreciation expense was approximately $7,000 for each of the years ended December 31, 2023 and 2022 and is included in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

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

Acquisitions

The Company evaluates acquisitions to first determine whether a set of assets acquired constitutes a business and should be accounted for as a business combination. If the assets acquired are not a business, the transaction is accounted as an asset acquisition in accordance with Accounting Standards Codification ("ASC") 805-50, *Asset Acquisitions* ("ASC 805-50"), which requires the acquiring entity to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, except for non-qualifying assets including financial assets such as inventory. Further, the cost of the acquisition includes the fair value of consideration transferred and direct transaction costs attributable to the acquisition. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values. Contingent consideration payments in asset acquisitions are recognized when the contingency is determined to be probable and reasonably estimable. If the assets acquired are a business, the Company accounts for the transaction as a business combination. Business combinations are accounted for by using the acquisition method of accounting. Under the acquisition method, assets acquired, and liabilities assumed are recorded at their respective fair values. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Acquisition related expenses are expensed as incurred, and are included in selling, general and administrative expense in the consolidated statements of operations and comprehensive loss.

Goodwill and Other Intangible Assets

Goodwill represents the excess of the cost of a business combination over the fair value of the net assets acquired. Goodwill and intangible assets deemed to have indefinite lives are not amortized but are subject to impairment tests on an annual basis, and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Goodwill is allocated to the reporting unit from which it was created. A reporting unit is an operating segment or sub-segment to which goodwill is assigned when initially recorded. The Company tests indefinite lived intangible assets for impairment, on an annual basis in the fourth quarter, or more frequently if an event occurs or circumstances indicate that the indefinite lived assets may be impaired. The Company may perform a qualitative assessment to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount. If the Company determines this is the case, the Company then performs further quantitative analysis to identify and measure the amount of goodwill impairment loss to be recognized, if any. To perform its quantitative test, the Company compares the fair value of the reporting unit to its carrying value. If the fair value of the reporting unit exceeds the carrying value of its net assets, goodwill is not impaired, and no further testing is required. If the fair value of the reporting unit is less than the carrying value, the Company measures the amount of impairment loss, if any, as the excess of the carrying value over the fair value of the reporting unit. The Company did not test its goodwill or indefinite lived assets for impairment during the year ended December 31, 2023, given that the acquisition date occurred after the annual testing date, and given that there were no impairment indicators from the date of acquisition through the end of the reporting period. The Company has determined that no impairment of its goodwill or indefinite lived intangible assets occurred as of December 31, 2023.

Intangible assets with finite lives are reported at cost, less accumulated amortization, and are amortized over their estimated useful lives, starting when sales for the related product begin. Amortization is calculated using the straight-line method, and recorded within selling, general, and administrative expenses, or cost of revenue, depending on the nature and use of the asset.

During the ordinary course of business, the Company has entered into certain license and asset purchase agreements. Potential milestone payments for development, regulatory, and commercial milestones are recorded when the milestone is probable of achievement. Upon a milestone being achieved, the associated milestone payment is capitalized and amortized over the remaining useful life for approved products, or expensed as research and development expense for milestones relating to products whose FDA approval has not yet been obtained.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including intangible assets with finite useful lives, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable (a "triggering event"). Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the long-lived asset in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value. During the fourth quarter of 2023, the Company determined that there were certain triggering events that indicated that the carrying amount of the assets recorded in connection with the ENTADFI acquisition (see Note 5) may not be fully recoverable. A related impairment loss of $14.7 million was recorded during the year ended December 31, 2023 (see Note 4). The Company also recorded an impairment loss of approximately $267,000 during the year ended December 31, 2023, related to implementation costs incurred under cloud computing hosting arrangements that were capitalized during the year. There were no other impairment losses on long-lived assets for the years ended December 31, 2023 and 2022.

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

Fair Value Measurements

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

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

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

The fair value of the contingent warrant liability that became issuable upon the closing of the private placements the Company closed on during 2022, the warrant inducement the Company closed on during 2023 (see Note 9), and the subscription agreement liability that was recorded in connection with a subscription agreement (see Note 8) are valued using significant unobservable measures and other fair value inputs, and are therefore classified as Level 3 financial instruments.

The fair value of financial instruments measured on a recurring basis is as follows:

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

	As of December 31, 2022			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Contingent warrant liability	$ 14,021	—	—	$ 14,021

During the year ended December 31, 2023, in connection with the acquisition of Proteomedix, the Company recorded intangible assets, which were recognized at fair value (see Note 5). None of the Company's other non-financial assets or liabilities are recorded at fair value on a non-recurring basis. There were no transfers between levels during the periods presented.

The following table summarizes the activity for the subscription agreement liability, using unobservable Level 3 inputs, for the year ended December 31, 2023:

	Subscription Agreement Liability
Balance at December 31, 2022	$ —
Fair value upon issuance	729,900
Change in fair value	134,100
Balance at December 31, 2023	$ 864,000

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

The following table summarizes the activity for the contingent warrant liability, using unobservable Level 3 inputs, for the years ended December 31, 2023 and 2022:

	Contingent Warrant Liability
Balance at December 31, 2021	$ —
Fair value at issuance	75,431
Change in fair value	(61,410)
Balance at December 31, 2022	14,021
Fair value at issuance	25,837
Reclassification to equity	(129,184)
Change in fair value	91,967
Balance at December 31, 2023	$ 2,641

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financing as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity as a reduction of proceeds generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to expenses in the consolidated statements of operations and comprehensive loss.

Leases

The Company accounts for leases in accordance with ASC 842, *Leases*. The Company has one lease agreement for office space, which contains an initial term of two years with renewal options. The Company determines if an arrangement is a lease at inception. This determination generally depends on whether the arrangement conveys to the Company the right to control the use of an explicitly or implicitly identified asset for a period of time in exchange for consideration. Control of an underlying asset is conveyed to the Company if the Company obtains the rights to direct the use of and to obtain substantially all of the economic benefits from using the underlying asset.

Operating lease right of use assets and operating lease liabilities are recognized on the lease commencement date. Operating lease right of use assets represent the Company's right to use an underlying asset for the estimated lease term and operating lease liabilities represent the Company's present value of its future lease payments. In assessing its lease and determining its lease liability at lease commencement or upon modification, the Company was not able to readily determine the rate implicit for its lessee arrangements, and thus has used its incremental borrowing rate on a collateralized basis to determine the present value of the lease payments. The Company's right of use asset is measured as the balance of the lease liability plus or minus any prepaid or accrued lease payments and any unamortized initial direct costs. The operating lease payments are recognized as lease expense on a straight-line basis over the lease term, and are included in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss. Lease payments included in the measurement of the lease liability are comprised of fixed payments. If the Company's lease agreements include renewal option periods, the Company includes such renewal options in its calculation of the estimated lease term when it determines the options are reasonably certain to be exercised. When such renewal options are deemed to be reasonably certain, the estimated lease term determined under ASC 842 will be greater than the non-cancelable term of the contractual arrangement.

Leases with an initial term of 12 months or less are not recorded on the consolidated balance sheet and the Company recognizes lease expense for these leases on a straight-line basis over the lease term. The Company applies this policy to all underlying asset categories.

The Company additionally evaluates leases at their inception to determine if the leases are to be accounted for as an operating lease or a finance lease. Lease expense for operating leases is recognized on a straight-line basis over the lease term. Variable lease payments are recognized in the period in which the obligations for those payments are incurred. Lease expense for finance leases is bifurcated into two components, with the amortization expense component of the right-of-use asset recognized on a straight-line basis and the interest expense component recognized using the effective interest method over the lease term. The Company has no financing leases as of December 31, 2023 or 2022.

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

Defined Benefit Pension Plan

Proteomedix sponsors a defined benefit pension plan (the "Swiss Plan") covering its eligible Swiss employees. The Swiss Plan is government-mandated and provides retirement benefits based on employees' years of service and compensation levels. The Company recognizes an asset for the Swiss Plan's overfunded status or a liability for underfunded status in its consolidated balance sheets. Additionally, the Company measures its plan's assets and obligations that determine its funded status as of the end of the year and recognizes the changes in the funded status in the year in which the changes occur. Those changes are reported in accumulated other comprehensive loss in the accompanying consolidated statements of convertible redeemable preferred stock and stockholders' equity. The Company uses actuarial valuations to determine its pension and postretirement benefit costs and credits. The amounts calculated depend on a variety of key assumptions, including discount rates and expected return on plan assets. Current market conditions are considered in selecting these assumptions.

Collaborative Agreements

The Company periodically enters into strategic alliance agreements with counterparties to produce products and/or provide services to customers. Alliances created by such agreements are not legal entities, have no employees, no assets and have no true operations. These arrangements create contractual rights and the Company accounts for these alliances as a collaborative arrangement by reporting costs incurred and reimbursements received from transactions within research and development expense within the consolidated statements of operations and comprehensive loss.

Revenue Recognition

During the year ended December 31, 2023, the Company recorded approximately $59,000 of revenue, which was solely generated from Proteomedix development services from the period from the acquisition date of December 15, 2023, through December 31, 2023.

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

Completion of the service and satisfaction of the performance obligation under a SOW is typically evidenced by access to the data or test made available to the customer or any other form or applicable manner of delivery defined in the SOW. However, for certain SOWs under which work is performed pursuant to the customer's highly customized specifications, the Company has the enforceable right to bill the customer for work completed, rather than upon completion of the SOW. For those SOWs, the Company recognizes revenue over a period of time during which the work is performed based on the expended efforts (inputs). As the performance obligation under the SOW is satisfied, any amounts earned as revenue and billed to the customer are included in accounts receivable. Any revenues earned but not yet billed to the customer as of the date of the consolidated financial statements are recorded as contract assets and are included in prepaids and other current assets as of the financial statement date, and these amounts as of December 31, 2023 are not significant. Amounts recorded in contract assets are reclassified to accounts receivable in our consolidated financial statements when the customer is invoiced according to the billing schedule in the contract. Accounts receivable was approximately $87,000 and $150,000 as of December 15, 2023, the date of acquisition of Proteomedix (see Note 5), and December 31, 2023, respectively.

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

In circumstances where a SOW includes a variable consideration component, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method, depending on which method is expected to better predict the amount of consideration to which the Company will be entitled. The value of variable consideration is included in the transaction price if, and to the extent, it is probable that a significant reversal of the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. These estimates are reassessed each reporting period, as required, and any adjustment required is recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

Research and Development

The Company expenses the cost of research and development as incurred. Research and development expenses include costs incurred in funding research and development activities, license fees, and other external costs. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved. When billing terms under research and development contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations as of period end to those third parties. Accrual estimates are based on several factors, including the Company's knowledge of the progress towards completion of the research and development activities, invoicing to date under the contracts, communication from the research institution or other companies of any actual costs incurred during the period that have not yet been invoiced, and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical accrual estimates made by the Company have not been materially different from the actual costs (see Note 6).

In accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 730-10-25-1, *Research and Development,* costs incurred in obtaining licenses and patent rights are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. The licenses purchased by the Company (see Note 6) require substantial completion of research and development, regulatory and marketing approval efforts to reach commercial feasibility and have no alternative future use. Accordingly, the total purchase price for the licenses acquired is reflected as research and development on the Company's consolidated statements of operations and comprehensive loss.

Contingencies

Accruals are recorded for loss contingencies when it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously. Considering facts known at the time of the assessment, the Company determines whether potential losses are considered reasonably possible or probable and whether they are estimable. Based upon this assessment, the Company carries out an evaluation of disclosure requirements and considers possible accruals in the consolidated financial statements.

Stock-Based Compensation

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards to employees with graded-vesting schedules are recognized, using the accelerated attribution method, on a straight-line basis over the requisite service period for each separately vesting portion of the award.

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

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Expected Term — The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term. The simplified method is used as the Company has insufficient historical information to provide a basis for an estimate of the expected term.

Expected Volatility — Volatility is a measure of the amount by which the Company's share price has historically fluctuated or is expected to fluctuate (i.e., expected volatility) during a period. Due to the lack of an adequate history of a public market for the trading of the Company's common stock and a lack of adequate company-specific historical and implied volatility data, the Company computes stock price volatility over expected terms based on comparable companies' historical common stock trading prices. For these analyses, the Company has selected companies with comparable characteristics, including enterprise value, risk profiles, and position within the industry.

Common Stock Fair Value — The fair value of the common stock underlying the Company's stock options is based on the closing price of the Company's common stock, as reported by the Nasdaq Capital Market, on the grant date of the award.

Risk-Free Interest Rate — The Company bases the risk-free interest rate on the implied yield available on U.S. Treasury securities with a remaining term commensurate with the estimated expected term.

Expected Dividend — The Company has never declared or paid any cash dividends on its shares of common stock and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

The Company recognizes forfeitures of equity awards as they occur.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts expected to be realized by the use of a valuation allowance.

Comprehensive Loss

The Company is required to report all components of comprehensive loss, including net loss, in the accompanying consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss for the year ended December 31, 2023 is comprised of net loss, the effect of currency translation adjustments, and the change in pension benefit obligation. Net loss and comprehensive loss were the same for the year ended December 31, 2022.

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

Financial instruments

The Company determines the accounting classification of financial instruments that are issued, including its warrants and a subscription agreement, as either liability or equity, by first assessing whether the financial instruments are freestanding financial instruments, and if they meet liability classification in accordance with ASC 480, *Distinguishing Liabilities from Equity*, ("ASC 480"), and then in accordance with ASC 815-40, *Derivatives and Hedging – Contracts in Entity's Own Equity* ("ASC 815-40"). Under ASC 480-10, financial instruments are considered liability-classified if the instruments are mandatorily redeemable, obligate the issuer to settle the instruments or the underlying shares by paying cash or other assets, or must or may require settlement by issuing a variable number of shares.

If the instruments do not meet liability classification under ASC 480, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the financial instruments do not require liability classification under ASC 815-40, in order to conclude equity classification, the Company assesses whether the instruments are indexed to the Company's common stock and whether the instruments are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments are made, the Company concludes whether the instruments are classified as liability or equity. Liability-classified instruments are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. Equity-classified instruments are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Preferred Stock

The Company applies the guidance enumerated in ASC 480, when determining the classification and measurement of preferred stock. Preferred stock subject to mandatory redemption, if any, is classified as a liability and is measured at fair value. The Company classifies conditionally redeemable preferred stock, which includes preferred stock that features redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. At all other times, the Company classifies its preferred stock in stockholders' equity.

Treasury Stock

The Company records treasury stock activities under the cost method whereby the cost of the acquired stock is recorded as treasury stock.

Net Loss Per Share

Basic loss per share is computed by dividing the net loss applicable to common shares by the weighted average number of common shares outstanding during the period. The weighted average number of shares of common stock outstanding includes (i) pre-funded warrants because their exercise requires only nominal consideration for delivery of shares and (ii) the shares held in abeyance because there is no consideration required for delivery of the shares; it does not include any potentially dilutive securities or any unvested restricted stock of common stock. Certain restricted shares, although classified as issued and outstanding at December 31, 2023 are considered contingently returnable until the restrictions lapse and will not be included in the basic net loss per share calculation until the shares are vested. Unvested shares of the Company's restricted stock do not contain non-forfeitable rights to dividends and dividend equivalents. Diluted earnings per share is computed using the weighted average number of common shares and, if dilutive, potential common shares outstanding during the period. Potential common shares consist of the Company's Series A preferred stock, warrants, unvested restricted stock, and stock options. Diluted loss per share excludes the shares issuable upon the conversion of Series A preferred stock, as well as unvested restricted stock, common stock options and warrants, from the calculation of net loss per share if their effect would be anti-dilutive.

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

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

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

	Years Ended December 31,	
	2023	**2022**
Stock options	1,904,830	1,392,654
Warrants	7,899,661	5,264,274
Unvested restricted stock	256,580	—
Common stock issuable upon conversion of Series A preferred stock	5,709,935	—
Total	**15,771,006**	**6,656,928**

New Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures*. This ASU updates reportable segment disclosure requirements by requiring disclosures of significant reportable segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. This ASU is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Adoption of the ASU should be applied retrospectively to all prior periods presented in the financial statements. Early adoption is permitted. The Company is currently evaluating the impact that this guidance will have on its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740*): Improvements to Income Tax Disclosures*. This ASU requires disclosure of specific categories in the rate reconciliation and additional information for reconciling items that meet a quantitative threshold. The amendment also includes other changes to improve the effectiveness of income tax disclosures, including further disaggregation of income taxes paid for individually significant jurisdictions. This ASU is effective for annual periods beginning after December 15, 2024. Adoption of this ASU should be applied on a prospective basis. Early adoption is permitted. The Company is currently evaluating the impact that this guidance will have on its consolidated financial statements.

The Company's management does not believe that any other recently issued, but not yet effective, accounting standards, if currently adopted, would have a material effect on the accompanying consolidated financial statements.

Note 4 — Balance Sheet Details

Inventories

Inventories primarily relate to ENTADFI® product and consisted of the following as of December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Raw materials	$ 139,208	$ -
Work-in-process	194,805	-
Finished goods	30,039	-
Total	**$ 364,052**	**$ -**

Note 4 — Balance Sheet Details (cont.)

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Prepaid insurance	$ 122,004	$ 148,789
Prepaid regulatory fees	312,551	-
Prepaid research and development	89,195	231,981
Prepaid professional fees	70,708	-
Prepaid other	175,695	88,462
Total	**$ 770,153**	**$ 469,232**

Intangible Assets

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

	Cost	Impairment	Effect of Currency Translation	Balance
Cost basis:				
Trade name	$ 9,018,000	$ —	$ 294,739	$ 9,312,739
Product rights for developed technology	28,447,771	(14,610,128)	344,514	14,182,157
Customer relationships	1,891,000	—	61,803	1,952,803
Total	**$ 39,356,771**	**$ (14,610,128)**	**$ 701,056**	**$ 25,447,699**

	Amortization	Balance
Accumulated amortization:		
Trade name	$ —	$ —
Product rights for developed technology	(31,213)	(31,213)
Customer relationships	(5,599)	(5,599)
Total	**$ (36,812)**	**$ (36,812)**
Intangible assets, net		**$ 25,410,887**

The finite lived intangible assets held by the Company, which includes customer relationships and product rights for developed technology, are being amortized over their estimated useful lives, which is 15 years for customer relationships, and 15 and 6 years for product rights for developed technology related to Proclarix and ENTADFI, respectively. Amortization expense related to intangible assets was approximately $37,000 for the year ended December 31, 2023, of which approximately $31,000 and $6,000 was recorded as cost of revenue and selling, general, and administrative expenses, respectively, in the accompanying consolidated statements of operations and comprehensive loss.

During the fourth quarter of 2023, the Company determined that there were certain triggering events that indicated that the carrying amount of the assets recorded in connection with the ENTADFI acquisition (see Note 5) may not be fully recoverable. Specifically, as a result of the Proteomedix acquisition (see Note 5) and continued significant cash constraints, the Company decided to pause the commercialization of ENTADFI until a later date, and consider strategic alternatives, which combined, decreased the cash flows expected to be generated from these assets. The Company performed an undiscounted cash flow analysis over the ENTADFI asset group and determined that the carrying value of the asset group is not recoverable. The Company then estimated the fair value of the asset group to measure the impairment loss. Significant assumptions used to determine this non-recurring fair value measurement include projected sales driven by market share and product sales price estimates, associated expenses, growth rates, the discount rate used to measure the fair value of the net cash flows associated with this asset group, as well as Management's estimates of the probability of each potential strategic alternative taking place. The Company recorded an impairment charge of $14.7 million during the year ended December 31, 2023, which was allocated on a pro rata basis across the assets within the asset group as follows: approximately $14.6 million and approximately $0.1 million was allocated to the product rights intangible asset and other assets, respectively. After recording this impairment charge, the long-lived assets in the ENTADFI asset group have a remaining carrying amount of approximately $3.3 million as of December 31, 2023. In addition, the Company also recorded an impairment charge on acquired ENTADFI inventory, see Note 3.

Note 4 — Balance Sheet Details (cont.)

Future annual amortization expense related to the Company's finite lived intangible assets is as follows as of December 31, 2023:

Years ending December 31,	
2024	$ 1,012,870
2025	1,326,837
2026	1,326,837
2027	1,326,837
2028	1,326,837
Thereafter	9,777,930
Total	**$ 16,098,148**

As of December 31, 2023, the weighted-average remaining amortization period for intangible assets was approximately 13.5 years.

Trade names, which do not have legal, regulatory, contractual, competitive, economic, or other factors that limit the useful lives are considered indefinite lived assets and are not amortized but are tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. As of December 31, 2023, $9.3 million of intangible assets relate to a trade name that has been identified as having an indefinite life.

Goodwill

Goodwill was recorded during the year ended December 31, 2023, in connection with the Proteomedix acquisition (see Note 5), and consisted of the following as of December 31, 2023:

	December 31, 2023
Balance as of December 31, 2022	$ —
PMX Transaction goodwill	53,914,055
Effect of currency translation	1,762,087
Balance as of December 31, 2023	**$ 55,676,142**

Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Accrued research and development	$ 616,707	$ 847,747
Accrued compensation	487,579	1,132,859
Accrued deferred offering costs	125,000	125,000
Accrued professional fees	550,415	—
Accrued implementation fees	93,787	—
Other accrued expenses	265,849	125,922
Accrued franchise taxes	60,530	177,600
Total	**$ 2,199,867**	**$ 2,409,128**

Note 5 — Acquisitions

ENTADFI®

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

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

Note 5 — Acquisitions (cont.)

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

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

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

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

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

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

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

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

Note 5 — Acquisitions (cont.)

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

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

In accordance with ASC 805-50, the acquired inventory was recorded at fair value. The remaining consideration transferred was allocated to the ENTADFI® intangible asset, which will be amortized over its estimated useful life, starting when ENTADFI® sales begin. Acquired inventory is comprised of work-in-process and raw materials. The fair value of work-in-process inventory was determined based on an estimated sales price of the finished goods, adjusted for costs to complete the manufacturing process, costs of the selling effort, a reasonable profit allowance for the remaining manufacturing and selling effort, and an estimate of holding costs, and resulted in a fair value adjustment of approximately $0.3 million. The fair value of raw materials was determined to approximate replacement cost. The Company recorded an impairment charge on the ENTADFI asset group of $14.7 million during the fourth quarter of 2023 (see Note 4), as well as an impairment charge on the ENTADFI acquired inventory of approximately $1.2 million, which included impairment of 100% of the acquired work-in-process inventory.

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

WraSer:

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

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

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

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

Note 5 — Acquisitions (cont.)

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

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

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

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

Proteomedix

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

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

Note 5 — Acquisitions (cont.)

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

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

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

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

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

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

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

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

Note 5 — Acquisitions (cont.)

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

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

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

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

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

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

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

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

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

Note 5 — Acquisitions (cont.)

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

The Company recognized approximately $1.5 million of acquisition related costs that were expensed during 2023, including the fair value of the subscription agreement liability, which was a closing condition for the PMX Transaction (see Note 8). These costs are included in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

The amounts of revenue and loss of Proteomedix, included in the Company's consolidated statements of operations and comprehensive loss from the Acquisition Date through December 31, 2023 are as follows:

Revenue	$ 58,465
Net loss	$ 315,688

The following summary, prepared on a pro forma basis, presents the Company's unaudited consolidated results of operations for 2023 and 2022 as if the PMX Transaction had been completed as of January 1, 2022. The pro forma results below include the impact of amortization of intangible assets. This pro forma information is presented for illustrative purposes only, is not necessarily indicative of future results of operations and does not include any impact of transaction synergies. In addition, the pro forma results are not necessarily indicative of the results of operations that actually would have been achieved had the PMX Transaction been consummated as of that date:

	Unaudited For the Years Ended December 31,	
	2023	**2022**
Revenue	$ 2,601,310	$ 392,460
Net loss	38,577,046	16,326,247

Note 6 — Significant Agreements

Ology Bioservices, Inc. (which was later acquired by National Resilience, Inc.)

The Company entered into a Master Services Agreement ("Ology MSA"), dated July 19, 2019, with Ology, Inc. ("Ology") to provide services from time to time, including but not limited to technology transfer, process development, analytical method optimization, cGMP manufacture, regulatory affairs, and stability studies of biologic products. Pursuant to the Ology MSA, the Company and Ology shall enter into a Project Addendum for each project to be governed by the terms and conditions of the Ology MSA.

The Company entered into two Project Addendums as of December 31, 2023. The initial Project Addendum was executed on October 18, 2019, and the Company was required to pay Ology an aggregate of approximately $4 million. Due to unforeseen delays associated with COVID-19, the Company and Ology entered into a letter agreement dated January 9, 2020 to stop work on the project, at which point the Company had paid Ology $100,000 for services to be provided. The second Project Addendum was executed on May 21, 2021, and the Company is obligated to pay Ology an aggregate amount of approximately $2.8 million, plus reimbursement for materials and outsourced testing, which will be billed at cost plus 15%. During 2023 and 2022, the Company and Ology entered into contract amendments that resulted in a net decrease in the Company's obligations of approximately $137,000.

During the years ended December 31, 2023 and 2022, the Company incurred related research and development expenses of approximately $15,000 and $1,329,000, respectively, and had approximately $685,000 recorded as related accounts payable at December 31, 2023, and approximately $476,000 and $669,000 recorded as related accounts payable and accrued expenses, respectively, at December 31, 2022.

Note 6 — Significant Agreements (cont.)

Cincinnati Children's Hospital Medical Center

The Company entered into a license agreement (the "CHMC Agreement"), dated June 1, 2021, with Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center ("CHMC"). Under the terms of the CHMC Agreement, the Company holds an exclusive, worldwide license (other than the excluded field of immunization against, and prevention, control, or reduction in the severity of gastroenteritis caused by rotavirus and norovirus in China and Hong Kong) to certain specified patent and biological materials relating to the use of norovirus nanoparticles and practice processes that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing CHMC patents and related technology directed to a virus-like particle vaccine platform that utilizes nanoparticle delivery technology that may have potential broad application to develop vaccines for multiple infectious diseases. The term of the CHMC Agreement begins on the effective date and extends on a jurisdiction by jurisdiction and product by product basis until the later of: (i) the last to expire licensed patent; (ii) ten (10) years after the first commercial sale; or (iii) entrance onto the market of a biosimilar or interchangeable product. The Company is obligated to use commercially reasonable efforts to bring licensed products to market through diligent research and development, testing, manufacturing, and commercialization, to use best efforts to make all necessary regulatory filings and obtain all necessary regulatory approvals, to achieve milestones relating to development and sales, and report to CHMC on progress. The Company is obligated to pay certain milestone and royalty payments in the future, as the related contingent events occur. Specifically, the Company is obligated to pay CHMC a single-digit royalty on net sales, being 5%, 4% or 2% depending on the product, until the last valid claim covering a licensed product exists, at which point the royalty rates decrease by 50%. The Company is also obligated to pay up to a 25% royalty on any non-royalty sublicense revenue paid to the Company by any sublicensee. The CHMC Agreement also provides the Company with an option to license any CHMC or jointly patented modification, alteration or improvement of any invention claimed in a Licensed Patent ("CHMC Improvement" and "Joint Improvement, respectively"), with a $50,000 option fee for each Improvement that the Company elects to include in the license grant of the CHMC Agreement. In addition, the Company is required to pay CHMC milestone payments of up to an aggregate of $59.75 million; specifically, upon the achievement of specified development milestones of approximately $0.5 million, regulatory milestones of approximately $1.25 million, and commercial milestones of approximately $58.0 million.

The Company may terminate the CHMC Agreement for convenience at any time prior to first commercial sale of a product or process by providing one hundred and eighty (180) days' written notice to CHMC. It may also terminate for a CHMC uncured material breach. CHMC may terminate the CHMC Agreement for an uncured Company material breach or insolvency or bankruptcy. Pursuant to the terms of the CHMC Agreement, if the Company fails to achieve the milestones, and cannot mutually agree with CHMC on an amendment to the milestones, then CHMC will have the option of converting any and all of such exclusive licenses to nonexclusive licenses, to continue developing indications that have already entered development at any stage or in which the Company has invested in developing. CHMC may also terminate the CHMC Agreement to the fullest extent permitted by law in the countries of the worldwide territory, in the event the Company or its affiliates challenge or induce others set up challenges to the validity or enforceability of any of the Licensed Patents, as defined in the CHMC Agreement, and the Company will be obligated to reimburse CHMC for its costs, including reasonable attorneys' fees.

Oxford University Innovation Limited

In December 2018, the Company entered into an option agreement with Oxford University Innovation ("OUI"), which was a precursor to a license agreement (the "OUI Agreement"), dated July 16, 2019. Under the terms of the OUI Agreement, the Company held an exclusive, worldwide license to certain specified patent rights and biological materials relating to the use of epitopes of limited variability and virus-like particle products and practice processes that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for influenza. The Company was obligated to use its best efforts to develop and market Licensed Products, as defined in the OUI Agreement, in accordance with its development plan, report to OUI on progress, achieve certain milestones and was required to pay OUI nonrefundable milestone fees when it achieved them. Pursuant to the OUI Agreement, the Company was obligated to pay certain milestone and royalty payments in the future, as the related contingent events occur. Specifically, the Company was obligated to pay a 6% royalty on all net sales of licensed products, as defined in the OUI Agreement, with an annual minimum royalty payment of $250,000 starting post-product launch, until the expiration of the OUI Agreement or revocation of the last valid claim covering a licensed product, at which point a royalty rate of 3% will apply. An annual maintenance fee of $10,000 and $20,000 was required in the pre-phase III year and Phase III year, respectively, and as defined in the OUI Agreement. The Company was also obligated to pay a 25% royalty on any sums received by the Company from any sublicensee (including all up-front, milestone and other one-off payments received by the Company from any sub-licenses or other contracts granted by the Company with respect to the licensed technology). In addition, the Company was required to pay OUI milestone payments of up to an aggregate of $51.25 million; specifically, upon the achievement of specified development milestones of approximately $2.25 million, regulatory milestones of approximately $9.5 million, and commercial milestones of approximately $39.5 million.

Note 6 — Significant Agreements (cont.)

The OUI Agreement was to expire upon ten (10) years from the expiration of the last patent contained in the licensed patent rights, unless terminated earlier. Either party had the right to terminate the OUI Agreement for an uncured material breach. The Company was able to terminate the OUI Agreement for any reason at any time upon six months' written notice until July 16, 2022, which was the third anniversary of the OUI Agreement. OUI was able to terminate immediately if the Company had a petition presented for its winding-up or passed a resolution for winding up other than for a bona fide amalgamation or reconstruction or compounds with its creditors or had a receiver or administrator appointed. OUI could also terminate if the Company opposed or challenged the validity of any of the patents or applications in the Licensed Technology, as defined in the OUI Agreement; raised the claim that the know-how of the Licensed Technology was not necessary to develop and market Licensed Products; or in OUI's reasonable opinion, was taking inadequate or insufficient steps to develop or market Licensed Products and did not take any further steps that OUI requested by written notice within a reasonable time.

The Company terminated the agreements with Oxford during the year ended December 31, 2023, and amounts due upon termination were not significant.

St. Jude Children's Hospital

The Company entered into a license agreement (the "St. Jude Agreement"), dated January 27, 2020, and as amended on May 11, 2022 and March 22, 2023, with St. Jude Children's Research Hospital ("St. Jude"). Under the terms of the St. Jude Agreement, the Company held an exclusive, worldwide license to certain specified patent rights and biological materials relating to the use of live attenuated streptococcus pneumoniae and practice processes that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for streptococcus pneumoniae. The Company was obligated to pay certain milestone and royalty payments in the future, as the related contingent events occur. Specifically, pursuant to the terms of the St. Jude Agreement, as amended, the Company was obligated to make 5% royalty payments for each licensed product(s) sold by the Company or its affiliates, based on the net sales for the duration of the St. Jude Agreement, and also pay 15% of consideration received for any sublicenses. The Company was also required to pay an additional one-time $5,000 license fee, and an annual maintenance fee of $10,000 beginning on the first anniversary of the Effective Date (which was waived if all of the developmental milestones scheduled for completion before such annual fee is due have been achieved). In addition, the Company was required to pay St. Jude milestone payments of up to an aggregate of $1.9 million; specifically, upon the achievement of specified development milestones of $0.3 million, regulatory milestones of $0.6 million, and commercial milestones of $1.0 million.

The St. Jude Agreement was to expire upon the expiration of the last valid claim contained in the licensed patent rights, unless terminated earlier. The Company was obligated to use commercially reasonable efforts to develop and commercialize the licensed product(s) and included defined development milestones. If the Company failed to achieve the development milestones contained in the St. Jude Agreement, and if the Company and St. Jude failed to agree upon a mutually satisfactory revised timeline, St. Jude had the right to terminate the St. Jude Agreement. Either party was able to terminate the St. Jude Agreement in the event the other party (a) filed against it a petition under the Bankruptcy Act (among other things) or (b) failed to perform or otherwise breached its obligations under the St. Jude Agreement and did not cure such failure or breach within sixty (60) days. The Company was able to terminate for any reason on thirty (30) days written notice.

The Company terminated the agreement with St. Jude during the year ended December 31, 2023, and amounts due upon termination were not significant.

University of Texas Health Science Center at San Antonio

The Company entered into a patent and technology license agreement (the "UT Health Agreement"), dated November 18, 2022, with the University of Texas Health Science Center at San Antonio ("UT Health"). Under the terms of the UT Health Agreement, the Company held an exclusive, worldwide license (other than the excluded field of vectors, as defined in the UT Health Agreement) to certain specified patent rights relating to the development of a live attenuated, oral Chlamydia vaccine candidate. An initial non-refundable license fee of $100,000 was due upon execution of the agreement, and expensed during the year ended December 31, 2022, with subsequent annual license fees thereafter until expiration or termination of the UT Health agreement. Pursuant to the UT Health Agreement, the Company was obligated to pay certain milestone and royalty payments in the future, as the related contingent events occur. Specifically, the Company was obligated to pay UT a single-digit royalty on net sales, being 5% or 3% depending on whether the product was covered by a valid claim or not, as defined in the agreement. The Company was also obligated to pay a 20% royalty on any sums received by the Company from any sublicensee. In addition, the Company was required to pay UT Health milestone payments of up to an aggregate of approximately $2.2 million; specifically, upon the achievement of specified development milestones of approximately $0.7 million and regulatory milestones of approximately $1.5 million.

Note 6 — Significant Agreements (cont.)

The UT Health Agreement was to expire upon the expiration of the last date of expiration or termination of the patent rights, unless terminated earlier. Under the UT Health Agreement, the Company had the right to terminate the UT Health Agreement for convenience, by providing 90 days' written notice to UT Health. UT Health was able to terminate the UT Health Agreement in the event the Company (a) became arrears in payment due and did not make payment within 30 days after notification from UT Health or (b) was in breach of any non-payment provision and does not cure such breach within 60 days after notification from UT Health or (c) UT Health delivered notice to the Company of three or more actual material breaches of the UT Health Agreement in any 12-month period or (d) in the event the Company or its affiliates initiated any proceeding or action to challenge the validity, enforceability, or scope of any of the licensed patents.

The Company terminated the agreement during the year ended December 31, 2023, and amounts due upon termination were not significant.

Co-development Agreement with AbVacc, Inc.

On February 1, 2023, the Company entered into a co-development agreement (the "Co-Development Agreement") with AbVacc, Inc. ("AbVacc"), for the purpose of conducting research aimed at co-development of specific vaccine candidates, including monkeypox and Marburg virus disease with the potential to expand to others using the Norovirus nanoparticle platform ("Co-Development Project"), and to govern the sharing of materials and information, as defined in the Co-Development Agreement, for the Co-Development Project. Under the Co-Development Agreement, AbVacc and the Company will collaborate, through a joint development committee, to establish and implement a development plan or statement of work for each Co-Development Project targeted product. Under the Co-Development Agreement, either the Company or AbVacc, whichever party is the primary sponsor of any resulting product (as defined in the Co-Development Agreement), will be obligated to compensate the other party for certain milestone payments that would range between $2.1 million and $4.75 million, plus royalties of between 2% to 4%. There is no fixed obligation for either party, and each party will be responsible for their own costs. The term of the Co-Development Agreement is three years from the effective date, unless previously terminated by either party, in accordance with the Co-Development Agreement. During the year ended December 31, 2023, the Company incurred approximately $21,000 in costs for research and development related to the Co-Development Agreement. As of December 31, 2023, the Company evaluated the likelihood of the Company achieving the specified milestones and generating product sales and determined that the likelihood is not yet probable and as such no accrual of these payments is required as of December 31, 2023.

Services Agreement

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

Note 6 — Significant Agreements (cont.)

Laboratory Corporation of America

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

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

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

Note 7 — Notes Payable

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

The Company imputed interest on the Notes using an average discount rate of 8.2% and recorded a debt discount of approximately $1.1 million at the issuance date. The debt discount is reflected as a reduction in the carrying amount of the Notes and amortized to interest expense through the respective maturity dates, using the effective interest method. The Company recorded approximately $0.7 million of associated interest expense during the year ended December 31, 2023. The unamortized debt discount as of December 31, 2023 was approximately $0.4 million.

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

To determine the fair value of the Series A Preferred Stock, the Company first derived the business enterprise value ("BEV") using a discounted cash flow method. The BEV was adjusted to an equity value assuming $3.0 million of debt converted to Series A Preferred Stock, which was then allocated across the Company's securities. The concluded value for the Series A Preferred Stock utilized the Black-Scholes option pricing model, which was classified as level 3 in the valuation hierarchy due to the presence of significant unobservable inputs. The following key assumptions were used in the model: volatility rate of 100%, risk free interest rate of 4.6%, 5.0 year expected term, and the Company's aggregate equity value. The volatility was based on the historical and implied volatility of a peer group and the risk-free interest rate was based on the implied yield available on U.S. Treasury securities with a term commensurate with the estimated expected term.

Future minimum principal payments on the Notes as of December 31, 2023, includes $10 million in principal payments that are due in 2024.

The Company also assumed an obligation in the amount of 100,000 CHF, in connection with the Proteomedix acquisition. This obligation relates to a loan from an investor that was advanced to Proteomedix in March 2010. This loan bears no interest, is unsecured and may be cancelled by the Company at its discretion, however it is the intent of the Company to repay this loan in the future. The loan payable, in the amount of approximately $119,000, is included in long term note payable in the accompanying consolidated balances sheet as of December 31, 2023.

Note 8 — Subscription Agreement

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

The Subscription Agreement is accounted for as a liability in accordance with ASC 480, as the make-whole provision could result in a variable number of shares being issued upon settlement. The subscription agreement liability is measured at fair value at the commitment date and at each subsequent reporting period, with changes in fair value recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company recorded the fair value of the Subscription Agreement liability at the issuance date of approximately $0.8 million, as an acquisition related cost, as the Subscription Agreement was a condition to close the PMX Transaction (see Note 5). As of December 31, 2023, the fair value of the subscription agreement liability is estimated to be approximately $0.9 million, determined using a Monte-Carlo option pricing model, and the Company estimated a 55.0% probability that the Subscription Agreement will close. The significant assumptions used in the Monte-Carlo model, which utilizes Level 3 inputs (see Note 3), are as follows as of the commitment date and at December 31, 2023:

	December 18, 2023	December 31, 2023
Exercise price	$ 0.25	$ 0.25
Term (years)	1.5	1.2
Expected stock price volatility	100%	95%
Risk-free rate of interest	4.64%	4.64%

Note 9 — Convertible Redeemable Preferred Stock and Stockholders' Equity

Authorized Capital

As of December 31, 2023 and 2022, the Company is authorized to issue 250,000,000 shares and 10,000,000 shares of common stock and preferred stock, respectively, with a par value of $0.00001 for both common stock and preferred stock. As of December 31, 2023, the Company had designated and authorized the issuance of up to 1,150,000 shares, 10,000 shares, and 2,700,000 shares of Series Seed Preferred Stock, Series A Preferred Stock, and Series B Preferred Stock, respectively.

On February 23, 2022, in connection with the closing of the IPO, the Company filed with the Secretary of State of the State of Delaware an amended and restated certificate of incorporation (the "A&R COI"), which became effective immediately. There was no change to the Company's authorized shares of common stock and preferred stock or the par value. Prior to this amendment, the Company had designated 1,150,000 shares of preferred stock, with par value $0.00001 per share. In addition, on February 23, 2022 and in connection with the closing of the IPO, the Company's board of directors adopted Amended and Restated Bylaws.

Preferred Stock

Series A Convertible Preferred Stock

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

On October 3, 2023, the Company issued 3,000 shares of Series A Convertible Preferred Stock in exchange for the settlement of $3.0 million in notes payable due to Veru, Inc. (see Notes 5 and 7). The significant terms of the Series A Preferred Stock are as follows:

Voting – The shares of Series A Preferred Stock carry no voting rights, except as to certain significant matters specified in the Series A Certificate of Designations.

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

Redemption - Onconetix shall have the right to redeem in cash any outstanding shares of Series A Preferred Stock along with accrued but unpaid dividends beginning immediately after issuance of such shares of Preferred Stock. The holder of the Series A Preferred Stock shall not under any circumstances have any right to require redemption.

Liquidation Preference - Each share of Series A Preferred Stock will have a liquidation preference equal to the stated value (initially $1,000 per share), plus any accrued but unpaid dividends thereon (the "Liquidation Preference"). In the event of a liquidation, dissolution or winding up of the Company (which shall include any merger, reorganization, sale of assets in which control of Onconetix is transferred or event which results in all or substantially all of the Company's assets being transferred), the holders of the Series A Preferred Stock shall be entitled to receive out of the assets of the Company, before any payment is made to the holders of common stock and either in preference to or pari pasu with the holders of any other series of preferred stock that may be issued in the future, a per share amount equal to the Liquidation Preference. Any remaining assets of the Company following payment of the Liquidation Preference to the holders of Series A Preferred Stock shall be distributed to the holders of the Corporation's common stock and any junior series of preferred stock then outstanding.

Dividends - The holders of Series A Preferred Stock shall be entitled to receive dividends on shares of Series A Preferred Stock (on an as-if-converted-to-common-stock basis) equal to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends shall be paid on shares of Series A Preferred Stock.

Conversion - Each share of Series A Preferred Stock shall automatically convert into common stock of the Company one year from the date of issuance, if the required stockholder approval is obtained. If this approval is not obtained, then the Series A Preferred Stock is convertible, at the option of the holder, at any time and from time to time from and after one year from the date of issuance into that number of shares of common stock (subject to certain limitations) determined by dividing the Stated Value by the Conversion Price. If the required vote discussed above is not obtained, and the Series A Preferred Stock is converted at the option of the holder, the Company may not issue a number of shares of common stock which, would exceed 19.99% shares of common stock (subject to adjustment for forward and reverse stock splits, recapitalizations and the like). The Conversion Price, which is subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization and other adjustments, as defined in the Series A Certificate of Designations, is initially $0.5254. The maximum number of shares that the Series A Preferred Stock is convertible into, based on the Conversion Price as of December 31, 2023 is approximately 5,709,935 shares of the Company's common stock.

The Company evaluated the terms of the Series A Preferred Stock, and in accordance with the guidance of ASC 480, the Series A Preferred Stock is classified as permanent equity in the accompanying consolidated balance sheet. The Series A Preferred Stock was recorded at its fair value as of the issuance date (see Note 7).

Series B Convertible Preferred Stock

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

On December 15, 2023, in connection with the PMX Transaction, as part of the purchase consideration, the Company issued 2,696,729 shares of Series B Convertible Preferred Stock (see Note 5). The significant terms of the Series B Preferred Stock are as follows:

Voting - The shares of Series B Preferred Stock carry no voting rights except with respect to the election of the Proteomedix Director (as defined in the Certificate of Designations) and except as to certain significant matters specified in the Series B Certificate of Designations.

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

Liquidation Preference - Upon a liquidation, dissolution or winding-up of Onconetix, whether voluntary or involuntary, the holders of Series B Preferred Stock shall be entitled to receive out of the assets, whether capital or surplus, of Onconetix, the same amount that a holder of common stock would receive if such holder's Series B Preferred Stock were fully converted to common stock at the effective conversion ratio, 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 common stock.

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

Conversion - Following Stockholder Approval, each share of Series B Preferred Stock shall be converted into shares of common stock (the "Conversion Shares") at a ratio of 100 Conversion Shares for each share of Series B Preferred Stock (the "Conversion Ratio"). All shares of Series B 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 Common Stock issuable upon Conversion in excess of 20% of the issued and outstanding Common Stock on the Closing Date and (ii) Onconetix has effected an increase in the number of shares of Common Stock authorized under its certificate of incorporation, to the extent required to consummate the PMX Transaction. The Conversion ratio is subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization and other adjustments, as defined in the Series B Certificate of Designations The Series B Preferred Stock is initially convertible into approximately 269,672,900 shares of the Company's common stock.

Cash Settlement - If, at any time after the earlier of the date of the Stockholder Approval or January 1, 2025 (the earliest such date, Onconetix (x) has obtained the Stockholder Approval but fails to deliver certificates representing the Conversion Shares, or other documentation as required under the terms of the Share Exchange Agreement, or (y) has failed to obtain the Stockholder Approval, Onconetix shall, at the request of the holder, pay to such holder an amount in cash equal to (i) the Fair Value (as defined below) of the shares of Series B 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. "Fair Value" of shares shall be fixed with reference to the last reported closing stock price on the principal trading market of the Common Stock on which the Common Stock is listed as of the trading day on which the request is delivered to Onconetix.

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

The Company evaluated the terms of the Series B Preferred Stock, and in accordance with the guidance of ASC 480, the Series B Preferred Stock is classified as temporary equity in the accompanying consolidated balance sheet, as the shares may be redeemable by the holders for cash, upon certain conditions that are not within the control of the Company. Additionally, the Company does not control the actions or events necessary to deliver the number of required shares upon exercise by the holders of the conversion feature. The Series B Preferred Stock was recorded at its fair value as of the issuance date (see Note 5). The Series B Preferred Stock is not currently redeemable or probable of becoming redeemable because it is subject to, among other things, Stockholder Approval as described above, and therefore the carrying amount is not currently accreted to its redemption value as of December 31, 2023.

Series Seed Convertible Preferred Stock

The Company has 1,150,000 shares of preferred stock designated as Series Seed Preferred Stock ("Series Seed") and there are no shares of Series Seed outstanding as of December 31, 2023 and 2022.

Prior to the closing of the IPO in 2022, there were 1,146,138 shares of Series Seed issued and outstanding. Each share of the Series Seed was convertible, at the option of the holder, at a conversion price of $1.52 per share, subject to certain adjustments. The holders of the Series Seed were entitled to receive cumulative dividends at a per share rate of 8% per annum, compounded annually. Each Series Seed share was automatically convertible into common stock of the Company, at the then-effective conversion price, upon the closing of a firmly underwritten public offering netting proceeds of at least $50 million with an offering price of at least three hundred percent (300%) of the Original Issue Price of the Series Seed. On February 18, 2022, the majority of the holders of the Series Seed approved the automatic conversion of the outstanding shares of the Series Seed and all related accrued and unpaid dividends, upon the closing of the IPO. The number of shares of Common Stock to be issued upon the closing of the IPO pursuant to the conversion were to be calculated in accordance with the original conversion terms provided by the Company's Amended and Restated Certificate of Incorporation ("COI") dated July 1, 2019. This conversion occurred on February 23, 2022, upon the closing of the Company's IPO. Also, upon the close of the IPO, aggregate cumulative dividends of $1,586,162, or $1.38 per Series Seed share, were automatically converted into shares of common stock. There were an aggregate of 5,626,365 shares of common stock issued upon conversion of the Series Seed shares and cumulative dividends as of the close of the IPO.

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

Common Stock

As of December 31, 2023 and 2022, there were 22,841,975 and 15,724,957 shares of common stock issued, respectively, and 22,324,576 and 15,265,228 shares of common stock outstanding, respectively.

Holders of the Company's common stock are entitled to one vote for each share held of record, and are entitled upon liquidation of the Company to share ratably in the net assets of the Company available for distribution after payment of all obligations of the Company and after provision has been made with respect to each class of stock, if any, having preference over the common stock. The shares of common stock are not redeemable and have no preemptive or similar rights.

On December 15, 2023, in connection with the Proteomedix acquisition, the Company issued 3,675,414 shares of the Company's common stock as part of the purchase consideration (see Note 5).

On February 17, 2022, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Boustead Securities, LLC, acting as representative of the underwriters ("Boustead"), in relation to the Company's IPO, pursuant to which the Company agreed to sell to the underwriters an aggregate of 2,222,222 shares of the Company's common stock, at a price of $9.00 per share. The IPO closed on February 23, 2022 and resulted in net proceeds to the Company, after deducting the 8% underwriting discount, and other offering costs, of approximately $17.1 million.

Pursuant to the Underwriting Agreement, the Company issued to Boustead warrants to purchase 111,111 shares of common stock, exercisable for five years at the option of the holder, at a per share exercise price equal to $10.35. The Company evaluated the terms of the warrants issued at the close of the IPO and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480 and ASC 815-40. Since the Company determined that the warrants were equity-classified, the Company recorded the proceeds from the IPO, net of issuance costs, within common stock at par value and the balance of the net proceeds to additional paid in capital.

During October 2022, in connection with a settlement agreement that was entered into with Boustead, these warrants were exchanged for 93,466 shares of restricted common stock ("the Warrant Exchange") (see Note 10). The Warrant Exchange was accounted for as a modification of the warrant, with an incremental fair value of approximately $10,000, which was recorded as selling, general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss. In addition, 200,000 restricted shares of common stock were issued to Boustead upon execution of an advisory agreement, which was entered into concurrent with the settlement agreement. The fair value of the restricted shares of common stock, which had no vesting provisions, was valued at $254,000, and was recorded as selling, general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss.

The restricted shares of common stock issued under the settlement and advisory agreements with Boustead was valued based on the closing trading price on the date the agreements were executed, adjusted to reflect the effect of the restriction on the sale of the common stock. The value of the restriction was measured using the Black-Scholes model to measure the discount for lack of marketability, using the following assumptions: expected term of 0.5 years, expected volatility of 96.36%, risk-free interest rate of 4.09% and dividend yield of 0.0%.

Treasury Stock

On November 10, 2022, the board of directors approved a stock repurchase program (the "Repurchase Program") to allow the Company to repurchase up to 5 million shares of common stock with a maximum price of $1.00 per share, with discretion to management to make purchases subject to market conditions. On November 18, 2022, the board of directors approved an increase to the maximum price to $2.00 per share. There is no expiration date for this program.

During the year ended December 31, 2023, the Company repurchased 57,670 shares of common stock, for an aggregate of approximately $59,000, at an average price of $1.02 per share. During the year ended December 31, 2022, the Company repurchased 459,729 shares of common stock at an average price of $1.23 per share, for approximately $0.6 million. Shares that are repurchased are classified as treasury stock pending future use and reduce the number of shares outstanding used in calculating earnings per share. As of December 31, 2023, there are approximately 4.5 million shares remaining, that can be repurchased under the Repurchase Program.

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

Private Investments in Public Equity

April 2022 Private Placement

On April 19, 2022, the Company consummated the closing of a private placement (the "April 2022 Private Placement"), pursuant to the terms and conditions of a securities purchase agreement, dated as of April 13, 2022. At the closing of the April 2022 Private Placement, the Company issued 590,406 shares of common stock, pre-funded warrants to purchase an aggregate of 590,406 shares of common stock and preferred investment options to purchase up to an aggregate of 1,180,812 shares of common stock. The purchase price of each share of common stock together with the associated preferred investment option was $6.775, and the purchase price of each pre-funded warrant together with the associated preferred investment option was $6.774. The aggregate net cash proceeds to the Company from the April 2022 Private Placement were approximately $6.9 million, after deducting placement agent fees and other offering expenses. The pre-funded warrants had an exercise price of $0.001 per share and were exercised in full on May 24, 2022. The preferred investment options, which had an exercise price of $6.65 per share, were exchanged in connection with the August 2022 Private Placement. See *August 2022 Private Placement* below for further detail.

H.C. Wainwright & Co., LLC ("Wainwright") acted as the exclusive placement agent for the April 2022 Private Placement. The Company agreed to pay Wainwright a placement agent fee and management fee equal to 7.5% and 1.0%, respectively, of the aggregate gross proceeds from the April 2022 Private Placement and reimburse certain out-of-pocket expenses up to an aggregate of $85,000. In addition, the Company issued warrants to Wainwright (the "April Wainwright Warrants") to purchase up to 70,849 shares of common stock. The Wainwright Warrants are in substantially the same form as the preferred investment options, except that the exercise price is $8.46875. The form of the preferred investment options is a warrant, and as such the preferred investment options, the pre-funded warrants, and the Wainwright Warrants are collectively referred to as the "April 2022 Private Placement Warrants". Further, upon any exercise for cash of any preferred investment options, the Company agreed to issue to Wainwright additional warrants to purchase the number of shares of common stock equal to 6.0% of the aggregate number of shares of common stock underlying the preferred investment options that have been exercised, also with an exercise price of $8.46875 (the "April Contingent Warrants"). The maximum number of April Contingent Warrants issuable under this provision of 70,849 were exchanged in connection with the August 2022 Private Placement. See *August 2022 Private Placement* below for further detail.

The Company evaluated the terms of the April 2022 Private Placement Warrants and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480 and ASC 815-40. Since the Company determined that the April 2022 Private Placement Warrants were equity-classified, the Company recorded the proceeds from the April 2022 Private Placement, net of issuance costs, within common stock at par value and the balance of the net proceeds to additional paid in capital.

The Company evaluated the terms of the April Contingent Warrants and determined that they should be classified as a liability based upon accounting guidance provided in ASC 815-40. Since the April Contingent Warrants are a form of compensation to Wainwright, the Company recorded the value of the liability of approximately $36,000, as a reduction of additional paid in capital, with subsequent changes in the value of the liability recorded in other income (expense) in the accompanying consolidated statements of operations and comprehensive loss. The Company measured the liability upon the close of the April Private Placement using a Monte Carlo simulation, using the following significant assumptions: expected term of 4.0 years, expected volatility of 117.0%, risk-free interest rate of 4.00% and dividend yield of 0.0%.

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

August 2022 Private Placement

On August 11, 2022, the Company consummated the closing of a private placement (the "August 2022 Private Placement"), pursuant to the terms and conditions of a securities purchase agreement, dated as of August 9, 2022. At the closing of the August 2022 Private Placement, the Company issued 1,350,000 shares of common stock, pre-funded warrants to purchase an aggregate of 2,333,280 shares of common stock and preferred investment options to purchase up to an aggregate of 4,972,428 shares of common stock. The purchase price of each share of common stock together with the associated preferred investment option was $2.715, and the purchase price of each pre-funded warrant together with the associated preferred investment option was $2.714. The aggregate net cash proceeds to the Company from the August 2022 Private Placement were approximately $8.7 million, after deducting placement agent fees and other offering expenses. In addition, the investors in the August 2022 Private Placement, who are the same investors from the April 2022 Private Placement, agreed to cancel preferred investment options to purchase up to an aggregate of 1,180,812 shares of the Company's common stock issued in April 2022. The pre-funded warrants had an exercise price of $0.001 per share. During 2022, an aggregate of 1,686,640 of the pre-funded warrants were exercised. The remaining 646,640 of pre-funded warrants were exercised during the year ended December 31, 2023. The preferred investment options are exercisable at any time on or after August 11, 2022 through August 12, 2027, at an exercise price of $2.546 per share, subject to certain adjustments as defined in the agreement. During the year ended December 31, 2023, 2,486,214 of these preferred investment options were exercised at a reduced exercise price of $1.09, in connection with the warrant inducement transaction discussed below. As of December 31, 2023, 2,486,214 preferred investment options are outstanding.

Wainwright acted as the exclusive placement agent for the August 2022 Private Placement. The Company agreed to pay Wainwright a placement agent fee and management fee equal to 7.5% and 1.0%, respectively, of the aggregate gross proceeds from the August 2022 Private Placement and reimburse certain out-of-pocket expenses up to an aggregate of $85,000. In addition, the Company issued warrants to Wainwright (the "August Wainwright Warrants") to purchase up to 220,997 shares of common stock. The August Wainwright Warrants are in substantially the same form as the preferred investment options, except that the exercise price is $3.3938. The form of the preferred investment options is a warrant, and as such the preferred investment options, the pre-funded warrants, and the August Wainwright Warrants are collectively referred to as the "August 2022 Private Placement Warrants". Further, upon any exercise for cash of any preferred investment options, the Company agreed to issue to Wainwright additional warrants to purchase the number of shares of common stock equal to 6.0% of the aggregate number of shares of common stock underlying the preferred investment options that have been exercised, also with an exercise price of $3.3938 (the "August Contingent Warrants"). The maximum number of August Contingent Warrants issuable under this provision is 298,346, which includes 70,849 of April Contingent Warrants that were modified in connection with the August 2022 Private Placement.

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

The Company evaluated the terms of the August 2022 Private Placement Warrants and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480 and ASC 815-40. Since the Company determined that the August 2022 Private Placement Warrants were equity-classified, the Company recorded the proceeds from the August 2022 Private Placement, net of issuance costs, within common stock at par value and the balance of the net proceeds to additional paid in capital.

The investors in the April 2022 Private Placement agreed to cancel the aggregate of 1,180,812 preferred investment options issued in the April 2022 Private Placement, as part of their participation in the August 2022 Private Placement. The preferred investment options that were cancelled were effectively exchanged for 1,289,148 new preferred investment options in the August 2022 Private Placement, and accordingly have been accounted for as a modification or exchange of equity-linked instruments. In accordance with ASC 815-40, as the preferred investment options were classified as equity instruments before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the exchange as an equity issuance cost. The increase in the fair value of the preferred investment options as a result of the exchange was approximately $860,000, and was determined using the Black-Scholes option pricing model, with the following assumptions:

	Original	Exchanged
Exercise price	$ 6.65	$ 2.546
Term (years)	3.67	5.0
Expected stock price volatility	116.2%	120.2%
Risk-free rate of interest	3.16%	2.98%

The Company evaluated the terms of the August Contingent Warrants and determined that they should be classified as a liability based upon accounting guidance provided in ASC 815-40. As a result of the exchange of the preferred investment options issued in the April Private Placement, the underlying equity-linked instruments that would trigger issuance of the April Contingent Warrants was replaced, and therefore the 70,849 of April Contingent Warrants were exchanged for 70,849 of the August Contingent Warrants. The value of the April Contingent Warrant liability was adjusted to fair value on the date of modification, using a Monte Carlo simulation, with the change in fair value of approximately $8,000 recognized in the accompanying consolidated statements of operations and comprehensive loss. The remaining 227,497 August Contingent Warrants were measured as a liability upon the close of the August Private Placement. Since the Contingent Warrants are a form of compensation to the placement agent, the Company recorded the value of the liability of approximately $39,000, as a reduction of additional paid in capital. The entire 298,346 of August Contingent Warrants were remeasured at December 31, 2022, using a Monte Carlo simulation, with the change in the value of the liability recorded in other income (expense) in the accompanying consolidated statements of operations and comprehensive loss. The following significant assumptions were used in the valuation of the contingent warrant liability, related to the August Contingent Warrants, as of the date of the August 2022 Private Placement and as of December 31, 2022:

	August 11, 2022	December 31, 2022
Exercise price	$ 3.3938	$ 3.3938
Term (years)	5.00	4.61
Expected stock price volatility	127.8%	120.8%
Risk-free rate of interest	2.98%	4.03%

During the year ended December 31, 2023, in connection with the warrant inducement transaction, the Company issued warrants to Wainwright as settlement of the contingent warrant liability associated with 149,173 of the August 2022 Contingent Warrants, which was triggered upon exercise of the underlying preferred investment options. See *Warrant Inducement* below for further discussion.

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

At the Market Offering Agreement

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

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

As of December 31, 2023, no shares have been sold under the ATM Offering.

Warrant Inducement

On July 31, 2023, the Company entered into a common stock preferred investment options exercise inducement offer letter (the "Inducement Letter") with a holder (the "Holder") of existing preferred investment options ("PIOs") to purchase shares of the Company's common stock at the original exercise price of $2.546 per share, issued on August 11, 2022 (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 (the "Inducement PIO Shares"), at a reduced exercised price of $1.09 per share, in exchange for the Company's agreement to issue new preferred investment options (the "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 transactions contemplated by the Inducement Letter (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.

Upon the close of the transaction, the Company issued the Holder 1,575,000 of the 2,486,214 shares of common stock that were issuable upon exercise of the Existing PIOs. Due to the beneficial ownership limitation provisions in the Inducement Letter, the remaining 911,214 shares were initially unissued, and held in abeyance for the benefit of the Holder until notice from the Holder that the shares may be issued in compliance with such limitation is received. These shares were issued to the Holder in October 2023.

The Company agreed to file a registration statement covering the resale of the Inducement PIO Shares issued or issuable upon the exercise of the Inducement PIOs (the "Resale Registration Statement"), as soon as practicable, and to use commercially reasonable efforts to have such Resale Registration Statement declared effective by the SEC within 90 days following the date of the Inducement Letter, and to keep the Resale Registration Statement effective at all times until there are no Inducement PIO Shares. The provision to register the underlying shares in the Warrant Inducement does not require payment related to the registration rights provided. As such, while the shares were not registered within 90 days of the date of the Inducement Letter, there is no accounting impact for this provision.

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

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 ("Wainwright Inducement Warrants"), which were issuable in accordance with the terms of the August Contingent Warrants, 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 "Inducement Contingent Warrants"). The maximum number of Inducement Contingent Warrants issuable under this provision is 298,346.

The Company evaluated the terms of the Inducement PIOs and the Wainwright Inducement Warrants (collectively, the "August 2023 Inducement Warrants"), and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480 and ASC 815-40.

The Warrant Inducement, which resulted in the lowering of the exercise price of the Existing PIOs and the issuance of the Inducement PIOs, is considered a modification of the Existing PIOs under the guidance of Accounting Standards Update ("ASU") No. 2021-04, *Issuer's Accounting for Certain Modifications or Exchanges of Equity Classified Written Call Options*. The modification is consistent with the "Equity Issuance" classification under that guidance as the reason for the modification was to induce the holders of the Existing PIOs to cash exercise their warrants, resulting in the imminent exercise of the Existing PIOs, which raised equity capital and generated net proceeds for the Company of approximately $2.3 million. As the Existing PIOs and the Inducement PIOs were classified as equity instruments before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately $2.6 million as an equity issuance cost.

In addition, the change in fair value of the contingent warrant liability associated with 149,173 of the August Contingent Warrants that were settled through issuance of the Wainwright Inducement Warrants, of approximately $122,000, was recognized in other income (expense) in the accompanying consolidated statements of operations and comprehensive loss, and the fair value of the contingent warrant liability of approximately $129,000 was derecognized as of the settlement date. The corresponding amount, representing the fair value of the Wainwright Inducement Warrants, was recognized as additional paid in capital. The Company measured the liability on the settlement date using a Black Scholes model, with the following significant assumptions: expected term of 5.0 years, expected volatility of 117.8%, risk-free interest rate of 4.24% and dividend yield of 0.0%.

The Company evaluated the terms of the Inducement Contingent Warrants and determined that they should be classified as a liability based upon accounting guidance provided in ASC 815-40. Since the Inducement Contingent Warrants are a form of compensation to Wainwright, the Company recorded the value of the liability of approximately $26,000 as a reduction of additional paid in capital, with subsequent changes in the value of the liability recorded in other income (expense) in the accompanying consolidated statements of operations and comprehensive loss. The Company measured the liability on the settlement date using a Black Scholes model, with the following significant assumptions: expected term of 5.0 years, expected volatility of 117.8%, risk-free interest rate of 4.24% and dividend yield of 0.0%.

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

Warrants

The following summarizes activity related to the Company's outstanding warrants, excluding contingent warrants issuable upon exercise of the preferred investment options, for the year ended December 31, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2022	5,910,914	$ 2.37	4.7
Granted	5,121,601	1.10	
Exercised	(3,132,854)	0.865	
Cancelled	—	—	
Outstanding as of December 31, 2023	7,899,661	1.68	4.3
Warrants vested and exercisable as of December 31, 2023	7,899,661	$ 1.68	4.3

As of December 31, 2023, the outstanding warrants include 70,849 April 2022 Private Placement Warrants, 2,707,211 August 2022 Private Placement Warrants, and 5,121,601 August 2023 Inducement Warrants, which are exercisable into 7,899,661 shares of common stock which had a fair value of $0.20 per share, based on the closing trading price on that day.

Additionally, as of December 31, 2023 and 2022, the value of the August Contingent Warrants and the Inducement Contingent Warrants (collectively the "Contingent Warrants") was approximately $3,000 and $14,000, respectively. The maximum number of warrants issuable upon settlement of the Contingent Warrants as of December 31, 2023 and 2022 was 447,519 and 298,346, respectively.

Onconetix Equity Incentive Plans

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

On February 23, 2022 and in connection with the closing of the IPO, the Company's board of directors adopted the Company's 2022 Equity Incentive Plan (the "2022 Plan"), which is the successor and continuation of the Company's 2019 Plan. Under the 2022 Plan, the Company may grant stock options, restricted stock, restricted stock units, stock appreciation rights, and other forms of awards to employees, directors, and consultants of the Company. Upon its effectiveness, a total of 1,600,000 shares of common stock were reserved for issuance under the 2022 Plan. In August 2022, the number of shares of common stock reserved for issuance under the 2022 Plan was increased to 2,600,000 and in May 2023, the number of shares of common stock reserved for issuance under the 2022 Plan was increased to 3,150,000. The stock options and restricted stock granted during the years ended December 31, 2023 and 2022 were all granted under the 2022 Plan. As of December 31, 2023, there are 718,402 shares available for issuance under the 2022 Plan.

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

Stock Options

The following summarizes activity related to the Company's stock options under the 2019 Plan and the 2022 Plan for the year ended December 31, 2023:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2022	1,392,654	$ 3.30	$ 670,161	8.2
Granted	962,154	0.48	—	—
Forfeited / cancelled	(404,058)	4.87	—	—
Exercised	(45,920)	0.01	45,920	—
Outstanding as of December 31, 2023	1,904,830	1.63	94,239	8.4
Options vested and exercisable as of December 31, 2023	861,177	$ 2.23	$ 94,239	7.1

The fair value of options granted in 2023 and 2022 was estimated using the following assumptions:

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022
Exercise price	$ 0.26 – 1.29	$1.06 – 6.45
Term (years)	5.00 – 10.00	5.00 – 10.00
Expected stock price volatility	101.1% – 119.5	112.6% – 121.2%
Risk-free rate of interest	3.5% – 4.7%	2.9% – 4.3%

The weighted average grant date fair value of stock options granted during the years ended December 31, 2023 and 2022 was $0.41 and $3.40, respectively. The aggregate fair value of stock options that vested during the years ended December 31, 2023 and 2022 was approximately $0.7 million and $2.1 million, respectively.

On October 4, 2023, the Company's board of directors granted an aggregate of 709,768 stock options in connection with the appointment of the Company's newly hired Chief Executive Officer and Chief Financial Officer. The options granted have an exercise price of $0.4305 per share, vest quarterly over a three-year period, and have a grant date fair value of approximately $0.2 million. The Company recognized less than $0.1 million of stock-based compensation expense related to these awards during the year ended December 31, 2023. Subsequent to December 31, 2023, in connection with the resignation of the newly hired Chief Executive Officer, 487,965 of these options were forfeited (see Note 14).

During the year ended December 31, 2022, 200,000 stock options were granted to the Company's former Chief Executive Officer ("former CEO"), Chairman, and significant stockholder, 200,000 stock options were granted to the Company's former Chief Business Officer ("former CBO"), and 100,000 stock options were granted to the Company's former Chief Financial Officer ("former CFO"). The aggregate grant-date fair value of the stock options granted to these individuals was approximately $1.8 million, of which approximately $1.5 million was recognized as stock-based compensation expense during the year ended December 31, 2022. During the year ended December 31, 2023, in connection with the resignation of the former CEO and the former CFO, 250,000 of these stock options were forfeited.

Additionally, during the year ended December 31, 2022, the Company granted an aggregate of 72,223 stock options to non-executive directors. The grant-date fair value of the stock options granted to the non-executive directors was approximately $0.2 million, of which approximately $0.2 million was recognized as stock-based compensation expense during the year ended December 31, 2022.

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

Restricted Stock

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

On August 16, 2023 and October 4, 2023, upon their respective resignations, the Company's former CEO and former CFO forfeited 150,000 shares and 75,000 shares of unvested restricted stock, respectively.

	Number of Shares	Weighted Average Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2022	—	$ —
Granted	512,940	1.01
Forfeited / cancelled	(250,110)	1.02
Vested	(6,250)	1.03
Nonvested as of December 31, 2023	256,580	$ 1.03

Proteomedix Stock Option Plan

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

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

There was no activity under the PMX Option Plan between the Acquisition Date and December 31, 2023. As of December 31, 2023, there were 58,172 and 57,276 stock options outstanding and vested, respectively, with a weighted average exercise price of $3.46 and $3.17, respectively, and a weighted average remaining contractual life of 5.36 years and 5.20 years, respectively. The intrinsic value of options outstanding and vested, as of December 31, 2023 was approximately $7.4 million and $7.1 million, respectively. As of December 31, 2023 there were 47,990 stock options exercisable at a weighted average exercise price of $3.94 and a weighted average remaining contractual life of 4.53 years.

Stock-Based Compensation

Stock-based compensation expense for the years ended December 31, 2023 and 2022 was as follows:

	For the Years Ended December 31,	
	2023	2022
Selling, general and administrative	$ 234,298	$ 1,309,687
Research and development	95,462	664,879
Total	**$ 329,760**	**$ 1,974,566**

As of December 31, 2023, unrecognized stock-based compensation expense relating to outstanding stock options and unvested restricted stock under the Onconetix Equity Incentive Plans is approximately $345,000 and $35,000, respectively, which is expected to be recognized over a weighted-average period of 1.79 years and 1.57 years, respectively.

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

As of December 31, 2023, unrecognized stock-based compensation expense relating to outstanding stock options under the PMX Option Plan is approximately $0.1 million, which will be recognized over a weighted-average period of 2.98 years.

During the year ended December 31, 2023, in connection with the former CBO's resignation from the Company, the individual's outstanding stock options and restricted stock awards were modified to allow continued vesting during the term of the consulting agreement entered into in January 2024. The Company recognized a net credit of approximately $165,000 to stock-based compensation expense as a result of this modification, primarily due to the decrease in the Company's stock price.

During the year ended December 31, 2022, the Company's board of directors approved the accelerated vesting of an aggregate of 32,517 stock options to a former director and a former advisor, in connection with their separation from the Company. The Company recognized stock-based compensation expense of approximately $0.1 million related to these modifications during the year ended December 31, 2022.

Note 10 — Commitments and Contingencies

Leases

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

The Company entered into a short-term lease in Palm Beach, Florida with an unrelated party, with a commencement date of May 1, 2022, for approximately $14,000 per month. The lease, which was personally guaranteed by the Company's former CEO, ended on April 30, 2023. During the years ended December 31, 2023 and 2022, the Company incurred rent expense on this lease of approximately $51,000 and $129,000, respectively, and variable lease expense of approximately $4,000 and $12,000, respectively.

Litigation

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. As of December 31, 2023, the Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims.

On April 15, 2022, the Company received a demand letter (the "Demand Letter") from Boustead. The Demand Letter alleged that the Company breached the Underwriting Agreement entered into between Boustead and the Company, dated February 17, 2022, in connection with the Company's initial public offering. The Demand Letter alleged that, by engaging Wainwright as placement agent in the April Private Placement, the Company breached Boustead's right of first refusal ("ROFR") to act as placement agent granted to Boustead under the Underwriting Agreement and, as a result of selling securities in the April Private Placement, breached the Company's obligation under the Underwriting Agreement not to offer, sell, issue, agree or contract to sell or issue or grant or modify the terms of any option for the sale of, any securities prior to February 17, 2023 (the "Standstill").

Note 10 — Commitments and Contingencies (cont.)

On October 9, 2022, the Company and Boustead entered into a Settlement Agreement and Release (the "Settlement Agreement"), pursuant to which Boustead agreed to waive the ROFR and the Standstill, and to release the Company from certain claims with respect to the April Private Placement, the August Private Placement, and all future private, public equity or debt offerings of the Company. As consideration for such waiver and termination of the Underwriting Agreement, the Company paid Boustead a cash fee of $1,000,000, $50,000 in legal expenses, and released Boustead from all claims, subject to certain exceptions. In addition, the Company issued to Boustead 93,466 shares of restricted common stock in exchange for the cancellation of 111,111 warrants issued to Boustead in connection with the IPO (see Note 9). Concurrent with the execution of the Settlement Agreement, the Company and Boustead Capital Markets, LLP ("Boustead Capital") entered into a three-month Advisory Agreement (the "Advisory Agreement") for which consideration equal to 200,000 shares of restricted common stock, with no vesting provisions, was issued to Boustead Capital upon execution of the Advisory Agreement. The incremental fair value of the Warrant Exchange and the fair value of the restricted common stock issued in connection with these agreements totaled approximately $264,000. See Note 9.

The Company determined that all consideration due by the Company under the Settlement Agreement and the Advisory Agreement relates to the settlement of a liability that was incurred in 2022 and accordingly, recorded a related expense of approximately $1.3 million for the year ended December 31, 2022, which is included in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

Registration Rights Agreements

In connection with the April 2022 Private Placement (see Note 9), the Company entered into a Registration Rights Agreement with the purchasers, dated as of April 13, 2022 (the "April Registration Rights Agreement"). The April Registration Rights Agreement provides that the Company shall file a registration statement covering the resale of all of the registrable securities (as defined in the April Registration Rights Agreement) with the SEC. The registration statement on Form S-1 required under the April Registration Rights Agreement was filed with the SEC on May 3, 2022 and became effective on May 20, 2022. A post-effective amendment to the Form S-1 on Form S-3 relating to such registration statement was filed with the SEC on April 28, 2023.

In connection with the August 2022 Private Placement (see Note 9), the Company entered into a Registration Rights Agreement with the purchasers, dated as of August 9, 2022 (the "August Registration Rights Agreement"). The August Registration Rights Agreement provides that the Company shall file a registration statement covering the resale of all of the registrable securities (as defined in the August Registration Rights Agreement) with the SEC. The registration statement on Form S-1 required under the August Registration Rights Agreement was filed with the SEC on August 29, 2022 and became effective on September 19, 2022. A post-effective amendment to the Form S-1 on Form S-3 relating to such registration statement was filed with the SEC on April 28, 2023.

Upon the occurrence of any Event (as defined in the April Registration Rights Agreement and the August Registration Rights Agreement), which, among others, prohibits the purchasers from reselling the securities for more than ten consecutive calendar days or more than an aggregate of fifteen calendar days during any 12-month period, and should the registration statement cease to remain continuously effective, the Company would be obligated to pay to each purchaser, on each monthly anniversary of each such Event, an amount in cash, as partial liquidated damages and not as a penalty, equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such purchaser in the Private Placement. As of December 31, 2023, the Company determined that the likelihood of the Company incurring liquidated damages pursuant to the April Registration Rights Agreement and the August Registration Rights Agreement is remote, and as such, no accrual of these payments is required as of December 31, 2023.

Note 10 — Commitments and Contingencies (cont.)

Milestone and Royalty Obligations

The Company has entered into various license agreements with third parties that obligate the Company to pay certain development, regulatory, and commercial milestones, as well as royalties based on product sales (see Note 6). As of December 31, 2023, the Company terminated all license agreements, except for the CHMC Agreement, which could require the Company to pay CHMC milestone payments of up to an aggregate of $59.75 million. As of December 31, 2023, the Company evaluated the likelihood of the Company achieving the specified milestones and generating product sales, and determined the likelihood is not yet probable and as such, no accrual of these payments is required as of December 31, 2023.

Underwriter Termination Agreement

On February 7, 2022, the Company and its former underwriter, Maxim Group ("Maxim"), entered into a termination agreement, whereby the parties agreed to terminate their engagement of Maxim as the Company's lead managing underwriter and book runner in connection with the Company's IPO. Per the terms of the termination agreement, the Company agreed to pay Maxim a termination fee of $300,000, due upon the close of the Company's IPO. The termination fee was recorded as selling, general and administrative expense, and paid, during the year ended December 31, 2022.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not been required to defend any action related to its indemnification obligations. However, during the third quarter of 2023, the Company received a claim from its former CEO and a former accounting employee requesting advancement of certain expenses. The Company recorded approximately $209,000 in related expenses during the year ended December 31, 2023, of which approximately $159,000 was paid through reduction of the outstanding related party receivable due from the former CEO (see Note 11). As of December 31, 2023, the Company recorded a related accrual of approximately $50,000, which is included in accrued expenses in the accompanying consolidated balance sheets, and which was paid subsequent to year end. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is not estimable at this time.

Note 11 — Related Party Transactions

The Company originally engaged the former CEO, who was also the Board Chairman and prior to the close of the IPO, sole common stockholder of the Company, pursuant to a consulting agreement commencing October 22, 2018, which called for the Company to pay for consulting services performed on a monthly basis. Upon the close of the Company's IPO, the consulting agreement was terminated, and the former CEO's employment agreement became effective. During the year ended December 31, 2022, the Company incurred approximately $63,000 in fees under the consulting agreement, which are recognized in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

During 2022 the Company entered into a lease agreement that was personally guaranteed by the Company's former CEO. The lease expired in 2023. See Note 10.

During the year ended December 31, 2022, the Company's compensation committee approved one-time bonus awards of $140,000 and $100,000 to the Company's former CEO and former CBO, respectively, in recognition of their efforts in connection with the Company's IPO. These bonuses were recognized during the year ended December 31, 2022, as selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

During the year ended December 31, 2023, the Company's Audit Committee completed a review of the Company's expenses due to certain irregularities identified with regards to the related party balance. Based on the results of the review, it was determined that the Company paid and recorded within selling, general and administrative expenses, personal expenditures of the Company's former CEO and an accounting employee who was also the former CEO's assistant, during 2022 and during the first three quarters of 2023. The Company evaluated the receivable, which aggregated to approximately $522,000 as of September 30, 2023, and which represented the total of the items identified as personal in nature for which the Company did not anticipate recovery from the related party. As the Company concluded that the remaining amounts are not likely to be recovered, this would not cause an adjustment to previously issued financial statements. The Company recorded a corresponding reserve for the full amount, resulting in a net related party receivable balance of $0 and a loss on related party receivable of approximately $266,000, which was recorded in selling, general, and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2023. During the fourth quarter of 2023, the Company recorded a recovery of approximately $159,000 with respect to amounts that the former CEO agreed to repay the Company, through a reduction of amounts that were due to him from the Company under his indemnification rights pursuant to his employment agreement (see Note 10).

As of December 31, 2022, the Company had a receivable from related party of approximately $36,000, consisting of miscellaneous payments made by the Company on the behalf of the Company's CEO, and which was paid in full during the first quarter of 2023.

On December 18, 2023, the Company entered into the Subscription Agreement with the PMX Investor, a 5% stockholder of the Company as of December 31, 2023 (see Note 8). Subsequent to December 31, 2023, the Company issued a non-convertible debenture in the principal amount of $5.0 million to the PMX Investor, in connection with the Subscription Agreement (see Note 14).

A former director of the Company, who served on the Company's Scientific Advisory Board until August 2023, serves on the Advisory Board for the Cincinnati Children's Hospital Medical Center Innovation Fund, which is affiliated with CHMC. The Company has an exclusive license agreement with CHMC as disclosed in Note 5. This director resigned from the Company's board upon the close of its IPO.

Note 12 — Income Taxes

The components of loss before income taxes are as follows:

	For the Years Ended December 31,	
	2023	2022
U.S.	$ (37,106,599)	$ (13,419,830)
Foreign	(315,688)	—
Total loss before income taxes	**$ (37,422,287)**	**$ (13,419,830)**

The Company's major tax jurisdictions are the United States, Switzerland, and various state jurisdictions, and the Company does not have any pending tax audits. The income tax benefit recorded for the year ended December 31, 2023 related to the Company's deferred foreign taxes. There was no income tax provision or benefit recorded for the year ended December 31, 2022. Generally, the Company's federal returns from 2019 on and state returns from 2018 on, and foreign returns from 2018 on, are subject to examination by the United States, state, and foreign tax authorities; however, to the extent allowed by law, tax authorities have the ability to adjust the Company's carryforwards of unutilized net operating losses and research and development credits for all years.

At December 31, 2023, the Company had a net operating loss ("NOL") carryforward for federal, foreign, and state income tax purposes totaling approximately $27.9 million, $18.0 million, and $23.8 million, respectively, available to reduce future taxable income. The federal NOL and certain state NOLs of $16.8 million are carried forward indefinitely subject to a limitation of 80% of taxable income. State NOLs of approximately $6.8 million will begin to expire in 2024 if not utilized, and foreign NOLs of approximately $15.1 million will begin to expire in 2024 if not utilized.

The NOL carry forward is subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Under the Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss carryforwards and research credit carryforwards to offset taxable income and tax, respectively, may be limited based on cumulative changes in ownership. The Company has not completed an analysis to determine whether any such limitations have been triggered as of December 31, 2023. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

The tax effects of the temporary differences and carryforwards that give rise to deferred tax assets and liabilities consist of the following:

	As of December 31,	
	2023	2022
Deferred tax assets:		
Net-operating loss carryforward	$ 10,214,760	$ 2,986,738
Intangibles	3,349,919	885,176
Capitalized research and development	1,171,320	—
Stock-based compensation	690,760	308,552
Deposit on WraSer APA	854,896	—
Accrued compensation	150,099	186,573
License agreement	49,157	82,626
Other	520,207	65,886
Gross deferred tax assets	17,001,118	4,515,551
Valuation allowance	(15,697,701)	(4,512,546)
Deferred tax assets, net of allowance	$ 1,303,417	$ 3,005
Deferred tax liabilities:		
Intangible assets	(4,345,449)	—
Fixed assets	(2,560)	(3,005)
Other	(29,189)	—
Total deferred tax liabilities	$ (4,377,198)	$ (3,005)
Net deferred tax liability	**$ (3,073,781)**	**$ —**

Note 12 — Income Taxes (cont.)

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. The Company has recorded a valuation allowance against its United States and foreign deferred tax assets in each of the years ended December 31, 2023 and 2022, because the Company's management believes that it is more likely than not that these assets will not be realized. During the years ended December 31, 2023 and 2022, the valuation allowance increased by approximately $11.2 million and $3.2 million, respectively.

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2023 and 2022, due to the following:

	For the Years Ended December 31,	
	2023	**2022**
Expected income tax benefit at Federal statutory tax rate	$ (7,858,680)	$ (2,818,164)
State and local taxes, net of Federal tax benefit	(1,192,605)	(501,277)
Research credits	—	(16,477)
Foreign NOL expirations	315,927	—
Stock-based compensation	196,025	—
Subscription agreement liability	181,440	—
Officer's compensation	(126,337)	—
Acquisition related costs	164,073	—
Permanent items	55,486	194,705
State rate adjustment	(23,135)	19,600
Other	60,599	(37,260)
Change in valuation allowance	8,214,614	3,158,873
Income tax benefit	**$ (12,593)**	**$ —**

Under U.S. GAAP, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, U.S. GAAP provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure, and transition.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	For the Years Ended December 31,	
	2023	**2022**
Beginning balance	$ 17,010	$ —
Increases related to prior year tax positions	—	11,517
Increases related to current year tax positions	—	5,493
Ending balance	$ 17,010	$ 17,010

At December 31, 2023 and 2022, the Company's unrecognized tax benefits were $17,010. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the effective tax rate. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months.

The Company's policy is to recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2023 and 2022, there were no accrued interest and penalties associated with uncertain tax positions.

Note 13 — Retirement Plans

Defined Contribution Plans

Effective January 1, 2022, the Company adopted a defined contribution savings plan pursuant to Section 401(k) of the Internal Revenue Code ("the 2022 401 (k) Plan"). The 2022 401(k) Plan was for the benefit of all qualifying employees and permits voluntary contributions by employees of up to 100% of eligible compensation, subject to the maximum limits imposed by the Internal Revenue Service. The terms of the 2022 401(k) Plan allowed for discretionary employer contributions. No expenses were incurred related to the 2022 401(k) Plan during the year ended December 31, 2022 and the 2022 401(k) Plan lapsed during 2022 due to inactivity.

On May 31, 2023, the Board voted to adopt a 401(k) Safe Harbor Non-Elective Plan (the "2023 401(k) Plan"). The 2023 401(k) Plan was an employee savings and retirement plan to which substantially all employees could have contributed, including the Company's named executive officers, effective July 1, 2023. Pursuant to the 2023 401(k) Plan, employee and Company contributions would vest immediately, subject to a three-month waiting period for new hires. The Company was required to contribute 3% of gross pay to eligible employees' 401(k) Plans. On November 16, 2023, the 2023 401(k) Plan was terminated. No expenses were incurred related to the 2023 401(k) Plan during the year ended December 31, 2023.

Defined Benefit Plan

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

The value of the pension obligation is determined using the Projected Unit Credit method. This method sees each period of service as giving rise to an additional unit of benefit entitlements/employee benefits. The value of the Company's employee benefit obligations for active employees, or the Projected Benefit Obligation, on the reporting date is the same as the present value of the degree of entitlement existing on this date, in terms of future salary and pension increases and turnover rates. The valuation of pension obligations of pensioners is made on the basis of the present value of current pensions taking into account future increases in pensions. The service costs are calculated using the present value of the entitlements to employee benefits earned during the year for which calculations are made.

As is customary with Swiss pension plans, the assets of the Swiss Plan are invested in a collective fund with multiple employers. Neither Proteomedix nor Onconetix have investment authority over the assets of the Swiss Plan that are held and invested by a Swiss insurance company. Investment holdings are made with respect to Swiss laws and target allocations for plan assets, and are 38% debt securities and cash, 26% equity securities, 12% alternative investments and 24% real estate investments. The valuation of the collective fund assets as a whole is a Level 3 measurement; however, the individual investments of the fund are generally Level 1 (equity securities), Level 2 (fixed income) and Level 3 (real estate, infrastructure and alternative) investments. We determine the fair value of the plan assets based on information provided by the collective fund. See Note 3, "Summary of Significant Accounting Policies" for additional information on the three-tier fair value hierarchy.

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

Discount rate	1.45%
Expected long-term rate of return on plan assets	1.45%
Rate of compensation increase	3.00%

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

The components of net periodic benefit cost for the period from December 15, 2023 to December 31, 2023 are as follows:

Service cost	$	4,278
Interest cost		1,943
Expected return on plan assets		(1,581)
Amortization of net (gain)/loss		(1,534)
Settlements (gain)/loss		(1,157)
Total	$	1,949

Note 13 — Retirement Plans (cont.)

The components of accumulated comprehensive loss attributable to the Company's pension plan for the period from December 15, 2023 to December 31, 2023 are as follows:

Net loss (gain)	$	7,277
Amortization of net gain		1,534
Effect of settlement		1,157
Other adjustments		(4,005)
Total recorded during the period	$	5,963

As of December 31, 2023, the funded status of the plan and the amounts recognized in the accompanying consolidated balance sheet are as follows:

Projected benefit obligation	$	2,299,970
Fair value of plan assets		1,743,674
Overfunded (underfunded) status	$	(556,296)

There were no Company contributions made to the plan during the period from December 15, 2023 to December 31, 2023.

A reconciliation of the beginning and ending balances of the accumulated benefit obligation is provided in the table below:

As of December 15, 2023	2,288,273
Service cost	4,278
Interest cost	1,943
Actuarial (gain) loss	7,979
Benefits paid	(905)
Ordinary contributions paid by employees	4,005
Contributions paid by plan participants	769
Settlements	(6,372)
Projected benefit obligation as of December 31, 2023	2,299,970
Actuarial (gain)/loss due to assumption changes	8,834
Actuarial (gain)/loss due to plan experience	(855)
Accumulated benefit obligation as of December 31, 2023	$ 2,307,949

A reconciliation of the beginning and ending balances of the plan assets is provided in the table below:

As of December 15, 2023	$	1,739,889
Actual return on plan assets		2,283
Contributions paid by employer		4,005
Ordinary contributions paid by employees		4,005
Contributions paid by plan participants		769
Benefits paid		(905)
Settlements		(6,372)
As of December 31, 2023	$	1,743,674

Note 13 — Retirement Plans (cont.)

Projected benefit payments for the next five years as of December 31, 2023 are as follows:

Years ending December 31,	
2024	$ -
2025	95,100
2026	95,100
2027	95,100
2028	95,100
Thereafter	553,900
Total	$ 934,300

Note 14 — Subsequent Events

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

Effective as of January 10, 2024, Dr. Neil Campbell resigned as President and Chief Executive Officer and a member of the Board of Directors of the Company. The Company and Dr. Campbell entered into a Release of Claims agreement, pursuant to which Dr. Campbell will receive a severance payment of $158,333 in two equal payments.

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

During March 2024, Zydus Life Sciences received FDA approval for a combined finasteride-tadalafil capsule, which is a direct competitor product to ENTADFI. The Company determined that this is a triggering event during the first quarter of 2024 for its ENTADFI asset group, which includes long-lived assets with a remaining carrying amount of approximately $3.3 million as of December 31, 2023. As such, it is reasonably possible that the resulting impairment test will result in additional impairment losses in the near term.

Exhibit No.	Description
2.1	Share Exchange Agreement, dated December 15, 2023, by and among the Company, Proteomedix, Thomas Meier and the Sellers.[21]
3.1	Amended and Restated Certificate of Incorporation filed with Delaware Secretary of State on February 23, 2022.[3]
3.2	Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation[11]
3.3	Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation.[21]
3.4	Fourth Amended and Restated Bylaws of the Company.[21]
4.1	Specimen Common Stock Certificate.[1]
4.2	Description of Registered Securities
4.3	Certificate of Designation of Series A Preferred Stock.[19]
4.4	Certificate of Designation of Series B Convertible Preferred Stock.[21]
4.5	Form of Inducement PIO. [27]
10.1	2019 Equity Incentive Plan.[1]
10.2	2022 Equity Incentive Plan.[10]
10.3	2019 Equity Incentive Plan Form of Stock Option Grant Agreement.[1]
10.4	2022 Equity Incentive Plan Form of Incentive Stock Option Agreement (Employee).[28]
10.5	2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Consultant).[28]
10.6	2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Non-Employee Director).[28]
10.7	2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Employee).[28]
10.8	Exclusive License Agreement between the Registrant and Children's Hospital Medical Center, d/b/a Cincinnati Children's Hospital Medical Center, effective as of June 1, 2021.[2]
10.9	License Agreement between the Registrant and Oxford University Innovation Limited, effective as of July 16, 2019.[2]
10.10	Exclusive License Agreement between the Registrant and St. Jude Children's Research Hospital, Inc., effective as of January 27, 2020.[2]
10.11	Lease Agreement, dated as of April 29, 2021, between the Registrant and Regus Management Group, LLC.[1]
10.12	Master Services Agreement between the Registrant and Ology Bioservices, Inc., effective as of July 19, 2019.[1]
10.13	Project Addendum 1 to Master Services Agreement between the Registrant and Ology Bioservices, Inc., effective as of October 9, 2019.[1]
10.14	Letter Agreement between the Registrant and Ology Bioservices, Inc., dated as of January 9, 2020.[1]
10.15	Project Addendum II to Master Services Agreement between the Registrant and Ology Bioservices, Inc., effective as of May 21, 2021.[1]
10.16	Form of Employment Agreement with Joseph Hernandez.[1]
10.17	Form of Employment Agreement with Erin Henderson.[1]
10.18	Form of Employment Agreement with Jon Garfield.[1]
10.19	Form of Employment Agreement with Neil Campbell.[15]
10.20	Form of Employment Agreement with Bruce Harmon.[15]

10.21	Form of Employment Agreement with Ralph Schiess.*
10.22	Amendment to Employment Agreement, dated October 15, 2020, by and between Proteomedix and Ralph Schiess.*
10.23	Amendment to Employment Agreement by and between Proteomedix and Ralph Schiess.*
10.24	Form of Employment Agreement with Christian Brühlmann.*
10.25	Amendment to Employment Agreement, dated October 16, 2020, by and between Proteomedix and Christian Brühlmann.*
10.26	Amendment to Employment Agreement by and between Proteomedix and Christian Brühlmann.*
10.27	General Release of Claims, dated October 5, 2023, by and between Jon Garfield and the Company.(15)
10.28	Release, dated January 10, 2024, by and between the Company and Dr. Neil Campbell.(22)
10.29	Form of Indemnification Agreement for Directors and Officers.(15)
10.30	Form of Securities Purchase Agreement, dated as of April 13, 2022, by and among the Company and the Purchasers.(5)
10.31	Form of Registration Rights Agreement, dated as of April 13, 2022, by and among the Company and the Purchasers.(5)
10.32	Form of Securities Purchase Agreement, dated as of August 9, 2022, by and among the Company and the Purchasers.(6)
10.33	Form of Registration Rights Agreement, dated as of August 9, 2022, by and among the Company and the Purchasers.(6)
10.34	Settlement Agreement and Release, dated October 9, 2022, by and between the Registrant and Boustead Securities, LLC.(7)
10.35	Amendment No. 1 to Project Addendum 2 to Master Services Agreement, dated as of April 20, 2022, by and between the Registrant and Ology Bioservices, Inc.(9)
10.36	Amendment #1 to Exclusive License Agreement, dated as of May 11, 2022, by and between the Registrant and St. Jude Children's Research Hospital, Inc.(9)
10.37	Patent & Technology License Agreement, dated November 18, 2022, between the Company and the University of Texas Health Science Center at San Antonio.(14)
10.38	Co-Development Agreement, dated February 1, 2023, between the Company and AbVacc, Inc.(14)
10.39	At-the-Market Offering Agreement, dated March 29, 2023, between the Company and H.C. Wainwright & Co., LLC.(12)
10.40	Asset Purchase Agreement, dated April 19, 2023, between the Company and Veru Inc.(13)†
10.41	Amendment to Asset Purchase Agreement, dated September 29, 2023, between the Company and Veru Inc.(19)
10.42	Form of Non-Competition and Non-Solicitation Agreement, dated April 19, 2023.(13)
10.43	Asset Purchase Agreement, dated June 13, 2023, by and among WraSer, Xspire, and the Company.(16)
10.44	Management Services Agreement, dated June 13, 2023, by and among WraSer, Xspire and the Company.(16)
10.45	Form of Amendment, dated October 5, 2023, to Asset Purchase Agreement, dated June 13, 2023, by and among WraSer, Xspire, Legacy-Xspire Holdings, LLC, and the Company.(17)
10.46	Exclusive Distribution Agreement, dated September 20, 2023, between the Company and Cardinal Health 105, LLC.(20)†
10.47	Form of Lock-Up Agreement, dated December 15, 2023, by and among the Company and certain stockholders of Proteomedix.(21)
10.48	Form of Non-Competition and Non-Solicitation Agreement, dated December 15, 2023, by and among the Company and certain stockholders of Proteomedix.(21)
10.49	Form of Stockholder Support Agreement, dated December 15, 2023, by and among the Company, Proteomedix, and certain stockholders of Proteomedix.(21)
10.50	Form of Subscription Agreement, dated December 15, 2023, by and among the Company, Proteomedix, and the Investor.(21)
10.51	Separation Agreement, dated January 17, 2024, between the Company and Erin Henderson.(23)
10.52	Consulting Agreement, dated January 17, 2024, between the Company and The Aetos Group.(23)
10.53	Debenture, dated January 23, 2024 issued to the Investor.(24)
10.54	Consulting Agreement, dated January 4, 2024, by and between the Company and Thomas Meier.(25)
10.55	License Agreement, dated March 27, 2023, between Proteomedix and Laboratory Corporation of America Holdings.*†#
10.56	Form of Inducement Letter.(26)

10.57	Form of Letter Agreement.[27]
14	Code of Ethics.[2]
19	Insider Trading Policy, adopted August 7, 2023*
21	List of Subsidiaries.*
23.1	Consent of Mayer Hoffman McCann P.C.*
23.2	Consent of EisnerAmper LLP.*
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
97	Policy Related to Recovery of Erroneously Awarded Compensation, adopted January 17, 2024.*
101.INS*	XBRL Instance Document.*
101.SCH*	XBRL Taxonomy Schema Linkbase Document.*
101.CAL*	XBRL Taxonomy Calculation Linkbase Document.*
101.DEF*	XBRL Taxonomy Definition Linkbase Document.*
101.LAB*	XBRL Taxonomy Labels Linkbase Document.*
101.PRE*	XBRL Taxonomy Presentation Linkbase Document.*
104*	Cover Page Interactive Data File (Embedded as Inline XBRL document and contained in Exhibit 101).

* Filed herewith.
** Furnished herewith.
† Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Company agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.
# Certain portions of this exhibit (indicated by "[***]" have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K as we have determined they (1) are not material and (2) are the type that the Company treats as private or confidential. The Registrant hereby agrees to furnish a copy of any omitted portion to the SEC upon request.
(1) Incorporated by reference to the Company's Registration Statement on Form S-1, filed with the SEC on October 8, 2021.
(2) Incorporated by reference to the Company's Registration Statement on Form S-1/A, filed with the SEC on November 5, 2021.
(3) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on February 24, 2022.
(4) Incorporated by reference to the Company's Registration Statement on Form S-1/A, filed with the SEC on November 29, 2021.
(5) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on April 19, 2022.
(6) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on August 11, 2022.
(7) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 14, 2022.
(8) Incorporated by reference to the Company's Annual Report on Form 10-K, filed with the SEC on March 31, 2022.
(9) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2022.
(10) Incorporated by reference to the Company's Registration Statement on Form S-1/A, filed with the SEC on January 6, 2022.
(11) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 24, 2023.
(12) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on March 29, 2023.
(13) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 20, 2023.
(14) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2023.
(15) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on October 10, 2023.
(16) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on June 14, 2023.
(17) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the SEC on October 20, 2023.
(18) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the SEC on June 6, 2023.
(19) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on October 3, 2023.
(20) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 17, 2023.
(21) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on December 21, 2023.
(22) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on January 12, 2024.
(23) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on January 19, 2024.
(24) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on January 29, 2024.
(25) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on February 12, 2024.
(26) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2023.
(27) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on August 3, 2023.
(28) Incorporated by reference to the Company's Registration Statement on Form S-1/A filed with the SEC on January 6, 2022.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Onconetix, Inc.

Date: April 11, 2024

By: */s/ Ralph Schiess*
Ralph Schiess
Interim Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on April 11, 2024.

Signature	Title
/s/ Ralph Schiess Ralph Schiess	Interim Chief Executive Officer
/s/ Bruce Harmon Bruce Harmon	Chief Financial Officer
/s/ James Sapirstein James Sapirstein	Chairman of the Board and Lead Independent Director
/s/ Thomas Meier Thomas Meier	Director
/s/ Timothy Ramdeen Timothy Ramdeen	Director
/s/ Ajit Singh Ajit Singh	Director
/s/ Simon Tarsh Simon Tarsh	Director