

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, 2025

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 (State or other jurisdiction of incorporation or organization)	81-2262816 (I.R.S. Employer Identification No.)
201 E. Fifth Street, Suite 1900 Cincinnati, OH (Address of principal executive offices)	45202 (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, 2025 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately \$3.6 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 are not necessarily a conclusive determination for other purposes.

As of March 11, 2026, the registrant had 3,584,245 shares of common stock, \$0.00001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

EXPLANATORY NOTE

On June 13, 2025, the Company effected a reverse stock split of all shares of its issued and outstanding Common Stock at a ratio of one-for-eighty-five (1:85). The Company accounted for the reverse stock split on a retrospective basis pursuant to Accounting Standards Codification (“ASC”) 260, *Earnings Per Share*. All issued and outstanding common stock, common stock warrants, and share-based awards’ exercise prices and per share data have been adjusted in these consolidated financial statements, on a retrospective basis, to reflect the reverse stock split for all periods presented. The number of authorized shares and par value of the preferred stock and common stock were not adjusted because of the reverse stock split.

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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 and repay indebtedness;
- our ability to commercialize or monetize Proclarix and integrate the assets and commercial operations acquired in the share exchange with Proteomedix AG (“Proteomedix”);
- our reliance on third parties, including Laboratory Corporation of America (“LabCorp”), to develop, market, distribute and sell Proclarix;
- the successful development of our commercialization capabilities, including sales and marketing capabilities.
- our ability to consummate the transaction on a timely basis as contemplated by the Share Exchange Agreement with Realbotix, LLC (“Realbotix” and the “Share Exchange Agreement” and the transactions contemplated therein, the “Realbotix Transaction”) and the anticipated benefits of the Realbotix Transaction.
- our ability to maintain the necessary regulatory approvals to market and commercialize our product;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current product;

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

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

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 30 of this Report. These risks include, but are not limited to, the following:

- We could fail to complete the Realbotix Transaction, or the Realbotix Transaction may be completed on different terms.
- If completed, the Realbotix Transaction may not achieve its intended results and may result in us assuming unanticipated liabilities.
- We could fail to complete the Realbotix Transaction, or the Realbotix Transaction may be completed on different terms.
- Our stockholders may not realize a benefit from the acquisition of Realbotix commensurate with the ownership dilution they will experience in connection with the Realbotix Transaction contemplated by the Share Exchange Agreement.
- The failure to successfully integrate our business and Realbotix in the expected timeframe would adversely affect our future results.
- The pending Transactions may divert the attention of our management.
- Unexpected market disruptions may cause major losses for us not anticipated under the Share Exchange Agreement.
- Risks associated with changes in the technology industry.
- We may be unable to protect Realbotix’s intellectual property.
- The business of Realbotix is exposed to cybersecurity risks.
- We expect to incur significant transaction costs in connection with the Realbotix Transaction.
- Disruptions to or significantly increased costs associated with transportation and other distribution channels for Proclarix may adversely affect our margins and profitability.
- 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 Proclarix in the European market or other markets, if authorized, grow sales in the United States 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 single product. If we do not successfully commercialize our product or we experience significant delays in doing so, this product 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 product.
- We expect to rely on third party manufacturers for Proclarix.
- 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 product, others could compete against us more directly, which would harm our business, possibly materially.
- 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.
- There can be no assurance that we will be able to comply with the continued listing requirements of, and remain trading on, 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 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.
- 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.

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 acquisition of Proteomedix, which closed on December 15, 2023, we own Proclarix, an in vitro diagnostic test for prostate cancer originally developed by Proteomedix and approved for sale in the European Union under the In Vitro Diagnostic Regulation ("IVDR"), which we anticipate will be marketed in the U.S. as a lab developed test through our license agreement with LabCorp.

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

ENTADFI is an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of BPH, a disorder of the prostate. However, in light of (i) the time and resources needed to continue pursuing commercialization of ENTADFI, and (ii) the Company's cash runway and indebtedness, the Company abandoned commercialization of ENTADFI and no longer holds remaining inventory of the product as of December 31, 2025. In addition, as part of cost reduction efforts and in connection with our initial pause in commercializing ENTADFI, we terminated three employees involved with the ENTADFI program, effective April 30, 2024, with such individuals to continue assisting the Company on an as-needed, consulting basis. Based on the circumstances surrounding ENTADFI, at June 30, 2024, the ENTADFI assets were fully impaired. Refer to Note 4 in the consolidated financial statements for the period ended December 31, 2024 for further discussion.

We are currently focusing our efforts on commercializing Proclarix.

Proclarix is an easy-to-use next generation protein-based blood test that can be done with the same sample as a patient's regular Prostate-Specific Antigen ("PSA") test. The PSA test is a well-established prostate specific marker that measures the concentration of PSA molecules in a blood sample. A high level of PSA can be a sign of prostate cancer. However, PSA levels can also be elevated for many other reasons including infections, prostate stimulation, vigorous exercise or even certain medications. PSA results can be confusing for many patients and even physicians. It is estimated over 50% of biopsies with elevated PSA are negative or clinically insignificant resulting in an overdiagnosis and overtreatment that impacts the physician's routine, our healthcare system, and the quality of patients' lives. Approximately 10% of all men have elevated PSA levels., commonly referred to as the diagnostic "grey zone", of which only 20 - 40% present clinically with cancer. Proclarix is intended for use in diagnosing these patients where it is difficult to decide if a biopsy is necessary to verify a potential clinically significant cancer diagnosis. Proclarix helps doctors and patients with unclear PSA test results through the use of our proprietary Proclarix Risk Score which delivers clear and immediate diagnostic support for further treatment decisions. No additional intervention is required, and results are available quickly. Local diagnostic laboratories can integrate this multiparametric test into their current workflow because Proclarix assays use the enzyme-linked immunosorbent assay (ELISA) standard, which most diagnostic laboratories are already equipped to process.

Proclarix is CE-marked and for sale in Europe. We continue our sales efforts and expect growing revenues from sales of Proclarix in 2026 and beyond. We anticipate these sales to offset some expenses relating to commercial scale up and development, we expect our expenses also to increase in connection with our ongoing activities, as we:

- commercialize Proclarix;
- hire additional personnel;
- operate as a public company;
- obtain, maintain, expand, and protect our intellectual property portfolio; and
- perform product validation studies in connection with a license agreement.

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

We do not have any products approved for sale, aside from Proclarix. We have abandoned commercialization of ENTADFI and have destroyed our inventory of the product.

To date, we have financed our operations primarily with proceeds from our sale of preferred securities to seed investors, the initial public offering (“IPO”), and subsequent offerings of debt and equity securities. We will continue to require significant additional capital to commercialize Proclarix, and to fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and to rely on third-party resources for marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches, to support our operations.

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, 2025, we had cash of approximately \$5.2 million, a working capital deficit of approximately \$3.1 million and an accumulated deficit of approximately \$131.2 million. During the year ended December 31, 2025, we used approximately \$9.7 million in cash for operating activities. In addition, as of March 11, 2026, our cash balance was approximately \$3.6 million. We believe that our current cash balance is not sufficient to fund its operations for one year from the date of issuance of the consolidated financial statements for the year. As such, we have entered into Series D and Series E PIPE financings with certain investors in September 2025 and October 2025, respectively, which provided us additional cash flow to support our near-term operations. While such capital raises may enable us to sustain current operations and meet existing obligations, we continue to generate recurring net operating losses and have not yet established sustained positive cash flows to support our strategic growth initiatives. Such initiatives include the commercialization of Proclarix and our development and commercialization of future product candidates. These factors raise substantial doubt on our ability to continue as a going concern for one year from the date of issuance of our consolidated financial statements for the financial year ended December 31, 2025.

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, 2025, 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, 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.

Realbotix Corp. Share Exchange Agreement

On February 11, 2026, we entered into a Share Exchange Agreement (the “Share Exchange Agreement”), by and among (i) Onconetix, (ii) Realbotix Corp., a company existing under the laws of the Province of Ontario (“Parent”), (iii) Simulacra Corporation, a Delaware corporation and a wholly-owned subsidiary of Parent (the “Seller”) and (iv) Realbotix, LLC, a Delaware limited liability company and wholly owned subsidiary of the Seller (the “Realbotix”).

Pursuant to the Share Exchange Agreement, subject to the terms and conditions set forth therein, the Seller agreed to contribute and transfer to us, and we agreed to acquire and accept, all of the issued and outstanding equity interests of Realbotix (the “Realbotix Interests”) in exchange for newly issued shares of Common Stock. (the “Share Exchange” and the other transactions contemplated by the Share Exchange Agreement, the “Realbotix Transactions”).

Unless otherwise defined herein, the capitalized terms used below are defined in the Share Exchange Agreement.

Consideration

In full consideration for the contribution of the Realbotix Interests, we will issue shares of Common Stock to the Seller (the “Exchange Shares”), such that, immediately following the Closing and after giving effect to such issuance, the Seller will own a percentage of our fully diluted shares (the “Fully Diluted Shares”) that will be adjusted based on Net Cash (as defined below) as follows: (i) if Net Cash is greater than or equal to \$12.5 million, but less than \$15.0 million, Seller will own 90% of the Fully Diluted Shares, (ii) if Net Cash is greater than or equal to \$15.0 million, but less than \$18.0 million, Seller will own 85% of the Fully Diluted Shares, (iii) if Net Cash is greater than or equal to \$18.0 million, but less than \$20.0 million, Seller will own 80% of the Fully Diluted Shares and (iv) if Net Cash is greater than or equal to \$20.0 million, Seller will own 75% of the Fully Diluted Shares. “Net Cash” means the amount of cash and cash equivalents held by us upon the Closing, whether received by Realbotix or us in connection with the Realbotix Transactions, net of D&O tail insurance costs; change-of-control or other payments owed to our officers and director of as a result of the Realbotix Transactions; all our indebtedness; certain of our liabilities and our transaction expenses.

Conversion of Company Convertible Securities

Prior to the consummation of the Share Exchange, the holders of Realbotix Convertible Securities will exercise their rights to receive Realbotix Interests pursuant to the terms of such Realbotix Convertible Securities (as defined below) at the applicable conversion ratio as set forth in the Realbotix Convertible Securities (the “Realbotix Convertible Securities Conversion”). Upon completion of the Realbotix Convertible Securities Conversion and prior to Closing, all Realbotix Convertible Securities will be canceled or terminated, as applicable, will no longer be outstanding and will cease to exist and no payment or distribution will be made with respect thereto. Each holder of Realbotix Convertible Securities thereafter will cease to have any rights with respect to such securities.

Closing Conditions

The consummation of the Share Exchange is subject to customary closing conditions, including (i) the accuracy of the representations and warranties of the parties (subject to customary materiality qualifiers); (ii) compliance in all material respects by the parties with their respective covenants and agreements under the Share Exchange Agreement; (iii) delivery of customary closing certificates and good standing certificates; (iv) receipt by Board of a fairness opinion; (v) the absence of any law, order or injunction prohibiting the consummation of the Realbotix Transactions and (vi) receipt of any required third-party and regulatory approvals and consents.

The obligation of the Realbotix, Parent and Seller to complete the Closing is subject to the condition that, at Closing, we shall have an aggregate of at least \$12.5 million in Net Cash (the “Net Cash Condition”).

Additionally, the obligation of Realbotix, Parent and us to complete the Closing are subject to the conditions that (i) we have entered into an agreement with an investor, reasonably acceptable to us and Realbotix, providing for an equity line of credit pursuant to which such investor would commit to purchase up to an aggregate of \$125.0 million of Common Stock and (ii) the conversion of our Preferred Stock into Common Stock and the termination of or certain amendments to of all Onconetix Options and Onconetix Warrants (the “Convertible Securities Condition”).

Termination

In addition to termination by mutual written agreement, for the other party's uncured breach or if a governmental order permanently prohibits the Closing, the Share Exchange Agreement provides for termination:

- By either party if the Closing has not been consummated on or before November 30, 2026, provided the terminating party is not in breach in a manner that caused the failure to close by such date. The date is automatically extended to December 20, 2026 if all conditions to Closing other than the Net Cash Condition have been satisfied.
- By either party if our stockholder approval is not obtained at the stockholder meeting (including any adjournment or postponement thereof).
- By Realbotix if a Buyer Adverse Recommendation Change (as defined in the Share Exchange Agreement) occurs prior to receipt of Buyer stockholder approval.
- By us in connection with entering into a definitive agreement for a Buyer Superior Proposal (as define in the Share Exchange Agreement).
- By us if the audited Realbotix financial statements have not been delivered by April 30, 2026.

Each party will bear its own fees and expenses incurred in connection with the negotiation, execution and performance of the Share Exchange Agreement and the Realbotix Transactions. However, the Share Exchange Agreement provides for the payment of termination fees and reimbursement of transaction expenses in the following termination scenarios:

- In the event of a termination of the Share Exchange Agreement as a result of a material breach by either party, the breaching party will be required to pay a termination fee to the non-breaching party of \$500,000 plus transaction expenses, with such transaction expenses not to exceed \$500,000.
- In the event of a termination of the Share Exchange Agreement (i) by the Company as the result of a Buyer Adverse Recommendation Change or (ii) by Buyer upon entering into an agreement in respect of a Buyer Superior Proposal as a result of a Buyer Adverse Recommendation Change, Buyer must pay a termination fee of (A) \$500,000 plus all Seller transaction expenses plus (B) if the transaction in respect of a Buyer Superior Proposal closes, an additional \$1,500,000 upon closing of such transaction. If the transaction contemplated by the Buyer Superior Proposal doesn't close, Buyer is only obligated to pay \$500,000 plus all Seller transaction expenses.
- In the event of a termination of the Share Exchange Agreement by Realbotix for failure to satisfy the Net Cash Condition, if Net Cash at the time of termination would be greater than \$5.0 million (assuming the consummation of any Transaction Financing pursuant to Financing Agreements), we are obligated to pay Realbotix's transaction expenses, with such transaction expenses not to exceed \$500,000.

Representations and Warranties

We, Realbotix, and the Seller have made customary representations and warranties in the Share Exchange Agreement. The representations and warranties of us, Realbotix, and the Seller will not survive the Closing.

Covenants of the Parties

Each party to the Share Exchange Agreement agreed to use its commercially reasonable efforts to consummate the Realbotix Transaction.

The Share Exchange Agreement contains certain covenants by each of the parties, to be observed during the period between the execution of the Share Exchange Agreement and Closing, including covenants regarding: (1) the provision of access to information, properties, books, records and personnel; (2) delivery of audited financial statements of the Company; (3) litigation support; (4) the preparation and filing of a registration statement, SEC reports and related disclosure documents and compliance with Nasdaq listing and reporting requirements; (5) no insider trading; (6) further assurances; (7) public announcements; (8) confidentiality; (9) indemnification of directors and officers and tail insurance; and (10) transfer taxes.

The parties have agreed to take all necessary actions to cause our Board, immediately after closing, to consist of five directors, including: (i) one person who is designated by us and reasonably acceptable to Realbotix and (ii) four persons who are designated by Realbotix and reasonably acceptable to us.

We have also agreed to prepare and file with the Securities and Exchange Commission ("SEC") a registration statement on Form S-4 in connection with the registration under the Securities Act of 1933, as amended (the "Securities Act"), of the issuance of the Exchange Shares to be issued under the Share Exchange Agreement and containing a proxy statement (a "Proxy Statement") for the purpose of soliciting proxies from our stockholders for the matters to be acted on at the special meeting of our stockholders. We have also agreed to use reasonable best efforts to maintain its listing on the Nasdaq and to enable the listing on Nasdaq of the Exchange Shares.

During the time between the execution of the Share Exchange Agreement and the Closing, Realbotix agreed to conduct its business in the ordinary course of business in all material respects and to comply with certain covenants regarding the operation of its business, including covenants related to (i) amendments to the Realbotix's organizational documents; (ii) recapitalization of the Realbotix's equity interests; (iii) issuance of additional securities; (iv) incurrence of additional indebtedness; (v) material changes to tax elections; (vi) amendments to or termination of material contracts; (vii) maintenance of books and records; (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 as required to comply with U.S. GAAP; (xi) waiver, settlement or compromise of material claims, actions or proceedings, subject to specified thresholds; (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 specified thresholds; (xiv) adoption of a plan of liquidation, dissolution, merger, consolidation, restructuring, recapitalization or other reorganization; (xv) voluntary incurrence of liabilities or obligations in excess of specified thresholds other than pursuant to contracts in existence as of the date of the Share Exchange Agreement or entered into in the ordinary course of business; (xvi) sale, lease, license or other disposition of any material portion of the Realbotix's assets, properties or rights; (xvii) entry into any agreement, understanding or arrangement relating to the voting of the Realbotix's equity interests; (xviii) taking any action that would reasonably be expected to materially delay or impair the obtaining of any required governmental or regulatory consents in connection with the Share Exchange Agreement; or (xix) authorization or agreement to take any of the foregoing actions.

During the same period, we also agreed to conduct its business in the ordinary course of business in all material respects and to comply with certain interim operating covenants, including covenants restricting our ability, without Realbotix's prior written consent (subject to specified exceptions), to (i) amend its organizational documents; (ii) effect mergers, consolidations, acquisitions, liquidations, restructurings or other business combinations; (iii) issue, repurchase, redeem or otherwise modify its equity securities or declare dividends or other distributions; (iv) incur additional indebtedness or guarantee obligations of third parties; (v) dispose of material assets or subsidiaries; (vi) make material loans, advances or capital contributions; (vii) make material tax elections or changes in accounting methods, principles or practices, except as required by applicable law, GAAP or Regulation S-K; (viii) amend, terminate, waive or assign material contracts other than in the ordinary course of business; (ix) fail to maintain books, records or insurance coverage in the ordinary course of business; (x) establish subsidiaries or enter into new lines of business; (xi) settle material litigation or other proceedings other than within specified thresholds; (xii) make capital expenditures or incur liabilities in excess of specified thresholds; (xiii) enter into arrangements relating to the voting of Common Stock; (xiv) take actions that would reasonably be expected to materially delay or impair the receipt of required governmental or regulatory approvals; or (xv) authorize, commit or publicly propose any of the foregoing actions.

Governing Law

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

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.

Karina M. Fedasz had been appointed as our Interim Chief Executive Officer since April 2025 and Chief Financial Officer since June 2024, respectively. For more than two decades, Ms. Fedasz has helped companies raise capital, model and forecast business, manage cash flow and conduct mergers and acquisitions. She is a dynamic, data-driven executive with a bold, high-growth mindset. From January 2023 to June 2024, Ms. Fedasz worked with various clients, including a not-for-profit and an early-stage artificial intelligence and data-driven health and wellness tracker. From February 2022 to December 2022, Ms. Fedasz served as Head of Business Development for Evofem Biosciences, a Nasdaq-listed public biotech company developing innovative products for women's health. From August 2019 to October 2021, Ms. Fedasz served in various positions of increasing responsibility, including Chief Financial Officer, at IDW Media Holdings, a micro-cap media company, where she managed the company's initial public offering. From April 2018 to August 2019, Ms. Fedasz served as Chief Financial Officer of MOCEAN, an integrated agency for entertainment, gaming, and brands. Ms. Fedasz's breadth of experience has seen her lead teams in media, technology, services, manufacturing, and education, and she has worked with companies whose clients and customers include Fortune 500 companies such as Netflix, Disney, Amazon, Apple, Activision, and EA. Ms. Fedasz received an MBA with an emphasis in finance from Columbia Business School and a BA from University California at Los Angeles (UCLA). She holds an inactive CPA in the state of California.

Additionally, members of our board of directors ("Board") have extensive expertise in the fields of life sciences, business and finance. Our directors include Andrew Oakley, who had held several CFO positions at publicly-traded pharmaceutical companies, Sarah Romano, who has over a decade of experience leading the finance function of multiple publicly-traded companies, Dr. Thomas Meier, who has over two decades of experience as life-science and biotech entrepreneur, executive manager, and board member on life-science and biotech companies, and Timothy Ramdeen, who has nearly a decade of experience in private equity and hedge fund investing, capital markets, and company formation.

Nasdaq Compliance

On January 24, 2025, the Company received a letter from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of the Company's Common Stock from November 25, 2024 to January 10, 2025, the Company is no longer in compliance with the requirement for continued listing on The Nasdaq Capital Market to maintain a minimum bid price of \$1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Rule"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), Nasdaq provided the Company with 180 calendar days to regain compliance with the Minimum Bid Price Rule.

On April 14, 2025, Nasdaq issued a further notice (the "Notice") to the Company that it determined that the Company's securities had a closing bid price of \$0.10 or less for ten consecutive trading days. Accordingly, the Company is subject to the provisions under Nasdaq Listing Rule 5810(c)(3)(A)(iii). As a result, unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"), trading of the Common Stock would be suspended at the opening of business on April 23, 2025, and a Form 25-NSE would be filed with the SEC, which would remove the Company's securities from listing and registration on Nasdaq. On May 27, 2025, the Company appeared before the Nasdaq Hearings Panel and requested a stay of suspension. The Panel's decision about the stay request is still pending as of the date these financials were filed.

On April 24, 2025, the Company received an additional deficiency notice from Nasdaq that the Company was not in compliance with Nasdaq's continued listing standards as set forth in Listing Rule 5250(c)(1) (the "Filing Rule") given the Company's failure to timely file its Annual Report on Form 10-K for the fiscal year ended December 31, 2024, and that this matter serves as an additional basis for delisting the Company's securities from Nasdaq. As the Company was already before a Panel for its failure to comply with Minimum Bid Price Rule, the Company had seven calendar days from the date of the Notice, or until May 1, 2025, to request a stay of the suspension, which request would stay the suspension of the Company's securities pending the Panel's decision. The Company submitted a stay request on or before May 1, 2025.

On May 20, 2025, the Company received an additional deficiency notice from Nasdaq that the Company was not in compliance with Nasdaq's continued listing standards as set forth in Listing Rule 5250(c)(1) given the Company's failure to timely file its Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, and that this matter serves as an additional basis for delisting the Company's securities from Nasdaq. The Company had seven calendar days from the date of the Notice, or until May 27, 2025, to request a stay of the suspension, which would stay the suspension of the Company's securities pending the Panel's decision. On May 27, 2025, the Company appeared before the Panel and requested a stay of suspension.

Following the hearing before the Panel, on June 11, 2025, the Panel issued its decision, whereby it granted the Company's request for continued listing, ultimately subject to the Company's compliance with all applicable continued listing criteria by June 30, 2025.

On June 2, 2025, the Company filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2024 with the SEC, and on June 12, 2025, its Quarterly Report for the period ended March 31, 2025. Effective with the open of the market on June 13, 2025, the Company implemented a reverse stock split of its outstanding shares of Common Stock at a ratio of 1-for-85 shares.

On July 7, 2025, Nasdaq formally notified the Company that it had regained compliance with both the Filing Rule and the Bid Price Rule and otherwise satisfied all other applicable criteria for continued listing on The Nasdaq Capital Market. Nasdaq further noted, however, that Onconetix is subject to a Mandatory Panel Monitor, as defined in Nasdaq Listing Rule 5815(d)(4)(B), through July 7, 2026 (the "Panel Monitor"). If, within the one-year period, Nasdaq determines that the Company fails to satisfy the Filing Rule or the Bid Price Rule, Nasdaq will issue a delisting determination, which determination would be stayed upon the Company's subsequent timely request for a new hearing before the Panel, rather than providing the Company with the opportunity to present a plan to regain compliance with the Filing Rule for consideration by Nasdaq Listing Qualifications Staff or a 180-day grace period to regain compliance with the Bid Price Rule as otherwise provided in the Nasdaq Listing Rules.

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"). The closing of the acquisition of Proteomedix for all stock consideration provided Proteomedix shareholders with an initial 16.4% ownership stake of Onconetix, and Series B Preferred Stock convertible into 79,315 shares of Onconetix Common Stock, subject to Onconetix stockholder approval of the same ("Stockholder Approval"). On September 5, 2024, at the annual stockholders' meeting of the Company, the Company obtained the requisite Stockholder Approval from Onconetix stockholders. On September 24, 2024, all outstanding shares of Series B Preferred Stock converted into an aggregate of 79,315 shares of Onconetix Common Stock.

Consideration

Pursuant to the Share Exchange Agreement, on December 15, 2023, in full payment for the Purchased Shares, Onconetix issued shares (the “Exchange Shares”) consisting of: (i) 1,081 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 79,315 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, 6,718 and 6,566 shares of Common Stock were issued and outstanding, respectively.

The fair value of the 1,081 shares of Common Stock, was determined using the closing price of the Common Stock as of the Share Exchange Closing Date, which was \$809.88. 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. Immediately following the Conversion (as defined below) and closing of the investment pursuant to the Subscription Agreement (as defined below), Sellers owned approximately 87.2% of the outstanding equity interests of Onconetix, the PMX Investor owned approximately 7.5% of the outstanding equity interests of Onconetix, and the stockholders of Onconetix immediately prior to the Share Exchange Closing owned 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, remained outstanding until the Conversion unless otherwise terminated in accordance with its terms. At the Conversion, each outstanding Proteomedix Stock Option, whether vested or unvested, was 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 agreed, 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: (i) represented 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) had 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.

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.

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 \$3.40 per share, for an aggregate purchase price per Unit of \$850 (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.

On January 23, 2024, the Company issued a non-convertible debenture (the “Altos Debenture”) to the PMX Investor in the principal sum of \$5.0 million, the payment of which shall offset the \$5.0 million subscription amount for the Units pursuant to the Subscription Agreement.

The Altos Debenture had an interest rate of 4.0% per annum, and the principal and accrued interest was originally 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 Altos Debenture.

On April 24, 2024, the Altos Debenture was amended to extend the maturity date to the earlier of (i) the closing under the Subscription Agreement and (ii) October 31, 2024 (the “Altos Amendment”). On September 24, 2024, upon obtaining stockholder approval and pursuant to the Subscription Agreement, the Company issued an aggregate of 6,040 units (the “Units”) to Altos, each Unit comprised of (i) one share of Common Stock and (ii) one pre-funded warrant (collectively, the “Altos Warrants”) to purchase 0.3 shares of Common Stock at an exercise price of \$3.40 per share. The Altos Warrants were immediately exercisable at any time on or after the date of issuance and had a term of exercise of five (5) years from the date of issuance. The outstanding debt, as per the Altos Debenture agreement, is considered settled through the unit issuance.

Additional shares are issuable to Altos to the extent Altos continues to hold Common Stock included in the Units and if the VWAP during the 270 days following closing is less than \$850, as set forth in the Subscription Agreement.

On September 24, 2024, Altos exercised all the Altos Warrants, and the Company issued to Altos an additional 1,812 shares of Common Stock upon such exercise.

On June 24, 2025, the 270-day volume weighted average price after the closing of the Subscription Agreement was below \$850. In accordance with the Make-Whole Provision under the Subscription Agreement, the Company issued 241,514 shares of common stock (the “Make-Whole Shares”) to Altos Venture AG, following the determination that the 270-day volume weighted average price (“Issuer VWAP”) was below the \$850 threshold. The Company recorded common stock of \$2 and additional paid in capital of \$995,036 related to the issuance of the 241,514 shares in the accompanying consolidated balance sheet as of December 31, 2025.

ENTADFI

On April 19, 2023, the Company entered into an asset purchase agreement with Veru Inc., a Wisconsin corporation (“Veru”, and the 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 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 (the “April Veru Note”) and September 30, 2024 (the “September Veru Note,” together with the “April Veru Note”, the “Veru Notes”).

Additionally, the terms of the Veru APA required 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 were to be 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.

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 \$1.0 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, which converted in to 1,679 shares of Common Stock on September 24, 2024.

In 2024 and 2025, the Company and Veru modified and extended the payment terms under the Veru Notes on various occasions. Subsequently, on August 28, 2025, Veru and the Company agreed to amend and restate the September Veru Note (as amended and restated, the “Second A&R September Veru Note”). Pursuant to the Second A&R September Veru Note, the principal amount owed to Veru was increased by \$100,000 to an aggregate principal amount of \$5.2 million, and the maturity date was amended to September 19, 2025. All other terms of the September Veru Note remained the same. On August 28, 2025, Veru and the Company also entered into a waiver agreement (the “August 2025 Veru Waiver”) pursuant to which Veru agreed to waive and extend the date for payment of the April Veru Note to September 19, 2025.

As of September 22, 2025, approximately \$8.8 million was payable to Veru under the Veru Notes and related amendments. On September 22, 2025, the Company and Veru entered into a Settlement Agreement and Release (the “Veru Settlement Agreement”), pursuant to which Veru agreed to accept a cash payment of approximately \$6.3 million (including interest accrued through receipt of the Settlement Amounts (as defined herein), 3,125 shares of Series D Preferred Stock (as defined below) and 846,975 Series D Warrants (as defined below and such cash payment, shares of Series D Preferred Stock and Series D Warrants, collectively, the “Settlement Amounts”) in full satisfaction of all amounts due under the Veru Notes, as amended by all preceding amendments, forbearance agreements, and waivers, and Veru agreed that such acceptance constituted complete discharge of all obligations thereunder. The Settlement Agreement contains customary release provisions that upon timely delivery of the Settlement Amounts, Veru shall release all claims or actions against the Company.

As of September 24, 2025, Veru confirmed receipt of all Settlement Amounts in satisfaction of all outstanding amounts, and all Veru Notes and related amendments were deemed cancelled and terminated, respectively, and of no further force or effect.

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 abandoned commercialization of ENTADFI and no longer holds inventory of ENTADFI. There is currently no plan to resume commercialization of ENTADFI. In addition, as part of cost reduction efforts and in connection with our initial pause in commercializing ENTADFI, we terminated three employees involved with the ENTADFI program, effective April 30, 2024, with such individuals to continue assisting the Company on an as-needed, consulting basis. At December 31, 2024 and 2025, the ENTADFI assets were fully impaired.

Business of the Company

Business Model

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 excessive use of MRI and 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 on 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 can 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 currently corresponds to the market development stage and selected laboratories are offering Proclarix. In 2025, we had revenues of \$23,091 from sales of Proclarix. Prior to being acquired by Onconetix in 2023, Proteomedix had \$67,380 from sales of Proclarix. 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. med. Thomas Cerny, president of the Swiss Cancer Research Foundation, Prof. Ruedi Aebersold, a pioneer in proteomics technology development, and the late Prof. Dr. 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 Brühlmann (Chief Business Officer), with seasoned experience in finance, business development and product management. On February 18, 2025, Christian Brühlmann resigned from his position as Chief Strategy Officer of the Company. Mr. Brühlmann will remain in his position as Chief Business Officer of Proteomedix. On February 24, 2025, Dr. Schiess resigned from his positions as the Interim Chief Executive Officer of the Company and Chief Science Officer of Proteomedix, effective immediately, and from his position as Chief Executive Officer of Proteomedix, effective May 31, 2025.

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).

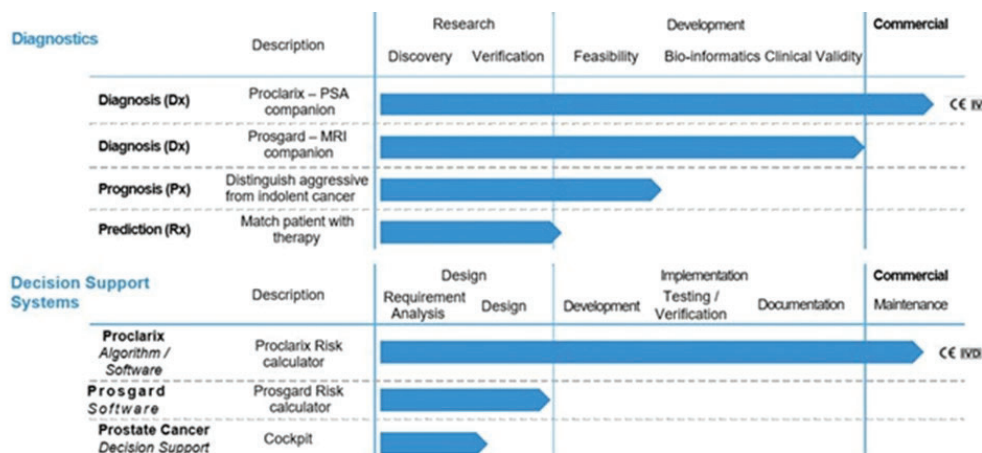


Figure 1: Product Pipeline

Proclarix 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.

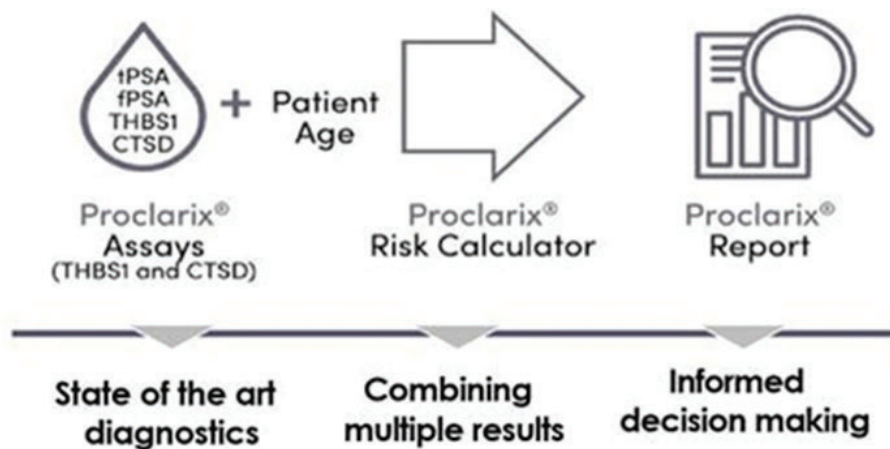


Figure 2: Proclarix: Assays and software algorithm for risk score calculation.

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.

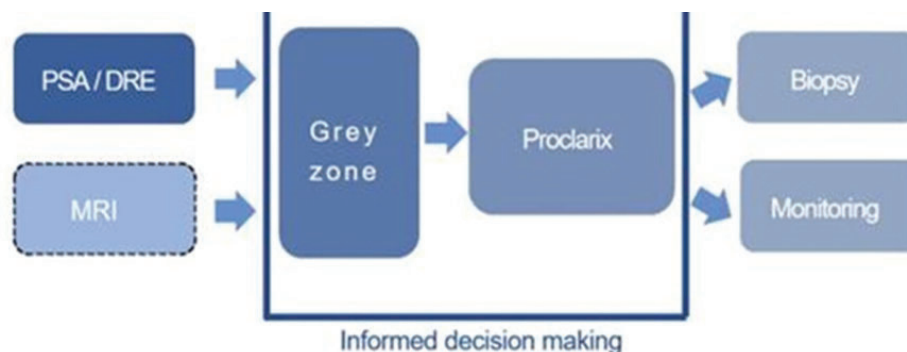


Figure 3: Proclarix: Finding clinically significant prostate cancer in the diagnostic “grey zone.”

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 metalloproteinase 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.

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. Additionally, in December 2025, Proteomedix and LabCorp entered into an amendment to the exclusive partnership whereby LabCorp would conduct a new validation study starting in 2026.

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, the first diagnostic product of Proteomedix, is addressing unmet medical needs related to the early detection of prostate cancer, which is the second most frequently diagnosed cancer in men. There were 1,467,854 new cases of prostate cancer and 397,430 prostate cancer related deaths worldwide in 2022 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 \$109 billion in 2025. 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.

Competition

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.

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 Proclarity 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.

Foreign Regulation

In order to market any product outside of the United States, we 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 product. 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 autoimmune 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. As of the date of this Report, Proteomedix transitioned from IVDD to IVDR and the Proclarix devices are certified under the new legislation and fully compliant with IVDR.

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.

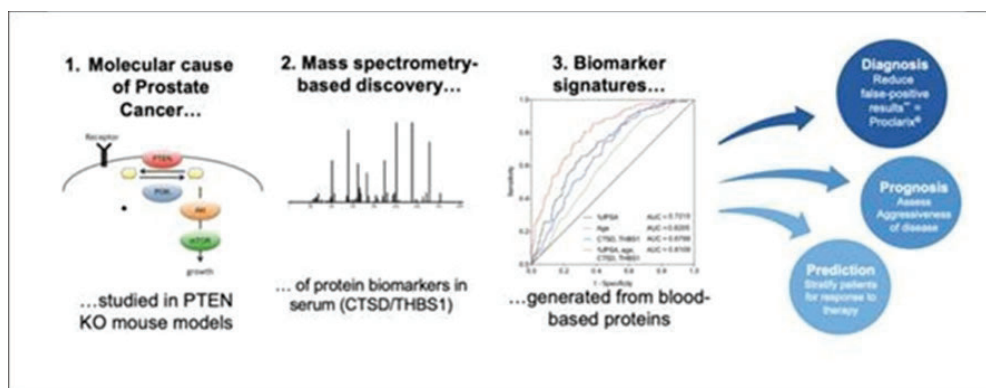


Figure 5: Proteomedix's approach to improve prostate cancer disease management.

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 complementary platform and biomarker developments with utility in cancer patient management.

In 2022, Immunovia AB (Sweden) ("Immunovia") 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.

In September 2025, Proteomedix and Immunovia furthered their relationship by entering into a separate licensing agreement. Under the licensing agreement, Proteomedix will produce master cell lines for three of the five biomarkers used in PancreaSure, a Immunovia pancreatic cancer diagnostic test, and license key intellectual property related to the manufacturing of associated reagents to Immunovia in consideration for two payments of \$300,000 each to Proteomedix, due on September 30, 2025, and March 31, 2026. Additionally, Immunovia will make a \$100,000 payment for materials and pay a 3% royalty on net sales of PancreaSure and any other products incorporating the licensed intellectual property from January 1, 2026, through December 31, 2032.

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 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 (expired May 3, 2024), that ETH Zurich licensed from the Institute for Systems Biology (ISB), Seattle. The license enabled Proteomedix to use the glycoprotein technology for the development of new diagnostic products. The license was terminated in connection with the expiration of the patent and no further license payments are required.

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.

Manufacturing and Supply

We currently do not own or operate any manufacturing facilities. For Proclarix, we outsource 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. 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.

Employees

As of March 10, 2026, we had 2 full-time and 6 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 expired on December 31, 2025 and was renewed for a two-year term with a monthly rent of \$2,000 per month. The lease will automatically renew for successive two-year terms, unless terminated. Either party may terminate the lease with twelve 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.

Fundraising Activities

On October 1, 2024, the Board authorized the Company to create a series of 10,000 shares of preferred stock designated as "Series C Preferred Stock", with a par value of \$0.00001, pursuant to the Certificate of Designations of Series C Preferred Stock. At any time after the initial issuance date of Series C Preferred Stock, each Series C Preferred Stock shall be convertible into validly issued, fully paid and non-assessable shares of Common Stock. On October 2, 2024, the Company entered into, and sold, to six institutional investors (collectively, the "Series C PIPE Investors"), pursuant to a securities purchase agreement, an aggregate of 3,499 shares of Series C Preferred Stock, which includes an issuance of 840 shares of Series C Preferred Stock to the lead investor in consideration for the Series C PIPE Investors' irrevocable commitment to purchase shares of the Series C Preferred Stock, and warrants to purchase 6,963 shares of Common Stock, for aggregate net cash proceeds to the Company of \$1.9 million.

On October 2, 2024, the Company entered into a Common Stock ELOC Purchase Agreement relating to a Committed Equity Facility with an institutional investor (the "ELOC Purchaser"), whereby the Company may offer and sell, from time to time at its sole discretion, and whereby the ELOC Purchaser has committed to purchase, up to \$25.0 million of the Company's newly issued Common Stock, subject to certain limitations. As of December 31, 2025, the Company has sold approximately 661,762 shares under the ELOC Purchase Agreement for gross proceeds of approximately \$7.1 million.

On July 16, 2025, the Company exercised its voluntary adjustment right under the Certificate of Designation of the Series C Preferred Stock to lower the conversion price of the Series C Preferred Stock to \$3.50, and holders of 1,920 shares Series C Preferred Stock agreed to convert their shares into shares of Common Stock.

As of December 31, 2025, 7 shares of Series C Preferred Stock were outstanding from the original issuance of 3,499, after the redemption of 1,369 shares of Series C Preferred Stock for an aggregate consideration of \$1.71 million, the conversion of 1,920 shares of Series C Preferred Stock into common stock, and the exchange of 203 shares of Series C Preferred Stock into 244 shares of Series D Preferred Stock.

On September 22, 2025, the Company entered into a securities purchase agreement (the "Series D Securities Purchase Agreement") with eleven institutional investors, and sold or exchanged debt, to such investors (collectively, the "Series D PIPE Investors") an aggregate of 16,099 shares of Series D convertible preferred stock, par value \$0.00001 per share ("Series D Preferred Stock"), which includes an issuance of 500 shares of Series D Preferred Stock to the lead investor in consideration for the Series D PIPE Investors' irrevocable commitment to purchase shares of the Series D Preferred Stock, and warrants (the "Series D Warrants") to purchase 4,362,827 shares of Common Stock, for an aggregate purchase price of approximately \$12.9 million and net cash proceeds of \$9.3 million. The exercise price of the Series D Warrants is \$3.6896, and the Series D Warrants are exercisable beginning on the issuance date and expire on the third anniversary of the issuance date.

On October 1, 2025, the Company entered into a securities purchase agreement (the "Series E Securities Purchase Agreement") with institutional investor(s) and sold to such institutional investors(s)(collectively, the "Series E PIPE Investors"), an aggregate of 7,813 shares of Series E convertible preferred stock, par value \$0.00001 per share ("Series E Preferred Stock"), which are convertible into shares of common stock and warrants (the "Series E Warrants") to purchase 2,025,223 shares of Common Stock, for an aggregate purchase price of approximately \$6.25 million, which was also equal to the net cash proceeds. The exercise price of the Series E Warrants is \$3.8576, and the Series E Warrants are exercisable beginning on the issuance date and expire on the third anniversary of the issuance date.

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 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 \$14.0 million and \$58.7 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of \$131.2 million. We also generated negative operating cash flows of \$9.7 million for the year ended December 31, 2025.

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

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

We have incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of December 31, 2025, we had cash of approximately \$5.2 million, a working capital deficit of approximately \$3.1 million and an accumulated deficit of approximately \$131.2 million. In addition, as of March 11, 2026, our cash balance was approximately \$3.6 million.

We estimate, as of the date of this Report, that our current cash balance is not sufficient to fund operations for one year from the date of issuance of these consolidated financial statements. 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 the commercialization of Proclarix, which is still subject to further successful development and commercialization activities within certain jurisdictions.

We have entered into Series D and Series E PIPE financings with certain investors in September 2025 and October 2025, respectively which provided us additional cash flow to support our near-term operations. While such capital raises may enable us to sustain current operations and meet existing obligations, we continue to generate recurring net operating losses and have not yet established sustained positive cash flows to support our strategic growth initiatives. Such initiatives include the commercialization of Proclarix and our development and commercialization of future product candidates. These factors raise substantial doubt on our ability to continue as a going concern for one year from the date of issuance of our consolidated financial statements for the financial year ended December 31, 2025.

Our management plans for funding our operations include generating product revenue from sales of Proclarix, which is currently subject to further successful development and commercialization activities within certain jurisdictions. Our management also intends to pursue additional equity or debt financing to support operations and strategic initiatives. However, other than the outstanding Committed Equity Facility, there are currently no committed sources of financing, and there is no assurance that additional funding will be available on favorable terms, if at all. This uncertainty raises significant concern about our ability to sustain operations and execute our strategic initiatives. If additional capital is not secured, we may need to curtail clinical trials, development, and commercialization efforts, and take further measures to reduce expenses to conserve cash.

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

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

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

Our current liabilities are significant, and if those to whom we owe accounts payable, were to demand payment, we would be unable to pay.

As of December 31, 2025, we had total current liabilities of approximately \$9.1 million, including accounts payable of approximately \$1.8 million, accrued expenses of approximately \$0.3 million, derivative liabilities of approximately \$7.0 million, and approximately \$0.03 million related to contingent warrant liabilities. As of the same date, we had cash of only \$5.2 million. In September 2025, we completed a Series D financing, which satisfied all amounts due under the Veru notes. In October 2025, we completed a Series E financing, and plan to seek additional funding as necessary to support our operations and growth initiatives. However, the level of our current liabilities may make it more difficult for us to obtain adequate financing on favorable terms, if at all. If those to whom these payments are due were to demand immediate payment, as they are entitled to do, and we are not able to make the required payments, we would be subject to liability if our creditors chose to enforce their rights, which could result in our bankruptcy and insolvency. Under such a scenario, our assets would be distributed to our creditors leaving nothing to be distributed to our stockholders.

Risks Related to the Commercialization of our Product

The marketing approval processes in the United States are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for Proclarix, our business may be harmed.

Although the FDA regulates in vitro diagnostic devices, some laboratory companies like LabCorp have successfully commercialized diagnostic tests for various conditions and disease states without seeking clearance or approval for such tests through a 510(k) or Premarket Application (“PMA”) approval process. These tests are known as LDTs and are designed, manufactured, and used within a single laboratory that is certified under the Clinical Laboratory Improvement Amendments (“CLIA”). CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for diagnostic, preventative or treatment purposes. Such LDT testing is currently under the purview of the Centers for Medicare & Medicaid Services (“CMS”) and state agencies that provide oversight of the safe and effective use of LDTs. A large number of laboratory testing in the United States consists of LDTs.

Proclarix has not yet advanced to the point when LabCorp could seek marketing approval for commercialization by CMS and state agencies in the United States. LabCorp cannot commercialize Proclarix in the United States without first obtaining approval from the CMS and state agencies, and Proclarix marketing approval could be delayed.

On May 6, 2024, the FDA issued a final rule to amend its regulations to make explicit that IVDs are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, the Food and Drug Administration is phasing out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. If the new requirements are phased in, future offerings may require a 510(k) submission or a PMA application to the FDA.

This regulatory review and approval process for medical devices can be costly, timely, and uncertain. This process may involve, among other things, successfully completing additional clinical trials and submitting a premarket clearance notice or filing a premarket approval application with the FDA. If premarket review is required by the FDA, there can be no assurance that Proclarix will be cleared or approved on a timely basis, if at all. In addition, there can be no assurance that the labeling claims cleared or approved by the FDA will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our products. Ongoing compliance with FDA regulations could increase the cost of conducting business, subject us to FDA inspections and other regulatory actions, and potentially subject us to penalties in the event we fail to comply with such requirements.

We depend entirely on the success of a single product. If we do not successfully commercialize our product or we experience significant delays in doing so, this product may not be profitable.

Our business currently depends heavily on the successful commercialization of our product Proclarix. We cannot be certain that our product will be successfully commercialized. The manufacturing, safety, efficacy, labeling, sale, marketing, and distribution of our product are, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. The success of our product 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 product;
- acceptance of our product 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 product;
- competing effectively with other therapies and diagnostics, including with respect to the sales and marketing of our product; 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 product, which would materially harm our business, financial condition, and results of operations.

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

Obtaining and maintaining regulatory approval of our product 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 product 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 product 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 product 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.

Even if we are able to commercialize our product, it 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 product 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 product 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 product.

Our product, 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 product, manufacturers or manufacturing processes and facilities or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on our product, 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 product 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 product;
- 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 product and product candidates internationally.

We intend to market our product and product candidates in international markets. In order to market our product 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 product in any market.

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

If the Company is unable to realize the full strategic and financial benefits previously anticipated from acquisition, our shareholders may experience a dilution of their ownership interests in our Company without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the Company is able to realize only part of the strategic and financial benefits previously anticipated from the transactions. 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 abandoned commercialization of ENTADFI and no longer holds inventory of ENTADFI. There is currently no plan to resume commercialization of ENTADFI.

Disruptions to or significantly increased costs associated with transportation and other distribution channels for 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 Proclarix. These third-party logistics companies may experience disruptions to the transportation channels used to distribute our product, 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 are dependent on third parties, including LabCorp, to develop, market, distribute and sell our product.

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

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

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

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

Physicians and other authorized health care practitioners may not prescribe our product, which would prevent our product from generating revenue. Market acceptance of our product 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 product is approved;
- acceptance by healthcare providers and payors of our product 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 product for the conditions for which it is intended;
- the availability and efficacy of competitive drugs or tests;
- the effectiveness of our sales and marketing efforts;
- the extent to which our product is 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 product is safe and efficacious for its approved indications, healthcare providers may not immediately be receptive to the use or may be slow to adopt such product 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 product as being superior to competing products. If our product does 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 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;
- unforeseen complications arise with respect to use of our product 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.

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 product 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, 2025, 100% of our development service revenue, 100% of our other revenue, and 92% of our product sales revenue came from Immunovia, and 5% and 3% of our remaining product sales revenue came from Zentrum für Labormedizin and Cambridge, respectively. For the year ended December 31, 2024, 100% of our development service revenue came from Immunovia, and 73% and 18% of our product sales revenue came from LabCorp and Cambridge, respectively.

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 product that will be generated by these customers or the future demand for our product 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 product, 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.

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 product 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 product.

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 product, it may have a negative impact on our business, financial condition, and results of operations.

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

We do not have any manufacturing facilities. We will rely on third-party manufacturers for commercial supply of Proclarix.

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 product, 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 product and harm our business and results of operations.

Our product may compete with other products and/or product candidates 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 product, 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 product may adversely affect our future profit margins and our ability to commercialize our product 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 product.

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 product 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 product 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 product 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 product 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 this product at a cost or in quantities sufficient to make this product 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 our finished product. 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 product 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 product, 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 product.

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 product, 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 product.

We face an inherent risk of product liability exposure related to the commercialization of our product. 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 product;
- 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 product;
- 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 product to include the sale of commercial product 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, product 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 product 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 March 11, 2026, we had 2 full-time and 6 subcontracted employees. We will need to increase the size of our organization in order to support our continued commercialization of our product. 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 product 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 product. 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 product 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 for 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 product.

In the event that our product is the subject of guidelines, clinical studies or scientific publications that are unhelpful or damaging, or otherwise call into question the benefits of our product, 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 product could adversely affect the prevailing market price for our common stock.

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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 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 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 product and/or product candidates that we seek to commercialize or develop, if any, that may affect our ability to commercialize such methods and/or product 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 product and/or product candidates. Even if all our main methods and/or product 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 product 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 product 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 product 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 product 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 product and/or product candidates, or manufacture or use of our product 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 product 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 product 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 product 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 product and/or product candidates to market and be precluded from manufacturing or selling our product 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 product and/or product candidates. 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 product or result in our inability to exploit and/or commercialize our technology and methods and/or product 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 product 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 product and/or product candidates or future product 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 product 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 product.

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 our product 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 manufacturers' 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.

The enhanced ACA premium subsidies that were extended through 2025 under the Inflation Reduction Act are still in effect, even though they were set to expire at the end of 2025. Extension efforts are ongoing, but Congress has not yet succeeded in securing a continuation of enhanced ACA exchange subsidies beyond 2025, and the outcome remains uncertain. Meanwhile, the Medicare drug price negotiation program created by the IRA is now being implemented: Medicare has negotiated lower prices for an initial set of high-cost Part D drugs effective January 1, 2026, and additional drugs have been selected for subsequent years, with negotiation expanding in 2027 and beyond to include more Part D and later Part B drugs.

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 product 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 product 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 product 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 product 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 product 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 13, 2025 and May 13, 2025, the closing price of our common stock on Nasdaq was \$46.07 and \$6.46, respectively, and daily trading volume on these days was approximately 2,498 and 95,267 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.

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.
- 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 expense payments 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.
- 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.

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 March 11, 2026, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own or control 557,604 shares of our common stock, which in the aggregate represents approximately 15.6% 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.

There are no assurances that the Panel will grant the Company's request for continued listing or an extension to demonstrate compliance. If the Company does not obtain a favorable decision from the Panel, its Common Stock will become subject to delisting.

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 3,584,245 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 17,058 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 23 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 market price of the securities.

The issuance or conversion of common shares or other securities convertible into common shares would result significant dilution in the equity interest of existing shareholders and adversely affect the market price of the common shares.

In particular, the Company is party to an ELOC, pursuant to which it may offer and sell, from time to time at its sole discretion, up to \$25.0 million of newly issued Common Stock, subject to certain limitations. As of December 31, 2025, the Company has sold approximately 661,762 shares under the ELOC Purchase Agreement for aggregate proceeds of approximately \$7.1 million. In addition, as of December 31, 2025, 7 shares of Series C Preferred Stock were outstanding from the original issuance of 3,499 shares of Series C Preferred stock to institutional investors, after (i) the redemption of 1,369 shares of Series C Preferred Stock for aggregate consideration of \$1.71 million, (ii) the conversion of 1,920 shares of Series C Preferred Stock into shares of common stock, and (iii) the exchange of 203 shares of Series C Preferred Stock into 244 shares of Series D Preferred Stock. As of December 31, 2025, 16,325 shares of Series D Preferred Stock and 7,813 shares of Series E Preferred stock, respectively, were outstanding. In addition, as of March 11, 2026, at the election of their holders, 1,916 shares of Series D Preferred Stock had converted into 1,852,715 shares of common stock and 132 shares of Series E Preferred Stock had converted into 176,363 shares of common 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 product 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.

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 product, 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.

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.

Risks Related to Pending Share Exchange

We could fail to complete the Realbotix Transactions, or the Realbotix Transactions may be completed on different terms.

There can be no assurance that the Realbotix Transactions will be completed, or if completed, that they will be completed on the same or similar terms to those set out in our previous disclosure. The Realbotix Transactions are subject to the satisfaction of a number of conditions precedent, some of which are outside our control, which include, among others, performance by Simulacra and Realbotix of their respective obligations and covenants in the Share Exchange Agreement. If these conditions are not satisfied (or waived) or the Realbotix Transactions are not completed for any other reason, our stockholders will not receive the consideration contemplated in the Share Exchange Agreement.

If the Realbotix Transactions are not completed, our ongoing business may be adversely affected as a result of the costs (including opportunity costs) incurred in respect of pursuing the Realbotix Transactions, and we could experience negative reactions from the financial markets, which could cause a decrease in the market price of our Common Stock, particularly if the current market price reflects market assumptions that the Realbotix Transactions will be completed or completed on certain terms. We may also experience negative reactions from our employees and there could be negative impact our ability to attract future business opportunities. Failure to complete the Realbotix Transactions or a change in the terms of the Realbotix Transactions could each have a material adverse effect on our business, financial condition and results of operations.

The issuance of securities would result in significant dilution in the equity interest of existing stockholders and adversely affect the marketplace of our Common Stock.

The issuance or conversion of Common Stock or other securities convertible into Realbotix Common Stock in connection with the Realbotix Transactions would result in significant dilution in the equity interest of our existing stockholders and adversely affect the market price of our Common Stock. In addition, future issuances of, or conversions of, securities may result in significant dilution to our existing stockholders, which could adversely impact your investment.

Our stockholders may not realize a benefit from the acquisition of Realbotix commensurate with the ownership dilution they will experience in connection with the Realbotix Transactions contemplated by the Share Exchange Agreement.

If we are unable to realize the full strategic and financial benefits currently anticipated from the Realbotix Transactions, our stockholders may experience a dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent we are able to realize only part of the strategic and financial benefits currently anticipated from the Realbotix Transactions. The Realbotix Transactions may pose integration challenges which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Realbotix Transactions to our stockholders.

The failure to successfully integrate the businesses of us and Realbotix in the expected timeframe would adversely affect our future results.

Our ability to successfully integrate our operations and those of Realbotix will depend, in part, on our ability to realize the anticipated benefits from the Realbotix Transactions. If we are not able to achieve the stated objectives, the anticipated benefits of the Realbotix Transactions may not be realized fully, or at all, or may take longer to realize than expected, and the value of our Common Stock may be adversely affected. In addition, the integration of our and Realbotix's respective businesses will be a time-consuming and expensive process. Proper planning and effective and timely implementation will be critical to avoid any significant disruption to our operations. It is possible that the integration process could result in the loss of key employees, the disruption of our business or the identification of inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with customers, suppliers, distributors, creditors or lessors, or to achieve the anticipated benefits of the Realbotix Transactions. Delays encountered in the integration process could have a material adverse effect on our operating results and financial condition, including the value of our Common Stock.

The pending Realbotix Transactions may divert the attention of our management.

The pending Realbotix Transactions could cause the attention of our management to be diverted from the day-to-day operations. These disruptions could be exacerbated by a delay in the completion of the Realbotix Transactions and could have an adverse effect on our business, operating results or prospects regardless of whether the Realbotix Transactions are ultimately completed.

Unexpected market disruptions may cause major losses for us not anticipated under the Share Exchange Agreement.

We may incur major losses in the event of disrupted markets and other extraordinary events in which market behavior diverges significantly from historically recognized patterns, which may offset any potential benefits achieved under the Share Exchange Agreement. The risk of loss in such events may be compounded by the fact that, in disrupted markets, many positions become illiquid, making it difficult or impossible to close out positions against which markets are moving. Market disruptions caused by unexpected political, military and terrorist events, or other factors, may from time to time cause dramatic losses for us.

Risks associated with changes in the technology industry.

Realbotix operates in a competitive industry characterized by rapid technological change and evolving industry standards. Realbotix's ability to attract new customers to its business, and generate revenue from existing customers will depend largely on its ability to anticipate industry standards and trends, respond to technological advances in its industry, and keep pace with technological developments and customers' increasingly sophisticated needs. The success of any enhancement of Realbotix's products or new related applications will depend on several factors, including the timely completion and market acceptance of the products.

Realbotix's services are expected to embody complex technology that may not meet those standards, changes and preferences. Realbotix's ability to design, develop and commercially launch products depends on a number of factors, including, but not limited to, its ability to design and implement solutions and services at an acceptable cost and quality, its ability to attract and retain skilled technical employees, the availability of critical components from third parties, and its ability to successfully complete the development of the products in a timely manner. There is no guarantee that Realbotix will be able to respond to market demands. If Realbotix is unable to effectively respond to technological changes or fails or delays to develop services in a timely and cost-effective manner, Realbotix may be unable to recover our development expenses which could negatively impact sales, profitability and the continued viability of its business.

We may be unable to protect Realbotix's intellectual property.

Realbotix's commercial success depends to a significant degree upon its ability to develop new or improved technologies, instruments, and services, and to obtain patents, where appropriate, or other intellectual property rights or statutory protection for these technologies and products in Canada and the United States. Despite devoting resources to the research and development of proprietary technology, Realbotix, may not be able to develop new technology that is patentable or protectable. Further, patents issued to Realbotix, if any, could be challenged, held invalid or unenforceable, or be circumvented and may not provide Realbotix with necessary or sufficient protection or a competitive advantage. Competitors and other third parties may be able to design around Realbotix's intellectual property or develop technology similar to Realbotix's products that is not within the scope of such intellectual property. Realbotix's inability to secure its indirectly owned, intellectual property rights may have a materially adverse effect on its business and results of operations.

The business of Realbotix is exposed to cybersecurity risks.

Cyber incidents can result from deliberate attacks or unintentional events, and may arise from internal sources (e.g., employees, contractors, suppliers and operational risks) or external sources (e.g., nation states, terrorists, hackers, competitors and acts of nature). Cyber incidents include unauthorized access to information systems and data (e.g., through hacking or malicious software) for purposes of misappropriating or corrupting data or causing operational disruption. Cyber incidents also may be caused in a manner that does not require unauthorized access, such as causing denial-of-service attacks on websites (e.g., efforts to make network services unavailable to intended users). A cyber incident that affects Realbotix might cause disruptions and adversely affect their respective business operations and might also result in violations of applicable law (e.g., personal information protection laws), each of which might result in potentially significant financial losses and liabilities, regulatory fines and penalties, reputational harm, and reimbursement and other compensation costs to Realbotix. In addition, substantial costs might be incurred to investigate, remediate, and prevent cyber incidents.

We expect to incur significant transaction costs in connection with the Realbotix Transactions

We expect to incur a number of non-recurring costs associated with negotiating and completing the Realbotix Transaction. These fees and costs have been, and will continue to be, substantial and, in many cases, will be borne by us whether or not the Realbotix Transaction is completed. A substantial majority of our non-recurring expenses will consist of transaction costs related to the Realbotix Transactions and include, among others, fees paid to financial, legal, accounting and other advisors. We will continue to assess the magnitude of these costs, and we may incur additional unanticipated costs. The costs described above and any unanticipated costs and expenses, many of which will be borne by us even if the Realbotix Transaction is not completed, could have an adverse effect on our financial condition and operating results.

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 have implemented 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. The program is subject to ongoing review and improvement as our threat environment and operations evolve. 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 include:

- conducting risk assessments to identify material cybersecurity threats to our critical systems, data, product, 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 awareness training for employees to promote a security-conscious culture and reduce the risk of human error.

Cybersecurity Governance

The governance of cybersecurity risks is a critical function of our Board, 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 receives 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 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 Interim Chief Financial Officer. This team is responsible for 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 expired on December 31, 2025, and was renewed for a successive two-year term, resulting in an additional right-of-use asset and lease liability of approximately \$49,000. The lease, as renewed, requires payments of approximately \$24,000 over the next twelve months. The lease will automatically renew for successive two-year terms, unless terminated. Either party may terminate the lease with twelve 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 March 11, 2026, there were approximately 27 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 that have not been previously reported on a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

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 acquisition of Proteomedix, which closed on December 15, 2023, we own Proclarix, an in vitro diagnostic test for prostate cancer originally developed by Proteomedix and approved for sale in the European Union under the In Vitro Diagnostic Regulation ("IVDR"), which we anticipate will be marketed in the U.S. as a lab developed test through our license agreement with LabCorp.

We also own ENTADFI, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of BPH, a disorder of the prostate. However, in light of (i) the time and resources needed to continue pursuing commercialization of ENTADFI, and (ii) the Company's cash runway and indebtedness, the Company abandoned commercialization of ENTADFI and no longer holds remaining inventory of the product as of December 31, 2025. In addition, as part of cost reduction efforts and in connection with our initial pause in commercializing ENTADFI, we terminated three employees involved with the ENTADFI program, effective April 30, 2024, with such individuals to continue assisting the Company on an as-needed, consulting basis. Based on the circumstances surrounding ENTADFI, at June 30, 2024, the ENTADFI assets were fully impaired.

We are currently focusing our efforts on commercializing Proclarix.

Proclarix is an easy-to-use next generation protein-based blood test that can be done with the same sample as a patient's regular Prostate-Specific Antigen ("PSA") test. The PSA test is a well-established prostate specific marker that measures the concentration of PSA molecules in a blood sample. A high level of PSA can be a sign of prostate cancer. However, PSA levels can also be elevated for many other reasons including infections, prostate stimulation, vigorous exercise or even certain medications. PSA results can be confusing for many patients and even physicians. It is estimated over 50% of biopsies with elevated PSA are negative or clinically insignificant resulting in an overdiagnosis and overtreatment that impacts the physician's routine, our healthcare system, and the quality of patients' lives. Approximately 10% of all men have elevated PSA levels., commonly referred to as the diagnostic "grey zone", of which only 20 – 40% present clinically with cancer. Proclarix is intended for use in diagnosing these patients where it is difficult to decide if a biopsy is necessary to verify a potential clinically significant cancer diagnosis. Proclarix helps doctors and patients with unclear PSA test results through the use of our proprietary Proclarix Risk Score which delivers clear and immediate diagnostic support for further treatment decisions. No additional intervention is required, and results are available quickly. Local diagnostic laboratories can integrate this multiparametric test into their current workflow because Proclarix assays use the enzyme-linked immunosorbent assay (ELISA) standard, which most diagnostic laboratories are already equipped to process.

Since our inception in October 2018 until April 2023, when we acquired ENTADFI, we devoted substantially all of our resources to performing research and development, undertaking preclinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and now halted vaccine candidates, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities. During the third quarter of 2023, we halted our vaccine discovery and development programs, and accordingly, we now operate in one segment: commercial. The commercial segment was new in the second quarter of 2023 and is currently dedicated to the development and commercialization of Proclarix.

Proclarix is CE-marked and for sale in Europe. We continue our sales efforts and expect growing revenues from sales of Proclarix in 2026 and beyond. We anticipate these sales to offset some expenses relating to commercial scale up and development, but we expect our expenses also to increase in connection with our ongoing activities, as we:

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

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

We do not have any products approved for sale, aside from (i) Proclarix and (ii) ENTADFI, which has not generated any revenue from product sales; we have determined to abandon commercialization of ENTADFI and no longer holds inventory of the product, we have financed our operations primarily with proceeds from our sale of preferred securities to seed investors, the initial public offering ("IPO"), and subsequent offerings of debt and equity securities. We will continue to require significant additional capital to commercialize Proclarix, and to fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and to rely on third-party resources for marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches, to support our operations.

Some recent key developments affecting our business include the following:

Realbotix Corp. Share Exchange Agreement

On February 11, 2026, we entered into a Share Exchange Agreement (the “Share Exchange Agreement”), by and among (i) Onconetix, (ii) Realbotix Corp., a company existing under the laws of the Province of Ontario (“Parent”), (iii) Simulacra Corporation, a Delaware corporation and a wholly-owned subsidiary of Parent (the “Seller”) and (iv) Realbotix, LLC, a Delaware limited liability company and wholly owned subsidiary of the Seller (the “Realbotix”).

Pursuant to the Share Exchange Agreement, subject to the terms and conditions set forth therein, the Seller agreed to contribute and transfer to us, and we agreed to acquire and accept, all of the issued and outstanding equity interests of Realbotix (the “Realbotix Interests”) in exchange for newly issued shares of Common Stock. (the “Share Exchange” and the other transactions contemplated by the Share Exchange Agreement, the “Realbotix Transactions”).

For more information about the Realbotix Transaction, see “*Realbotix Corp. Share Exchange Agreement*” in Item 1.

February 2026 Special Meeting of Stockholders

On February 3, 2026, the Company held a special meeting of stockholders (the “Special Meeting”), whereby its stockholders approved an amendment to the Company’s Amended and Restated Certificate of Incorporation to effect a reverse stock split of all of the outstanding shares of Common Stock at a ratio in the range of 1-for-2 to 1-for-50, at any time prior to the one-year anniversary date of the Special Meeting, with such ratio to be determined by the Board or without further approval or authorization of the Company’s stockholders.

Series E PIPE Financing

On October 1, 2025, the Company entered into a securities purchase agreement (the “Series E Securities Purchase Agreement”) with institutional investor(s) and sold to such institutional investors(s)(collectively, the “Series E PIPE Investors”), an aggregate of 7,813 shares of Series E convertible preferred stock, par value \$0.00001 per share (“Series E Preferred Stock”), which are convertible into common stock of the Company, \$0.00001 par value per share and warrants (the “Series E Warrants”) to purchase 2,025,223 shares of Common Stock, for an aggregate purchase price of approximately \$6.25 million, which was also equal to the net cash proceeds. The exercise price of the Series E Warrants is \$3.8576, and the Series E Warrants are exercisable beginning on the issuance date and expire on the third anniversary of the issuance date.

Concurrently with entering into the Series E Securities Purchase Agreement, the Company also entered into a registration rights agreement with the Series E PIPE Investors, pursuant to which it has agreed to provide the Series E PIPE Investors with certain registration rights related to the shares of Common Stock underlying the shares of Series E Preferred Stock and Series E Warrants.

Termination of Ocuvox Business Combination Agreement:

On July 16, 2025, the Company entered into an Agreement and Plan of Merger with (i) Onconetix Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of the Company, and (ii) Ocuvox Therapeutics, Inc., a Delaware corporation (“Ocuvox”, and such agreement, the “Ocuvox Merger Agreement”). Pursuant to the Merger Agreement, Merger Sub will merge with and into Ocuvox, with Ocuvox surviving the merger as a direct, wholly owned subsidiary of the Company (the “Ocuvox Merger” and the other transactions contemplated by the Merger Agreement, the “Ocuvox Transactions”).

Effective September 24, 2025, pursuant to Section 9.01(a) of the Ocuvex Merger Agreement, the Company and Ocuvex entered into a Termination and Release Agreement (the “Termination Agreement”) pursuant to which they agreed to terminate the Merger Agreement and the transactions contemplated thereby. The Termination Agreement also terminates and makes void the ancillary documents entered into in connection with the Ocuvex Merger Agreement. The Termination Agreement also provides for a mutual release of claims among Company and Ocuvex and their affiliates and in consideration of the foregoing, the Company agreed to pay to Ocuvex, an amount equal to \$302,343.55 (the “Termination Payment”), which represents all amounts payable by the Company to Ocuvex pursuant to Section 6.02(f) of the Ocuvex Merger Agreement.

As of September 24, 2025, Ocuvex confirmed receipt of the Termination Payment, and as a result the Merger Agreement is of no further force and effect.

Series D PIPE Financing

On September 22, 2025, the Company entered into a securities purchase agreement (the “Series D Securities Purchase Agreement”) with eleven institutional investors, and sold or exchanged debt, to such investors (collectively, the “Series D PIPE Investors”) an aggregate of 16,099 shares of Series D convertible preferred stock, par value \$0.00001 per share (“Series D Preferred Stock”), which includes an issuance of 500 shares of Series D Preferred Stock to the lead investor in consideration for the Series D PIPE Investors’ irrevocable commitment to purchase shares of the Series D Preferred Stock, and warrants (the “Series D Warrants”) to purchase 4,362,827 shares of Common Stock, for an aggregate purchase price of approximately \$12.9 million and net cash proceeds of \$9.3 million. The exercise price of the Series D Warrants is \$3.6896, and the Series D Warrants are exercisable beginning on the issuance date and expire on the third anniversary of the issuance date.

Concurrently with entering into the Series D Securities Purchase Agreement, the Company also entered into a registration rights agreement with the Series D PIPE Investors, pursuant to which it has agreed to provide the Series D PIPE Investors with certain registration rights related to the shares of Common Stock underlying the shares of Series D Preferred Stock and Series D Warrants.

Amendment to Series D and Series E Warrants

On December 23, 2025, the Company entered into Limited Waiver Agreements (the “Warrant Limited Waiver”) with all holders of the Series D and Series E Warrants, effective as of October 1, 2025, pursuant to which such holders agreed to waive certain provisions of their Series D Warrants and Series E Warrants. Specifically, in the event the Company issues securities with a conversion price dependent on the price of the Common Stock (the “Variable Price”), the holders of Series D Warrants and Series E Warrants will no longer have the optional right to convert their applicable Series D Warrants and Series E Warrants at the Variable Price.

Additionally, the Warrant Limited Waiver waived the right of the Series D Warrants and the Series E Warrants to receive a guaranteed cash payment in connection with a “Fundamental Transaction” (as such term is defined in the Series D Warrants and Series E Warrants). Instead, in connection with a “Fundamental Transaction” that is not within the Company’s control, the holders of Series D Warrants and Series E Warrants are entitled only to receive the same form and proportion of consideration (or deemed common stock of the successor entity, if no such consideration is paid) as is offered and paid to holders of Common Stock, the definition of “Fundamental Transaction” in Series D Warrants and the Series E Warrants was further amended by the Warrant Limited Waiver to replace each reference to “at least” 50% with “more than” 50% of the outstanding Common Stock.

Reverse Stock Split

On June 13, 2025, the Company effected a reverse stock split of all shares of its issued and outstanding Common Stock at a ratio of one-for-eighty-five (1:85). The Company accounted for the reverse stock split on a retrospective basis pursuant to Accounting Standards Codification (“ASC”) 260, Earnings Per Share. All issued and outstanding common stock, common stock warrants, and share-based awards’ exercise prices and per share data have been adjusted in these consolidated financial statements, on a retrospective basis, to reflect the reverse stock split for all periods presented. The number of authorized shares and par value of the preferred stock and common stock were not adjusted because of the reverse stock split.

Veru Settlement Agreement and Release

On April 19, 2023, the Company entered into an asset purchase agreement with 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, in a transaction that closed in April 2023. Pursuant to the terms of the Veru APA, the Company agreed to provide Veru with initial consideration totaling \$20.0 million, including (i) \$4.0 million in the form of a non-interest bearing note payable due on September 30, 2023, and (iii) \$10.0 million in the form of two equal (i.e. each for \$5.0 million) non-interest bearing notes payable, each due on April 19, 2024 (the “April Veru Note”) and September 30, 2024 (the “September Veru Note” and together with the April Veru Note, the “Veru Notes”).

Subsequently, the Company and Veru modified and extended the payment terms under the Veru Notes on various occasions. On August 28, 2025, Veru and the Company agreed to amend and restate the September Veru Note (as amended and restated, the “Second A&R September Veru Note”). Pursuant to the Second A&R September Veru Note, the principal amount owed to Veru was increased by \$100,000 to an aggregate principal amount of \$5.2 million, and the maturity date was amended to September 19, 2025. All other terms of the September Veru Note remained the same. On August 28, 2025, Veru and the Company also entered into a waiver agreement (the “August 2025 Veru Waiver”) pursuant to which Veru agreed to waive and extend the date for payment of the April Veru Note to September 19, 2025.

As of September 22, 2025, approximately \$8.8 million was payable to Veru under the Veru Notes and related amendments. On September 22, 2025, the Company and Veru entered into a Settlement Agreement and Release (the “Veru Settlement Agreement”), pursuant to which Veru agreed to accept a cash payment of approximately \$6.3 million (including interest accrued through receipt of the Settlement Amounts (as defined herein), 3,125 shares of Series D Preferred Stock and 846,975 Series D Warrants (such cash payment, shares of Series D Preferred Stock and Series D Warrants, collectively, the “Settlement Amounts”) in full satisfaction of all amounts due under the Veru Notes, as amended by all preceding amendments, forbearance agreements, and waivers, and Veru agreed that such acceptance constituted complete discharge of all obligations thereunder. The Settlement Agreement contains customary release provisions that upon timely delivery of the Settlement Amounts, Veru shall release all claims or actions against the Company.

As of September 24, 2025, Veru confirmed receipt of all Settlement Amounts in satisfaction of all outstanding amounts, and all Veru Notes and related amendments were deemed cancelled and terminated, respectively, and of no further force or effect.

Keystone Notes Payable

During the year ended December 31, 2025, the Company issued six subordinated promissory notes to Keystone Capital Partners, LLC, each with an original issue discount and payable upon the earlier of (i) receipt of sufficient proceeds from the Company’s Equity Line of Credit (“ELOC”) with an institutional investor (the “ELOC Purchaser”) or (ii) a specified maturity date. All notes are subordinated to the Company’s existing debt obligations to Veru, do not initially bear interest, and are subject to a late charge of 15% per annum on any unpaid amounts past due.

- On February 12, 2025, the Company issued a note with an aggregate principal amount of \$117,647, including an original issue discount of \$17,647. The note matures on November 12, 2025, unless prepaid earlier upon receipt of sufficient capital from other securities offerings (the “February Keystone Note”).
- On May 16, 2025, the Company issued a note with an aggregate principal amount of \$294,118, including an original issue discount of \$44,118. The note matures on February 16, 2026, subject to the same prepayment provisions (the “May Keystone Note”).
- On June 5, 2025, the Company issued a note with an aggregate principal amount of \$147,059, including an original issue discount of \$22,059. The note matures on March 5, 2026, subject to the same prepayment provisions (the “June Keystone Note”).
- On August 6, 2025, the Company issued a note with an aggregate principal amount of \$117,647, including an original issue discount of \$17,647. The note matures on March 6, 2026, subject to the same prepayment provisions (the “August 6 Keystone Note”).
- On August 28, 2025, the Company issued two notes with an aggregate principal amount of \$58,824 each, including an original issue discount of \$8,824 each. The notes mature on May 28, 2026, subject to the same prepayment provisions (the “August 28 Keystone Notes”).

On September 22, 2025, Keystone Capital Partners, LLC and the Company agreed to exchange the principal owed under the May Keystone Note, the June Keystone Note, the August 6 Keystone Note and the August 28 Keystone Notes for Series D Preferred Stock of 1,660 shares and Warrants of 449,395 shares of common stock in connection with the Series D PIPE Financing. The February Keystone Note was paid in full on October 10, 2025.

During the year ended December 31, 2025, the Company recorded approximately \$0.8 million of interest expense, respectively, which includes accrued interest and amortization of the debt discount. The unamortized debt discount as of December 31, 2025 and 2024 was \$0 and \$5,000, respectively. As of December 31, 2025 and 2024, the Company has recorded accrued interest of approximately \$0 and \$0.1 million, respectively, which is included in accrued expenses in the accompanying consolidated balance sheets.

Series C PIPE Financing and ELOC

On October 1, 2024, the Board authorized the Company to create a series of 10,000 shares of preferred stock designated as “Series C Preferred Stock”, with a par value of \$0.00001, pursuant to the certificate of designations. At any time after the initial issuance date of Series C Preferred Stock, each Series C Preferred Stock shall be convertible into validly issued, fully paid and non-assessable shares of Common Stock. On October 2, 2024, the Company entered into, and sold, to six institutional investors (collectively, the “Series C PIPE Investors”), pursuant to the securities purchase agreement an aggregate of 3,499 shares of Series C Preferred Stock which includes an issuance of 840 shares of Series C Preferred Stock to the lead investor in consideration for the Series C PIPE Investors’ irrevocable commitment to purchase shares of the Series C Preferred Stock, and warrants to purchase 6,963 shares of Common Stock (“Series C Warrants”) for aggregate net cash proceeds to the Company of \$1.9 million. The exercise price of the Series C Warrants is \$372.30 on a post-reverse split basis, and the Series C Warrants are exercisable six months after the issuance date and expire on the third anniversary of their initial issuance.

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

On July 16, 2025, the Company exercised its voluntary Series C Preferred Stock adjustment right to lower the conversion price of the Series C Preferred Stock to \$3.50, and holders of 1,920 Series C Preferred Stock shares agreed to convert their shares into shares of common stock.

As of December 31, 2025, 7 shares of Series C Preferred Stock were outstanding from the original issuance of 3,499 shares of Series C Preferred Stock to institutional investors, after the i) redemption of 1,369 shares of Series C Preferred Stock for aggregate consideration of \$1.71 million, ii) the conversion of 1,920 shares of Series C Preferred Stock into shares of Common Stock, and iii) the exchange of 203 shares of Series C Preferred Stock into 244 shares of Series D Preferred Stock.

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 5 to our consolidated financial statements included elsewhere in this Report.

Laboratory Corporation of America

On March 23, 2023, Proteomedix entered into a license agreement with LabCorp (“LabCorp License Agreement”) 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 LabCorp License Agreement. Additionally, Proteomedix is entitled to royalty payments between 5% and 10% on the net sales recognized by LabCorp of any Licensed Products plus milestone payments as follows:

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

A total of \$2.5 million in milestone payments are payable under the LabCorp License Agreement. An additional \$0.5 million was paid to Proteomedix as an initial license fee in 2023.

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

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

On December 6, 2025, Proteomedix and LabCorp entered into an amendment (the “LabCorp Amendment”) of the LabCorp License Agreement. The Amendment provides for a new validation study to be conducted by LabCorp for Proclarix, titled *Prostate Cancer Risk Identification in a Multi-Ethnic Cohort: A Prospective U.S.-Based Multi-Center Validation Study of Proclarix* (the “PRIME Study”). Pursuant to the LabCorp Amendment, LabCorp will not be required to pay any royalties or milestone payments in connection with its use of the risk calculator for purposes of the PRIME Study. The Company will compensate LabCorp with specified milestone-based payments for conducting the PRIME Study of up to \$300,000 in the aggregate and will bear all associated costs and expenses. Mid-five figure milestone payments will be made as subjects are enrolled, commencing on the effective date of the PRIME Study and to be paid for every additional batch of subjects enrolled. If the final milestone tier is not reached, the Company must pay Labcorp a fixed amount per subject enrolled beyond the last milestone tier that was paid. All payments are due within thirty (30) days of each invoice.

Pursuant to the LabCorp Amendment, LabCorp is also required to provide the Company with the results of each clinical study conducted by LabCorp upon completion; however, the Company may not use or disclose such results to any third party without LabCorp’s prior consent.

Immunovia-Proteomedix Licensing Agreement

On September 17, 2025, Proteomedix entered into a licensing agreement (the “Immunovia Agreement”) with Immunovia, Inc. (“Immunovia”), a pancreatic cancer diagnostics company based in Lund, Sweden. Under the Agreement, Proteomedix will provide Immunovia with master cell lines required to produce antibodies for three of the five biomarkers used in the PancreaSure test, as well as a license to key intellectual property related to the manufacturing of associated reagents.

In return, Immunovia will make total payments of \$0.6 million over two payments of \$0.3 million each to Proteomedix, due on September 30, 2025 (“Initial Up Front Payment”), and March 31, 2026 (“Second Up Front Payment”). Based on the terms of the agreement and the nature of the license, the Company determined that the performance obligations were satisfied upon the transfer of the licensed rights which occurred during 2025. Accordingly, the Company recognized \$0.6 million as license revenue during the year ended December 31, 2025.

Additionally, Immunovia will make a \$0.1 million payment for materials and pay a 3% royalty on net sales of PancreaSure and any other products incorporating the licensed intellectual property from January 1, 2026, through December 31, 2032.

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 IQVIA, pursuant to which IQVIA 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 IQVIA 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 net credits of approximately \$0.5 million related to this contract during the year ended December 31, 2024, which is included in selling, general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss. The Company had approximately \$0 and \$1.1 million recorded in related accounts payable as of December 31, 2025 and 2024, respectively, which includes amounts due for early termination of the contract. See Note 5 to our consolidated financial statements included elsewhere in this Report.

On January 15, 2025, the Company and IQVIA entered into a Settlement Agreement (the “IQVIA Settlement Agreement”) concerning potential termination payments under the Master Services Agreement and statements of work. Pursuant to the IQVIA Settlement Agreement, the Company agreed to pay to IQVIA an aggregate of \$150,000 in exchange for a mutual release of all claims in connection with the Master Services Agreement. As of December 31, 2025, the Company paid IQVIA the agreed upon amount of \$150,000 and recorded a gain of approximately \$(0.9) million on settlement of accounts payable.

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 related to Proteomedix will decrease when compared to historical levels due to cost reduction efforts, including headcount reductions, and the termination of Proteomedix's pension plan.

Research and Development Expenses

Historically, substantially all of our research and development expenses consisted 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.

As discussed above, we have terminated the vaccine programs that substantially all of our research and development historically related to. We do not anticipate incurring significant research and development expenses in the near future, unless we are able to resume such activities. 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, loss on extinguishment of notes payable, loss on issuance of preferred stock and warrants, loss on extinguishment of preferred stock, gain on forgiveness of accounts payable, the change in fair value of financial instruments that are recorded as liabilities, which includes the related party subscription agreement liability, the contingent warrant liability, derivative and warrant liabilities for share of Series D and E preferred stock, and other income.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Year Ended December 31, 2025	Year Ended December 31, 2024	\$ Change	% Change
Revenue	\$ 815,371	\$ 2,524,116	\$ (1,708,745)	(67.7)%
Cost of revenue	182,458	1,469,018	(1,286,560)	(87.6)%
Gross profit (loss)	632,913	1,055,098	(422,185)	(40.0)%
Operating expenses				
Selling, general and administrative	\$ 7,043,902	\$ 11,231,982	(4,188,080)	(37.3)%
Research and development	(66,133)	154,359	(220,492)	(142.8)%
Impairment of ENTADFI assets	—	3,530,716	(3,530,716)	(100.0)%
Impairment of Goodwill	11,512,000	32,347,000	(20,835,000)	(64.4)%
Impairment of Intangibles	—	10,279,796	(10,279,796)	(100.0)%
Total operating expenses	18,489,769	57,543,853	(39,054,084)	(67.9)%
Loss from operations	(17,856,856)	(56,488,755)	38,631,899	(68.4)%
Other income (expense)				
Loss on extinguishment of note payable	(5,384,719)	—	(5,384,719)	100.0%
Loss on issuance of preferred stock and warrants	(3,674,329)	—	(3,674,329)	100.0%
Loss on extinguishment of preferred stock	(196,244)	—	(196,244)	100.0%
Interest expense – related party	—	(534,245)	534,245	(100.0)%
Interest expense	(751,005)	(873,433)	122,428	(14.0)%
Interest Income	2	18	(16)	(88.9)%
Change in fair value of subscription agreement liability	3,127,962	(3,259,000)	6,386,962	196.0%
Change in fair value of contingent warrant liabilities	16,499	1,250,466	(1,233,967)	(98.7)%
Change in fair value of Series D Warrant Liability	10,377,638	—	10,377,638	100.0%
Change in fair value of Series D Derivative Liability	(3,809,333)	—	(3,809,333)	100.0%
Change in fair value of Series E Warrant Liability	4,486,847	—	4,486,847	100.0%
Change in fair value of Series E Derivative Liability	(1,539,014)	—	(1,539,014)	100.0%
Gain on forgiveness of accounts payable	944,694	—	944,694	100.0%
Other income	226,041	168,746	57,295	34.0%
Total other income (expense)	3,825,039	(3,247,448)	7,072,487	217.8%
Loss before income taxes	(14,031,817)	(59,736,203)	45,704,386	(76.5)%
Income tax (expense) benefit	(525)	1,045,180	(1,045,705)	(100.1)%
Net loss	\$ (14,032,342)	\$ (58,691,023)	44,658,681	(76.1)%
Deemed dividend Series C preferred stock	(1,498,595)	(206,404)	(1,292,191)	626.0%
Net loss applicable to common stockholders'	\$ (15,530,937)	\$ (58,897,427)	43,366,490	(73.6)%

Revenue, Cost of Revenue, and Gross Margin

For the year ended December 31, 2025, revenue decreased by approximately \$1.7 million to \$0.8 million from \$2.5 million for the year ended December 31, 2024. Revenues in both periods were generated entirely by the Company's Proteomedix subsidiary. The decrease was primarily attributable to a \$2.3 million reduction in development services revenue reflecting the completion of a service contract with Immunovia in 2024 which did not recur in 2025. The decline was partially offset by the increase in other revenue of \$0.6 million, attributable to a license agreement entered with Immunovia in 2025 that grants rights to use certain intellectual property and proprietary materials developed by Proteomedix. Product sales remained relatively consistent at approximately \$0.2 million in both 2025 and 2024.

For the year ended December 31, 2025, cost of revenue decreased by approximately \$1.3 million to \$0.2 million, compared to \$1.5 million in 2024. This decrease was primarily attributable to the absence of costs associated with the non-recurring development services project completed in 2024. Overall, gross margins were positive in both periods, and cost of revenue in 2025 primarily relates to product costs. Cost of revenue in 2024 primarily consisted of amortization of the product rights intangible asset of approximately \$0.5 million as well as standard production and sales costs of approximately \$1.0 million.

Selling, General and Administrative Expenses

For the year ended December 31, 2025, selling, general and administrative expenses decreased by approximately \$4.2 million to \$7.0 million compared to \$11.2 million in 2024. This decrease was primarily driven by a \$1.5 million reduction in payroll-related expenses due to headcount reductions, \$1.0 million reduction in net periodic benefit cost due to the settlement of the defined benefit plan, \$0.6 million reduction of professional services, \$0.3 million reduction of amortization expense as the intangibles were fully impaired or amortized in 2024, \$0.2 million reduction of stock based compensation, \$0.2 million reduction of insurance expense, \$0.2 million reduction of regulatory expenses, and \$0.2 million reduction of miscellaneous business expenses including travel and recruitment fees.

Research and Development Expenses

For the year ended December 31, 2025, there was a gain of approximately \$0.1 million in research and development expenses, compared to an expense of approximately \$0.2 million in the year ended December 31, 2024. The gain in 2025 resulted from the write-off of previously accrued R&D expenses that were related to terminated contracts and had no outstanding amounts payable as of December 31, 2025. There has been no substantial R&D expense since the Company decided to halt its vaccine programs, clinical studies, and other research activities in late 2023.

Impairments

During the year ended December 31, 2025, the Company recorded an impairment of goodwill related to the PMX acquisition totaling \$11.5 million, of which \$11.0 million was recognized at March 31, 2025 and the remainder at June 30, 2025. No additional goodwill impairment was recorded after June 30, 2025, primarily due to Series D and Series E PIPE financings that closed during the second half of 2025, which increased the Company's market capitalization and valuation for the remaining goodwill balance.

During the year ended December 31, 2024, the Company recorded impairments of goodwill and intangibles related to the PMX acquisition of \$32.3 million and \$10.3 million, respectively. In addition, the Company recorded an impairment charge of the ENTADFI asset of \$3.5 million.

Other Income (Expense)

For the year ended December 31, 2025, other income (expense) increased by approximately \$7.1 million to \$3.8 million, compared to \$(3.2) million in 2024. The increase was driven primarily by net fair value gains of \$14.9 million associated with the Company's Series D and Series E warrant liabilities as well as lower interest expense of \$0.7 million and a gain on the forgiveness of accounts payable related to the settlement of IQVIA balances of \$0.9 million. In addition, there was an increase of \$6.4 million in net fair value gains from the subscription agreement liability-related party arising from a lower valuation in the current year resulting from the expiration of the term and increased stock price volatility through settlement in 2025. These favorable items were partially offset by losses on debt extinguishment of \$5.4 million, losses on issuance of the Series D and E preferred stock and warrants of \$3.7 million, fair value losses of \$5.3 million on the embedded derivative liabilities fair value losses of \$1.2 million on the contingent warrants, and \$0.2 million loss on extinguishment of preferred stock with most of the volatility stemming from changes in the Company's stock price and financing-related fair value remeasurements (See Note 8).

Income Tax (Expense) Benefit

For the years ended December 31, 2025 and 2024, the Company recorded income tax (expense) benefit of approximately \$(525) and \$1.0 million, respectively. The 2024 income tax benefit is related to foreign deferred income taxes recorded in connection with the acquisition accounting for the Proteomedix transaction.

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 now halted commercial launch of ENTADFI and the commercialization of Proclarix.

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. As of December 31, 2025, the Company had cash of approximately \$5.2 million, a working capital deficit of approximately \$3.1 million and an accumulated deficit of approximately \$131.2 million. During the year ended December 31, 2025, the Company used approximately \$9.7 million in cash for operating activities. In addition, as of March 11, 2026, the Company's cash balance was approximately \$3.6 million.

During 2025, the Company closed a Series D Preferred Stock financing in September 2025 and a Series E Preferred Stock financing in October 2025. These financings provided the Company with additional cash flow to support near-term operations. While these capital raises may enable the Company to sustain current operations and meet existing obligations, the Company continues to generate recurring net operating losses and has not yet established sustained positive cash flows to support its strategic growth initiatives, which includes the commercialization of Proclarix, and the development and commercialization of the Company's future product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern for one year from the date of issuance of the consolidated financial statements for the year ended December 31, 2025.

Management's plans for funding the Company's operations include generating product revenue from sales of Proclarix, which is still subject to further successful development and commercialization activities within certain jurisdictions. Management also intends to pursue additional equity or debt financing to support operations and strategic initiatives. However, there are currently no committed sources of financing, and there is no assurance that additional funding will be available on favorable terms, if at all. This uncertainty raises significant concern about the Company's ability to sustain operations and execute its strategic initiatives. If additional capital is not secured, the Company may need to curtail clinical trials, development, and commercialization efforts, and take further measures to reduce expenses to conserve cash.

Because of historical and expected operating losses, net operating cash flow deficits, and debts due within one year, 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

We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to commercialize Proclarix.

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 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 development and commercialization of Proclarix, and the development and commercialization of our future product candidates. Until we can generate a sufficient amount of revenue from sales of Proclarix if at all, we expect to finance our future cash needs through public or private equity or debt financings, third-party funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

While the Company closed the Series D and E Preferred Stock financings in 2025, there are currently no other commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all. This creates significant uncertainty whether the Company will have the funds available to be able to sustain its operations and expand commercialization of Proclarix. If the Company is unable to secure additional capital, it may be required to curtail any future clinical trials, development and/or commercialization of future product candidates, and it may take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations, or, if it's required to, file for bankruptcy.

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

- the costs of future development and commercialization activities, including product manufacturing, marketing, sales, royalties, and distribution, for Proclarix, and other products for which we may 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 product;
- the expenses needed to attract, hire and retain skilled personnel;
- the revenue, if any, received from commercial sales of Proclarix, or other products for which we may have received or will receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights; and
- the costs of operating as a public company.

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

Cash Flows

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

	Year Ended December 31, 2025	Year Ended December 31, 2024
Net cash used in operating activities	\$ (9,678,390)	\$ (10,495,816)
Net cash used in investing activities	—	(28,471)
Net cash provided by financing activities	14,452,686	6,743,110
Effect of exchange rate changes on cash	(200,142)	(126,658)
Net increase (decrease) in cash	<u>\$ 4,574,154</u>	<u>\$ (3,907,835)</u>

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2025, was approximately \$9.7 million, which primarily resulted from a net loss of approximately \$14.0 million, a non-cash change in fair value of subscription liability of approximately \$3.1 million, a non-cash gain on forgiveness of accounts payable of approximately \$0.9 million, a non-cash change in fair value of Series D warrant liability of approximately \$10.4 million, a non-cash change in fair value of Series E warrant liability of approximately \$4.5 million, and net changes in our operating assets and liabilities of \$2.4 million. These items were offset by several non-cash items, which primarily include impairment of goodwill of approximately \$11.5 million, loss on extinguishment of notes payable of approximately \$5.4 million, loss on issuance of Series D preferred stock of approximately \$2.5 million, loss on issuance of Series E preferred stock of approximately \$1.1 million, change in fair value of Series D derivative liability of approximately \$3.8 million, and change in fair value of Series E derivative liability of approximately \$1.5 million.

Net cash used in operating activities for the year ended December 31, 2024 was approximately \$10.5 million, which primarily resulted from the net loss of \$58.7 million. This was offset by impairment losses of goodwill of \$32.3 million related to the acquisition of Proteomedix, loss on impairment of ENTADFI assets of \$3.5 million, impairment of cash the fair value of the subscription liability agreement of \$3.3 million, impairment of intangibles related to the acquisition of Proteomedix of \$10.3 million, depreciation and amortization of \$0.7 million noncash stock-based compensation expense \$0.4 million, change in the fair value of contingent warrant liability of \$1.3 million, and a net change in our operating assets and liabilities of \$1.5 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2025 was \$0.

Net cash used in investing activities for the year ended December 31, 2024 was approximately \$30,000, of which all was due to the purchase of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 was approximately \$14.5 million, and resulted primarily from proceeds of approximately \$9.3 million from the issuance of Series D preferred stock and warrants, proceeds of approximately \$6.3 million from the issuance proceeds of Series E preferred stock and warrants, \$6.4 million from the sale of common stock in connection with the ELOC and \$1.3 million from the issuance of notes payable. These proceeds were offset by payments on notes payable of approximately \$7.1 million and a payment of approximately \$1.7 million related to redemption of the Series C Preferred Stock.

Net cash provided by financing activities for the year ended December 31, 2024 was approximately \$6.7 million, which resulted from proceeds from issuance of notes payable for related parties of \$5.0 million, net proceeds from the exercise of preferred investment options of \$0.9 million, proceeds from the issuance of series C preferred stock of \$1.9 million, and proceeds from sale of common stock of \$0.7 million. These proceeds from investing activities was offset by payments in deferred financing costs and payments of note payable totaling \$1.7 million.

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.

Accounting for Series D and Series E PIPE Securities including Warrant and Derivative Liabilities

In connection with the Series D and Series E PIPE Financings, we issued Series D Preferred Stock and Series D Warrants to certain institutional investors on September 22, 2025, and Series E Preferred Stock and Series E Warrants to certain institutional investors on October 1, 2025. The accounting determinations in connection with the Series D and Series E PIPE Securities have a significant effect on our reported financial position and results of operations.

We determine the accounting classification of the instruments by first assessing each instrument under ASC 480, Distinguishing Liabilities from Equity, then assessing each instrument under ASC 815, Derivatives and Hedging Activities. Under ASC 480, instruments are considered liability classified if they are mandatorily redeemable, obligate us to settle the warrants or the underlying shares by paying cash or other assets, and instruments that must or may require settlement by issuing variable number of shares. If instruments do not meet the liability classification under ASC 480-10, we assess 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, we also assess whether the instruments are indexed to our Common Stock and whether the instruments are classified as equity under ASC 815-40 or other GAAP. After all such assessments, we conclude whether the instruments are classified as liability or equity.

In addition, ASC 815 requires companies to bifurcate certain features from their host instruments and account for them as free-standing derivative financial instruments should certain criteria be met. We evaluate our financial instruments to determine whether such instruments are derivatives or contain features that qualify as embedded derivatives. Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract and the features of the derivatives. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the consolidated statements of operations each period. Bifurcated embedded derivatives are classified with the related host contract in our consolidated balance sheets. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period.

Liability classified instruments require fair value accounting at issuance and subsequent to initial issuance with all changes in fair value after the issuance date recorded in the consolidated statements of operations.

The Company concluded the Series D Preferred Stock and Series E Preferred Stock were more akin to an equity-like host than a debt-like host and were classified as permanent equity as they were not redeemable in any manner that would require classification outside of permanent equity pursuant to ASC 480-10-S99. The Series D Warrants, Series E Warrants, and certain embedded share-settled redemption features of the Series D Preferred Stock and Series E Preferred Stock issued were determined to be liability-classified instruments pursuant to ASC 480 and ASC 815. The embedded features of the Series D Preferred Stock and Series E Preferred Stock were bifurcated and accounted for separately as derivative liabilities.

Fair Value Measurements for Series D and E Warrant Amendment Reclassification

On December 23, 2025, the Company executed a Limited Waiver Agreement (effective October 1, 2025) that amended the September and October 2025 Series D and E warrants (the “Amended Warrants”), including removal of the issuer-specific cash settlement upon certain Fundamental Transactions and a change to treat holders *pari passu* with common shareholders. Management concluded the Amended Warrants no longer embody an obligation to transfer assets under ASC 480 and, after evaluating exercise/settlement terms (including anti-dilution, buy-in, authorized-share-failure, and beneficial-ownership caps), determined they are indexed to the Company’s stock and meet equity-classification conditions under ASC 815-40. Accordingly, the Series D and Series E warrants were remeasured at fair value and reclassified to additional paid-in capital on December 23, 2025 (See Note 8).

Fair Value Measurements for Series D and E Warrant and Derivative Liabilities

The Company measured its Series D and E bifurcated embedded derivatives as of December 31, 2025, at fair value on a recurring basis using level 3 inputs. Prior to the Series D and E warrant amendments and reclassification to equity, the warrant liabilities were also measured at fair value on a recurring basis using level 3 inputs. These financial instruments are measured using management’s best estimate of fair value, where the inputs into the determination of fair value require significant management judgment to estimation. The derivative and warrant liabilities were both measured using Monte Carlo valuation models. Valuations based on unobservable inputs are highly subjective and require significant judgments. The key inputs used for the valuation include expected term, volatility, risk-free interest rate, dividend yield, and stock price. Changes in such judgments could have a material impact on fair value estimates.

Goodwill

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. Based on its evaluation, the Company identified and recognized partial impairment charges of goodwill during the years ended December 31, 2025 and 2024.

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.

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.

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-54 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.

Effective February 13, 2025, the Audit Committee authorized the appointment of MaloneBailey LLP (“MaloneBailey”) as the Company’s new independent registered public accounting firm for the fiscal year ended December 31, 2024, and MaloneBailey was appointed as the Company’s independent registered public accounting firm. During the Company’s two most recent fiscal years ended December 31, 2024 and 2023, and the subsequent interim period through February 13, 2025, neither the Company nor anyone acting on behalf of the Company had consulted MaloneBailey regarding either: (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company’s financial statements, nor did MaloneBailey provide a written report or oral advice to the Company that MaloneBailey concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issues; or (ii) any matter that was either the subject of a “disagreement” (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a “reportable event” (as described in Item 304(a)(1)(v) of Regulation S-K).

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 has concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2025, 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, 2025. 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, 2025, 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.

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.

Material Weaknesses in Internal Control Over Financial Reporting

We have identified the following internal control deficiencies, which we believe to be material weaknesses as of December 31, 2025:

- We did not maintain an effective control environment as there was an inadequate segregation of duties with respect to certain cash disbursements.
- 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 expense payments were not designed and maintained to achieve the Company's objectives.
- We do not yet have adequate internal controls in place for the timely identification, approval or reporting of related party transactions."
- 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.

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

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

Remediation of Material Weaknesses

As of the date of this Annual Report on Form 10-K, management is re-assessing the design of controls and modifying processes designed to improve our internal control over financial reporting and remediate the control deficiencies that led to the material weaknesses, including but not limited to (a) improving consistency in change management supported by standard operating procedures to govern the authorization, testing and approval of changes to information technology systems supporting all of the Company’s internal control processes, (b) enhancing design and implementation of our control environment, including the expansion of formal accounting and IT policies and procedures and financial reporting controls, (c) continuing to identify and design and implement effective review and approval controls, and (d) implementing appropriate timely review and oversight responsibilities within the accounting and financial reporting functions and ensuring appropriate segregation of duties.

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

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2025, there were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 December 31, 2025:

Name	Age	Position(s)
<i>Executive Officers and Directors</i>		
Karina Fedasz	53	Interim Chief Executive Officer, Interim Chief Financial Officer
<i>Non-Employee Directors</i>		
Andrew Oakley	63	Non-Executive Chairman
Sarah Romano	45	Director
Timothy Ramdeen	34	Director
Thomas Meier	63	Director

Executive Officers and Directors

Executive Officers and Directors

Karina Fedasz, our Interim CFO since June 2024 and our Interim CEO since April 2024. Ms. Fedasz has helped companies raise capital, model and forecast business, manage cash flow and conduct mergers and acquisitions. From January 2023 to June 2024, Ms. Fedasz worked with various clients, including a not-for-profit and an early-stage artificial intelligence and data-driven health and wellness tracker. From February 2022 to December 2022, Ms. Fedasz served as Head of Business Development for Evofem Biosciences, a Nasdaq-listed public biotech company developing innovative products for women's health. From August 2019 to October 2021, Ms. Fedasz served in various positions of increasing responsibility, including Chief Financial Officer, at IDW Media Holdings, a micro-cap media company, where she managed the company's initial public offering. From April 2018 to August 2019, Ms. Fedasz served as Chief Financial Officer of MOCEAN, an integrated agency for entertainment, gaming, and brands. Ms. Fedasz's breadth of experience has seen her lead teams in media, technology, services, manufacturing, and education, and she has worked with companies whose clients and customers include Fortune 500 companies such as Netflix, Disney, Amazon, Apple, Activision, and EA. Ms. Fedasz received an MBA with an emphasis in finance from Columbia Business School and a BA from University California at Los Angeles (UCLA). She holds an inactive CPA in the state of California.

Non-Executive Directors

Andrew Oakley, our Non-Executive Chairman since March 2025 and a member of the Board since February 2025, is an experienced pharmaceutical and biotech industry professional. Previously, he held CFO positions at listed pharmaceutical companies Autolus Therapeutics plc (NASDAQ: AUTL) from 2018 to 2022 and Sosei Group (TSE:4565) from 2017 to 2018, as well as Vectura Group plc (LSE: VEC) and Actelion Ltd, where he led the finance function for over a decade. Additionally, he is a board member at a number of privately held Biotech companies. Mr. Oakley holds a Bachelor of Economics Degree from Macquarie University and an MBA from London Business School and has been a Member of the Australian Institute of Chartered Accountants since 1987. With decades of senior financial leadership in the pharmaceutical and biotechnology sectors, Mr. Oakley brings extensive public company, capital markets, and strategic oversight experience that uniquely qualifies him to serve as a director and Chairman of Board of the Company.

Sarah Romano, one of our directors since December 2025, has over a decade of experience leading the finance function of multiple Nasdaq-listed companies. Ms. Romano has served as Chief Financial Officer and Treasurer of Vicarious Surgical Inc. (NYSE: RBOT), surgical robotics company, since April 2025. Ms. Romano previously served as the Chief Financial Officer of Entero Therapeutics, Inc. (Nasdaq: ENTO) (formerly First Wave BioPharma Inc.), a clinical-stage biopharmaceutical company specializing in the development of targeted, orally delivered therapies for gastrointestinal diseases, from March 2022 to March 2025. She previously served as Chief Financial Officer of Kiora Pharmaceuticals, Inc. (Nasdaq: KPRX) (formerly EyeGate Pharmaceuticals, Inc.), a clinical-stage specialty pharmaceutical company developing products for treating ophthalmic diseases, from February 2017 through February 2022, and as its Corporate Controller from August 2016 to January 2017. Before that, Ms. Romano served as Assistant Controller at TechTarget, Inc. from June 2015 through August 2016. Ms. Romano holds a Bachelor of Arts in Accounting from College of the Holy Cross and a Master of Accounting from Boston College. Given her more than ten years of experience leading the finance functions of Nasdaq-listed companies, Ms. Romano brings public company financial reporting, internal controls, and capital markets expertise that make her highly qualified to serve on the Board, including as its financial expert and Chair of the Audit Committee.

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.

Board of Directors and Corporate Governance

General

Our business and affairs are organized under the direction of our Board, which currently consists of four 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 Sarah Romano and Thomas Meier, and their terms will expire at our 2028 annual meeting of stockholders;
- the Class II director is Andrew Oakley, and his term will expire at our 2026 annual meeting of stockholders; and
- the Class III director is Timothy Ramdeen, and his term will expire at our 2027 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 Sarah Romano, who is the chair of the committee and financial expert, Timothy Ramdeen, and Andrew Oakley. 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:

- 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 Sarah Romano 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 Ms. Romano’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 Thomas Meier, who is the chair of the committee, Andrew Oakley, 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, and Andrew Oakley. 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 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, Karina Fedasz serves as our Interim Chief Executive Officer and Interim Chief Financial Officer and Andrew Oakley serves as Non-Executive Chairman of the Board and Lead Independent Director. All four members of our Board 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.

Board Member Attendance at Annual Stockholder Meetings

Although we do not have a formal policy regarding director attendance at annual stockholder meetings, directors are encouraged to attend these annual meetings. All of our directors virtually attended our 2025 annual meeting of stockholders held on December 5, 2025.

Number of Meetings

During the fiscal year ended December 31, 2025, our Board met twenty-five times, the audit committee met six times, the compensation committee met five times, and the nominating and corporate governance committee met one time. In the fiscal year ended December 31, 2025, each of our directors attended at least 75% of the meetings of the Board and committees on which he served as a member.

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

We have 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.

Communications with the Board

Any stockholder or any other interested party who desires to communicate with our Board, our non-management directors, or any specified individual director, may do so by directing such correspondence to the attention of the Interim Chief Executive Officer, Onconetix, Inc., 201 E. Fifth Street, Suite 1900, Cincinnati, OH. The Interim Chief Executive Officer will forward the communication to the appropriate director or directors as appropriate.

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, 2025, 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, 2025.

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, 2025 and 2024. 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, 2025; (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, 2025, whose salary and bonus for services rendered in all capacities exceeded \$100,000 during the fiscal year ended December 31, 2025 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, 2025 but not at the end of the fiscal year ended December 31, 2025 whose salary and bonus for services rendered in all capacities exceeded \$100,000 during the fiscal year ended December 31, 2025.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$) ⁽¹⁾	Option Awards (\$) ⁽¹⁾	All Other Compensation (\$)	Total (\$)
Ralph Schiess ⁽²⁾	2025	163,937	—	—	—	—	163,937
Former Chief Executive Officer and Former Chief Science Officer	2024	265,176	40,000 ⁽³⁾	—	—	—	305,176
Karina Fedasz ⁽⁴⁾	2025	307,060	45,000 ⁽⁵⁾	—	—	—	352,060
Interim Chief Executive Officer and Interim Chief Financial Officer	2024	197,125	—	—	—	—	197,125

- (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. Schiess was appointed as Interim Chief Executive Officer on January 12, 2024 and as Chief Science Officer on December 15, 2023. Mr. Schiess resigned from Interim Chief Executive Officer on February 24, 2025 and Chief Science Officer on May 31, 2025.
- (3) Mr. Schiess was awarded a bonus of \$40,000 for his role as Interim Chief Executive Officer.
- (4) Ms. Fedasz was appointed Interim Chief Financial Officer effective June 10, 2024 and Interim Chief Executive Officer effective April 2, 2025.
- (5) Ms. Fedasz was awarded a bonus of \$45,000 for her role as Interim Chief Executive Officer.

Employment Agreements of Named 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, of which summaries do not purport to contain all of the material terms and conditions of each such agreement.

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. Dr. Schiess received a bonus of CHF 90,804 for 2023.

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.

On February 24, 2025, Dr. Schiess resigned from his positions as the Interim Chief Executive Officer and Chief Science Officer of the Company, effective as of the date. On May 31, 2025, Dr. Schiess resigned from his position as Chief Executive Officer of Proteomedix, effective as of that date.

Karina Fedasz

On June 10, 2024, the Company appointed Karina M. Fedasz as Interim Chief Financial Officer of the Company, effective immediately. In connection with Ms. Fedasz's appointment as Interim Chief Financial Officer, on June 10, 2024, the Company and Ms. Fedasz entered into a consulting agreement (the "Fedasz Consulting Agreement"), pursuant to which Ms. Fedasz will serve as Interim Chief Financial Officer of the Company and will be paid \$15,000 per month for up to 80 hours of monthly service to the Company and \$200 per hour thereafter, and will provide signatory services for \$2,500 per month. The Fedasz Consulting Agreement is for a term of one year, subject to early termination by either party upon thirty (30) days' written notice.

On April 2, 2025, Ms. Fedasz was appointed Interim Chief Executive Officer of the Company. No additional compensation was granted in connection with this appointment at that time. On December 5, 2025, Ms. Fedasz was granted a bonus of \$45,000, to be paid in January 2026, for her role as Interim Chief Executive Officer during 2025, and an increase in compensation of \$5,000 per month, effective January 1, 2026, for her service as Interim Chief Executive Officer.

Potential Payments Upon Termination or Change-in-Control

See "Employment Agreements of Named Executive Officers" above.

Outstanding Equity Awards at Fiscal Year-End

None of our named executive officers had any outstanding equity incentive plan awards as of December 31, 2025.

Director Compensation

The Board has approved cash and equity compensation for directors, such that we 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:

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

Additionally, each non-director will receive an annual grant of restricted stock awards equal to 0.04% of the shares of Common Stock outstanding as of the date of the Company's annual meeting, such restricted stock vesting approximately one year from the grant dates and upon the director's death or disability or upon a change of control of the Company. Sarah Romano elected not to receive her grant of restricted stock for 2026.

Our Compensation Committee will continue to review and make recommendations to the Board regarding compensation for 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, 2025:

Name	Fees Earned or Paid In Cash (\$)	Stock Awards (\$) ⁽¹⁾	Option Awards (\$) ⁽¹⁾	All Other Compensation (\$)	Total (\$)
Thomas Meier	60,000 ⁽²⁾	1,811 ⁽³⁾	—	—	61,811
Timothy Ramdeen	72,500 ⁽⁴⁾	1,811 ⁽³⁾	—	—	74,311
James Sapirstein ⁽⁶⁾	21,896 ⁽⁵⁾	—	—	—	21,896
Ajit Singh ⁽⁸⁾	27,758 ⁽⁷⁾	—	—	—	27,758
Simon Tarsh ⁽¹⁰⁾	76,671 ⁽⁹⁾	1,811 ⁽³⁾	—	—	78,482
Andrew Oakley	248,657 ⁽¹¹⁾	2,016 ^(3, 12)	—	—	250,673
Sarah Romano	4,946 ⁽¹³⁾	—	—	—	4,946

- (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. Meier, for serving as a member of the Board and Chairman of the Compensation Committee, totaling \$60,000.
- (3) These directors were each granted 618 shares of restricted stock on August 15, 2025, which vest on August 16, 2026. All such shares are unvested and remain outstanding as of December 31, 2025.
- (4) 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 totaling \$72,500.
- (5) Represents fees earned by Mr. Sapirstein for serving as a member of the Board and Executive Chairman from February 24, 2025 until March 28, 2025.
- (6) As of March 28, 2025, James Sapirstein resigned as Executive Chairman and member of the Board.
- (7) Represents fees earned for serving as a member of the Board.
- (8) As of August 10, 2025, Ajit Singh resigned as a member of the Board.
- (9) 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 \$76,671.
- (10) Simon Tarsh served as Chairman of the Audit Committee and member of the Board until December 5, 2025 and as a member of the Compensation Committee and Nominating Governance Committee until October 23, 2025. As a result of his resignation, his grant of restricted stock, awarded on August 15, 2025, was accordingly forfeited.
- (11) Represents fees earned by Mr. Oakley for serving as a member of the Board, member of the Compensation Committee, member of the Audit Committee, member of the Nominating Governance Committee, and Lead Independent Director, totaling \$248,657. Mr. Oakley was paid \$36,000 per month for his role as the Lead Independent Director, effective July 12, 2025.
- (12) Mr. Oakley was granted 20 shares of restricted stock on February 24, 2025, when he joined the Board, which vest on August 31, 2026. All such shares are unvested and remain outstanding as of December 31, 2025.
- (13) Represents fees earned by Ms. Romano for serving as a member of the Board and Chairman of the Audit Committee.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2025, 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⁾	—	—	— ⁽¹⁾⁽²⁾
2022 Plan ⁽³⁾	23	\$ 5,700.95	7,899
Total	23	\$ 5,700.95	7,899

- (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 411 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 17,058 shares for issuance under the 2022 Plan, of which 7,899 are remaining.

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 470 shares of our common stock, which is the sum of (i) 59 new shares, plus (ii) an additional number of shares not to exceed 411 (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 294 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 161 shares of common stock that may be issued under the 2022 Plan. On September 5, 2024, at the Company's 2024 annual meeting of stockholders, the Company's stockholders approved an additional 16,132 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 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. 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 non-qualified 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 35,000 ISOs.

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 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; 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 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 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.

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 3,584,245 shares of common stock outstanding as of March 11, 2026.

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 March 11, 2026. 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.

Name and Address of Beneficial Owner ⁽¹⁾	Shares of Common Stock Owned	
	Number of Shares ⁽²⁾	Percentage
Executive Officers and Directors		
Timothy Ramdeen	658 ⁽³⁾	*
Thomas Meier	657 ⁽⁴⁾	*
Sarah Romano	—	—
Karina M. Fedasz	—	—
Ralph Schiess	7,922 ⁽⁵⁾	*
Andrew Oakley	638 ⁽⁶⁾	*
All directors and named executive officers as a group (6 persons)	9,875	*
5% Stockholders		
Altos Venture AG	273,230 ⁽⁷⁾	7.62%
Michael Young	274,499 ⁽⁸⁾	7.66%

* 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) On June 13, 2025, the Company effected a reverse stock split of all shares of its issued and outstanding Common Stock at a ratio of one-for-eighty-five (1:85). Amounts have been adjusted to reflect the reverse stock split.

(3) Includes 658 restricted stock awards, of which 657 shares do not vest until August 31, 2026 and 1 share which is fully vested.

(4) Includes 657 restricted stock awards, of which 657 shares do not vest until August 31, 2026.

(5) Dr. Schiess resigned as Chief Science Officer and Interim Chief Executive Officer on February 24, 2025.

(6) Includes 638 restricted stock awards, of which 638 shares do not vest until August 31, 2026.

(7) Per Schedule 13D/A filed on July 16, 2025, Altos Venture AG ("Altos") is the beneficial owner of 273,230 shares of Common Stock. The address of Altos is Obertorweg 64, CH-4123, Allschwil, Switzerland.

(8) The address of Michael Young is 3560 S Ocean Blvd, Palm Beach, FL 33480.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The following is a description of transactions since January 1, 2024 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. As of December 31, 2025 and 2024, the subscription agreement liability was \$0 and \$4.1 million, 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. The Company recorded approximately \$58,000 in related expenses during the year ended December 31, 2024, of which approximately \$11,000 is included in accrued expenses in the accompanying consolidated financial statements as of December 31, 2024.

On June 17, 2025, the Company entered into a separate consulting agreement with a firm affiliated with Dr. Meier. The agreement provides for the payment of certain success fees and reimbursement of related expenses. Under its terms, Dr. Meier is entitled to earn up to 10% of success fees for transactions greater than \$9 million earned by the affiliated firm. The Company recorded approximately \$33,000 in related expenses during the twelve months ended December 31, 2025. As of December 31, 2025, approximately \$16,500 related to the consulting agreement was included in the Company’s accounts payables.

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 Sarah Romano, Timothy Ramdeen, and Andrew Oakley 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

Malone-Bailey served as the independent registered public accounting firm to audit our books and accounts for the fiscal year ended December 31, 2025.

The table below presents the aggregate fees billed for professional services rendered by Malone-Bailey for the years ended December 31, 2025 and 2024, respectively.

Malone-Bailey

	2025	2024
Audit fees	\$ 417,974	\$ 267,800
Audit-related fees	61,800	—
Tax fees	—	—
All other fees	—	—
Total fees	<u>\$ 479,774</u>	<u>\$ 267,800</u>

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 Malone-Bailey in connection with regulatory filings or engagements for that fiscal period.

In the above table, “audit-related fees” consist of assurance and related services that are reasonably related to the performance of the audit or review of the Company’s financial statements and are not reported above under “Audit Fees.” These services include consultation regarding accounting and financial reporting matters, as well as consent fees.

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.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Onconetix, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Onconetix, Inc. and its subsidiary (collectively, the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for the years 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, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

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 losses from operations and has a net capital deficiency that 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 audits 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 audits 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ MaloneBailey, LLP

www.malonebailey.com

We have served as the Company's auditor since 2025.

Houston, Texas
March 13, 2026

ONCONETIX, INC.
Consolidated Balance Sheets

	December 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash	\$ 5,220,654	\$ 646,500
Accounts receivable, net	296,866	25,717
Inventories	149,961	64,079
Investor receivable, net	50,000	—
Prepaid expenses and other current assets	349,293	213,971
Total current assets	6,066,774	950,267
Property and equipment, net	37,085	62,896
Deferred offering costs	225,000	—
Operating right of use asset	48,774	119,427
Goodwill	18,549,005	27,048,973
Total assets	\$ 24,926,638	\$ 28,181,563
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,757,695	\$ 3,787,564
Accrued expenses	341,881	888,988
Notes payable, net of debt discount of \$0 and \$4,966 at December 31, 2025 and 2024, respectively	—	9,328,061
Operating lease liability, current	24,412	119,427
Subscription agreement liability – Related Party	—	4,123,000
Contingent warrant liabilities	26,590	43,089
Derivative liabilities	6,985,347	—
Total current liabilities	9,135,925	18,290,129
Pension benefit obligation	—	280,879
Operating lease liability, net of current portion	24,362	—
Total liabilities	9,160,287	18,571,008
Commitments and Contingencies		
Series C Redeemable Preferred Stock, \$0.00001 par value, 10,000 shares authorized, 7 and 3,499 shares issued and outstanding at December 31, 2025 and 2024, respectively	1,724	1,067,928
Stockholders' equity		
Common stock, \$0.00001 par value, 250,000,000 shares authorized at December 31, 2025 and 2024; 1,560,153 and 138,422 the shares issued at December 31, 2025 and 2024, respectively; 1,560,001 and 138,270 shares outstanding at December 31, 2025 and 2024, respectively	15	1
Series D Preferred Stock, \$0.00001 par value, 32,000 and 0 shares authorized at December 31, 2025 and 2024, respectively; 16,325 and 0 shares issued and outstanding at December 31, 2025 and 2024, respectively.	—	—
Series E Preferred Stock, \$0.00001 par value, 10,000 and 0 shares authorized at December 31, 2025 and 2024, respectively; 7,813 and 0 shares issued and outstanding at December 31, 2025 and 2024, respectively.	—	—
Additional paid-in capital	147,835,989	127,825,743
Treasury stock, at cost; 152 shares of common stock at December 31, 2025 and 2024	(625,791)	(625,791)
Due from shareholders	—	(250,308)
Accumulated deficit	(131,214,558)	(115,683,621)
Accumulated other comprehensive loss	(231,028)	(2,723,397)
Total stockholders' equity	15,764,627	8,542,627
Total liabilities, convertible preferred stock, and stockholders' equity	\$ 24,926,638	\$ 28,181,563

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

ONCONETIX, INC.
Consolidated Statements of Operations and Comprehensive Loss

	December 31, 2025	December 31, 2024
Revenue	\$ 815,371	\$ 2,524,116
Cost of revenue	182,458	1,469,018
Gross profit	<u>632,913</u>	<u>1,055,098</u>
Operating expenses		
Selling, general and administrative	7,043,902	11,231,982
Research and development	(66,133)	154,359
Impairment of ENTADFI assets	—	3,530,716
Impairment of intangibles	—	10,279,796
Impairment of goodwill	11,512,000	32,347,000
Total operating expenses	<u>18,489,769</u>	<u>57,543,853</u>
Loss from operations	<u>(17,856,856)</u>	<u>(56,488,755)</u>
Other (expense) income		
Loss on extinguishment of note payable	(5,384,719)	—
Loss on issuance of preferred stock and warrants	(3,674,329)	—
Loss on extinguishment of preferred stock	(196,244)	—
Interest expense – related party	—	(534,245)
Interest expense	(751,005)	(873,433)
Interest income	2	18
Change in fair value of subscription agreement liability	3,127,962	(3,259,000)
Change in fair value of contingent warrant liabilities	16,499	1,250,466
Change in fair value of Series D Warrant Liability	10,377,638	—
Change in fair value of Series D Derivative Liability	(3,809,333)	—
Change in fair value of Series E Warrant Liability	4,486,847	—
Change in fair value of Series E Derivative Liability	(1,539,014)	—
Gain on forgiveness of accounts payable	944,694	—
Other income	226,041	168,746
Total other income (expense)	<u>3,825,039</u>	<u>(3,247,448)</u>
Loss before income taxes	<u>(14,031,817)</u>	<u>(59,736,203)</u>
Income tax (expense) benefit	(525)	1,045,180
Net loss	<u>\$ (14,032,342)</u>	<u>\$ (58,691,023)</u>
Deemed dividend Series C preferred stock	<u>(1,498,595)</u>	<u>(206,404)</u>
Net loss applicable to common stockholders	<u>(15,530,937)</u>	<u>(58,897,427)</u>
Net loss per share, basic and diluted	\$ (16.56)	\$ (1,823.39)
Weighted average number of common shares outstanding, basic and diluted	937,690	32,301
Other comprehensive income (loss)		
Net loss	\$ (14,032,342)	\$ (58,691,023)
Foreign currency translation	2,834,170	(5,342,327)
Change in pension benefit obligation	—	238,010
Total comprehensive loss	<u><u>\$ (11,198,172)</u></u>	<u><u>\$ (63,795,340)</u></u>

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

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

	Series D Preferred Stock		Series E Preferred Stock		Common Stock		Additional	Treasury Stock		Accumulated	Accumulated	Due	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Paid-in Capital	Shares	Amount	Deficit	Comprehensive Income	from Shareholders	Stockholders' Equity (Deficit)
Balance at December 31, 2024	<u>-</u>	<u>\$ -</u>	<u>-</u>	<u>\$ -</u>	<u>138,422</u>	<u>\$ 1</u>	<u>\$127,825,743</u>	<u>(152)</u>	<u>\$(625,791)</u>	<u>\$(115,683,621)</u>	<u>\$ (2,723,397)</u>	<u>\$ (250,308)</u>	<u>\$ 8,542,627</u>
Issuance of common stock in connection with the ELOC	-	-	-	-	629,317	7	6,141,340	-	-	-	-	250,308	6,391,655
Stock-based compensation expense	-	-	-	-	-	-	74,267	-	-	-	-	-	74,267
Cash in lieu of shares	-	-	-	-	(127)	-	(926)	-	-	-	-	-	(926)
Redemption of Series C Preferred Stock	-	-	-	-	-	-	-	-	-	(1,498,595)	-	-	(1,498,595)
Issuance of restricted common stock	-	-	-	-	2,472	-	-	-	-	-	-	-	-
Issuance of Series D Preferred Stock	16,099	-	-	-	-	-	5,352,541	-	-	-	-	-	5,352,541
Conversion of Series C Preferred shares to common stock	-	-	-	-	544,409	5	801,246	-	-	-	-	-	801,251
Exchange of Series C Preferred Stock to Series D Preferred Stock	244	-	-	-	-	-	246,227	-	-	-	-	-	246,227
Conversion of Series D Preferred Stock to common stock	(18)	-	-	-	4,878	-	-	-	-	-	-	-	-
Cancellation of restricted common stock	-	-	-	-	(722)	-	-	-	-	-	-	-	-
Issuance of Series E Preferred Stock	-	-	7,813	-	-	-	-	-	-	-	-	-	-
Warrant Waiver Reclassification of Series D Warrant Liabilities to Equity	-	-	-	-	-	-	4,371,362	-	-	-	-	-	4,371,362
Warrant Waiver Reclassification of Series E Warrant Liabilities to Equity	-	-	-	-	-	-	2,029,153	-	-	-	-	-	2,029,153
Cancellation of Cede & Co. Shares	-	-	-	-	(10)	-	-	-	-	-	-	-	-
Settlement of subscription agreement liability	-	-	-	-	241,514	2	995,036	-	-	-	-	-	995,038
Foreign currency translation adjustment	-	-	-	-	-	-	-	-	-	-	2,834,170	-	2,834,170
Changes in pension benefit obligation	-	-	-	-	-	-	-	-	-	-	655,438	-	655,438
Settlement of pension obligation	-	-	-	-	-	-	-	-	-	-	(997,239)	-	(997,239)
Net loss	-	-	-	-	-	-	-	-	-	(14,032,342)	-	-	(14,032,342)
Balance at December 31, 2025	<u>16,325</u>	<u>\$ -</u>	<u>7,813</u>	<u>\$ -</u>	<u>1,560,153</u>	<u>15</u>	<u>\$147,835,989</u>	<u>(152)</u>	<u>\$(625,791)</u>	<u>\$(131,214,558)</u>	<u>\$ (231,028)</u>	<u>\$ -</u>	<u>\$ 15,764,627</u>

	Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Accumulated Other Comprehensive Income	Due from Shareholders	Total Onconetix Equity (Deficit)	Non-Controlling Equity (Deficit)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount		Shares	Amount						
Balance at December 31, 2023	3,000	\$ -	6,703	\$ -	\$ 49,429,037	(152)	\$(625,791)	\$(56,786,194)	\$ 2,380,920	\$ -	\$ (5,602,028)	\$ 7,006,504	\$ 1,404,476
Issuance of common stock and warrants from exercise of preferred investment options, net of issuance costs	-	-	2,193	-	765,029	-	-	-	-	-	765,029	-	765,029
Grant and immediate exercise of warrants	-	-	1,812	-	6,155	-	-	-	-	-	6,155	-	6,155
Issuance of shares in connection with related party subscription agreement	-	-	6,040	-	5,134,247	-	-	-	-	-	5,134,247	-	5,134,247
Conversion of Series A Preferred Stock to common stock	(3,000)	-	1,679	-	-	-	-	-	-	-	-	-	-
Conversion of Series B Preferred Stock to common stock	-	-	79,315	1	64,236,084	-	-	-	-	-	64,236,085	-	64,236,085
Exercise of stock options	-	-	4	-	163	-	-	-	-	-	163	-	163
Stock-based compensation	-	-	-	-	260,406	-	-	-	-	-	260,406	178,247	438,653
Issuance of restricted common stock	-	-	195	-	-	-	-	-	-	-	-	-	-
Forfeitures of restricted stock	-	-	(3)	-	-	-	-	-	-	-	-	-	-
Cash in lieu of shares	-	-	(2)	-	(719)	-	-	-	-	-	(719)	-	(719)
Foreign currency translation adjustment	-	-	-	-	-	-	-	-	(5,342,327)	-	(5,342,327)	-	(5,342,327)
Issuance of common stock in connection with the ELOC	-	-	32,446	-	935,590	-	-	-	-	(250,308)	685,282	-	685,282
Issuance of restricted common stock in exchange in exchange for options	-	-	8,040	-	7,184,751	-	-	-	-	-	7,184,751	(7,184,751)	-
Adjustment to redeemable Series C preferred Stock	-	-	-	-	(125,000)	-	-	(206,404)	-	-	(331,404)	-	(331,404)
Changes in pension benefit obligation	-	-	-	-	-	-	-	-	238,010	-	238,010	-	238,010
Net loss	-	-	-	-	-	-	-	(58,691,023)	-	-	(58,691,023)	-	(58,691,023)
Balance at December 31, 2024	-	\$ -	138,422	1	\$127,825,743	(152)	\$(625,791)	\$(115,683,621)	\$ (2,723,397)	\$ (250,308)	\$ 8,542,627	-	\$ 8,542,627

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

ONCONETIX, INC.
Consolidated Statements of Cash Flows

	For the year ended December 31, 2025	For the year ended December 31, 2024
Cash flows from operating activities		
Net loss	\$ (14,032,342)	\$ (58,691,023)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on impairment of goodwill	11,512,000	32,347,000
Loss on impairment of ENTADFI	—	3,530,717
Loss on impairment of intangibles	—	10,279,796
Amortization of debt discount	124,084	376,660
Amortization of debt discount - related party	—	400,000
Loss on extinguishment of note payable	5,384,719	—
Loss on extinguishment of Series C preferred stock	196,244	—
Loss on issuance of preferred stock and warrants	3,674,329	—
Depreciation and amortization	15,170	731,345
Net periodic pension benefit cost	(619,399)	(48,423)
Stock-based compensation	74,267	438,653
Loss on impairment of inventory of ENTADFI	—	356,637
Change in fair value of contingent warrant liabilities	(16,499)	(1,250,466)
Change in fair value of Series D warrant liability	(10,377,638)	—
Change in fair value of Series D derivative liability	3,809,333	—
Change in fair value of Series E warrant liability	(4,486,847)	—
Change in fair value of Series E derivative liability	1,539,014	—
Change in fair value of subscription agreement liability	(3,127,962)	3,259,000
Loss on disposal of property and equipment	17,283	—
Gain on forgiveness of accounts payable	(944,694)	—
Deferred tax benefit	—	(1,045,181)
Amortization of deferred offering costs	—	366,113
Gain on settlement of contingent warrant liabilities	—	(5,282)
Changes in assets and liabilities:		
Accounts receivable	(268,685)	116,676
Inventory	(73,720)	(62,273)
Investor receivable	(50,000)	—
Prepaid expenses and other assets	(128,360)	1,018,109
Prepaid expenses, long-term	—	(7,749)
Deferred offering costs	(225,000)	—
Accounts payable	(1,093,655)	(1,477,075)
Accrued expenses	(580,032)	(1,129,050)
Net cash used in operating activities	<u>(9,678,390)</u>	<u>(10,495,816)</u>
Cash flows from investing activities		
Purchase of property and equipment	—	(28,471)
Net cash used in investing activities	<u>—</u>	<u>(28,471)</u>
Cash flows from financing activities		
Proceeds from issuance of notes payable - related party	—	5,000,000
Proceeds from issuance of notes payable	1,335,875	—
Payment of financing costs	—	(400,000)
Payment on note payables	(7,111,548)	(1,345,521)
Payment of redemption of Series C Preferred Stock	(1,713,570)	—
Proceeds from exercise of preferred investment options, net	—	922,749
Proceeds from exercise of stock options	—	163
Proceeds from exercise of warrants	—	6,155
Proceeds from issuance of Series D Preferred Stock and warrants	9,301,200	—
Proceeds from issuance of Series E Preferred Stock and warrants	6,250,000	—
Proceeds from issuance of Series C Preferred Stock and warrants	—	1,875,000
Proceeds from issuance or sale of common stock	6,391,655	685,282
Cash in lieu of shares	(926)	(718)
Net cash provided by financing activities	<u>14,452,686</u>	<u>6,743,110</u>
Effect of exchange rate changes on cash	(200,142)	(126,658)
Net increase (decrease) in cash	4,574,154	(3,907,835)
Cash, beginning of period	646,500	4,554,335
Cash, end of period	<u>\$ 5,220,654</u>	<u>\$ 646,500</u>
Cash paid for interest	<u>\$ 766,330</u>	<u>\$ 379,409</u>
Noncash investing and financing activities:		
Recognition of contingent warrant liability	\$ —	\$ 157,720
Conversion of Series B Preferred Stock to common stock	\$ —	\$ 64,236,085
Conversion of Series C preferred stock to common stock	\$ 801,241	\$ —
Recognition of Series D warrant liabilities	\$ 14,749,000	\$ —
Recognition of Series D derivative liabilities	\$ 772,000	\$ —
Recognition of Series D preferred stock	\$ 5,884,719	\$ —
Recognition of Series E warrant liabilities	\$ 6,516,000	\$ —
Recognition of Series E derivative liabilities	\$ 865,000	\$ —
Reclassification of Series D warrant liabilities to equity	\$ 4,371,362	\$ —
Reclassification of Series E warrant liabilities to equity	\$ 2,029,153	\$ —

Series C preferred stock exchanged for Series D preferred stock	\$ 246,227	\$ —
Settlement of note payable through issuance of Series D preferred stock	\$ 3,176,471	\$ —
Settlement of related party note payable and accrued interest through issuance of common stock	\$ —	\$ 5,134,247
Settlement of subscription agreement liability	\$ 995,038	\$ —
Establishment of operating right-of-use asset	\$ —	\$ 87,864
Conversion to equity of non-controlling interest	\$ —	\$ 7,184,751
D&O insurance premium financed	\$ —	\$ 678,548
Receivable from shareholders for shares issued	\$ —	\$ 250,308
Measurement Period Adjustments from Proteomedix acquisition	\$ —	\$ 10,321,000
Adjustment to redeemable Series C preferred stock	\$ —	\$ 125,000
Deemed dividend Series C preferred stock	\$ 409,510	\$ 206,404

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

ONCONETIX, INC.
Notes to 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. 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.

In April 2023, the Company acquired ENTADFI®, a Food and Drug Administration (“FDA”)-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia.

Historically, the Company’s focus was on the research and development of transformational vaccines to prevent infectious diseases worldwide, until the third quarter of 2023, at which time the Company halted its efforts on vaccine development activities to focus on commercialization activities for ENTADFI and pursue other potential acquisitions. However, in light of (i) the time and resources needed to continue pursuing commercialization of ENTADFI, and (ii) the Company’s cash runway and indebtedness, the Company abandoned commercialization of ENTADFI and no longer holds inventory of ENTADFI. There is currently no plan to resume commercialization of ENTADFI. Based on the circumstances surrounding ENTADFI, the ENTADFI assets were fully impaired at June 30, 2024 (see Notes 4 and 5).

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.

Reverse Stock Split

On September 24, 2024, the Company effected a reverse stock split of all shares of its issued and outstanding Common Stock at a ratio of one-for-forty (1:40). The Company accounted for the reverse stock split on a retrospective basis pursuant to Accounting Standards Codification (“ASC”) 260, *Earnings Per Share*. All issued and outstanding common stock, common stock warrants, and share-based awards’ exercise prices and per share data have been adjusted in these consolidated financial statements, on a retrospective basis, to reflect the reverse stock split for all periods presented. The number of authorized shares and par value of the preferred stock and common stock were not adjusted because of the reverse stock split.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 1 — Organization and Basis of Presentation (cont.)

On June 13, 2025, the Company effected a reverse stock split of all shares of its issued and outstanding Common Stock at a ratio of one-for-eighty-five (1:85). The Company accounted for the reverse stock split on a retrospective basis pursuant to ASC 260, *Earnings Per Share*. All issued and outstanding common stock, common stock warrants, and share-based awards' exercise prices and per share data have been adjusted in these consolidated financial statements, on a retrospective basis, to reflect the reverse stock split for all periods presented. The number of authorized shares and par value of the preferred stock and common stock were not adjusted because of the reverse stock split.

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.

The non-controlling interest recorded in the accompanying consolidated financial statements as of December 31, 2023 relates to currently outstanding stock-based awards issued by Proteomedix, which were assumed by Onconetix in connection with the acquisition of Proteomedix. During the year ended December 31, 2024, the non-controlling interest converted to equity with the issuance of restricted common stock in exchange for PMX options.

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, expenditures associated with the previously planned commercial launch of ENTADFI, and the commercialization of Proclarix.

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future.

As of December 31, 2025, the Company had cash of approximately \$5.2 million, a working capital deficit of approximately \$3.1 million and an accumulated deficit of approximately \$131.2 million. During the year ended December 31, 2025, the Company used approximately \$9.7 million in cash for operating activities. In addition, as of March 11, 2026, the Company's cash balance was approximately \$3.6 million.

The Company successfully closed a Series D financing and a Series E financing in September 2025 and October 2025, respectively. These financings provided the Company with additional cash flow to support near-term operations. While these capital raises may enable the Company to sustain current operations and meet existing obligations, the Company continues to generate recurring net operating losses and has not yet established sustained positive cash flows to support its strategic growth initiatives, which includes the commercialization of Proclarix, and the development and commercialization of the Company's future product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the date of the issuance of these consolidated financial statements.

Management's plans for funding the Company's operations include generating product revenue from sales of Proclarix, which is still subject to further successful development and commercialization activities within certain jurisdictions. Management also intends to pursue additional equity or debt financing to support operations and strategic initiatives. However, there are currently no committed sources of financing, and there is no assurance that additional funding will be available on favorable terms, if at all. This uncertainty raises significant concern about the Company's ability to sustain operations and execute its strategic initiatives. If additional capital is not secured, the Company may need to curtail clinical trials, development, and commercialization efforts, and take further measures to reduce expenses to conserve cash.

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 under the going concern basis of accounting. These consolidated financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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 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, valuation of subscription agreement liability, valuation of warrant and derivative liabilities, 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.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. As of December 31, 2025 and 2024, 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.

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, 2025 and 2024, the Company has not experienced losses on these accounts and management believes the Company is not exposed to significant risks on such accounts.

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. For the years ended December 31, 2025 and 2024, foreign currency translation gain (loss) was approximately \$2.8 million and \$(5.3) million.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

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 credit losses that is based upon a review of outstanding receivables, historical collection information, expected future losses, and existing economic conditions. As of December 31, 2025, there was no allowance for credit losses. As of December 31, 2025, substantially all of the Company's accounts receivable are due from a single customer.

Inventories

Inventories consist of product acquired in the Proteomedix transaction. 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 alternative 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.

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 \$15,000 and \$22,000 for the years ended December 31, 2025 and 2024 and is included in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

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.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

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. For the years ended December 31, 2025 and 2024, the Company recorded losses on impairment of goodwill of approximately \$11.5 million and \$32.3 million.

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 years ended December 31, 2024, 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. Impairment losses of \$3.5 million were recorded during the years ended December 31, 2024 (see Note 4). No additional impairment charges, in relation to the ENTADFI acquisition, were recorded during the year-end December 31, 2025.

During the year ended December 31, 2024, the Company determined there were certain triggering events that indicated the carrying amounts of the assets recorded in connection with the PMX acquisition may not be fully recoverable. Impairment losses of approximately \$10.3 million related to the Company’s intangible assets were recorded during the year ended December 31, 2024 resulting in a zero balance of the intangible assets as of December 31, 2024 and 2025. There were no additional impairment charges during the year ended December 31, 2025. See Note 4 for further details.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

The fair value of financial instruments measured on a recurring basis is as follows as of December 31, 2025 and 2024:

Description	As of December 31, 2025			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Contingent warrant liability	\$ 26,590	—	—	\$ 26,590
Series D and E derivative liabilities	6,985,347	—	—	6,985,347
Total	<u>\$ 7,011,937</u>	<u>—</u>	<u>—</u>	<u>7,011,937</u>

Description	As of December 31, 2024			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Contingent warrant liability	\$ 43,089	—	—	\$ 43,089
Subscription agreement liability – related party	4,123,000	—	—	4,123,000
Total	<u>\$ 4,166,089</u>	<u>—</u>	<u>—</u>	<u>\$ 4,166,089</u>

These non-financial assets were valued using significant unobservable measures and other fair value inputs and are therefore classified as Level 3 measurements.

None of the Company's other non-financial assets or liabilities are recorded at fair value on a non-recurring basis as of December 31, 2025 and 2024. There were no transfers between levels during the periods presented.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

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 whether 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-cancellable 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, 2025 or 2024.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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 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. As of December 31, 2025, the plan was fully settled as a result of the Company terminating its remaining full-time employment arrangements and transitioning to outsourced consulting payroll structures during the year.

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 expenses within the consolidated statements of operations and comprehensive loss.

Revenue Recognition

Development Services

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

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

Product Sales

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

Other Revenue

The Company generates other revenue including license revenue through agreements that grant third parties rights to use its intellectual property and proprietary materials. In September 2025, the Company entered into a license agreement with Immunovia AB, under which it granted exclusive rights to certain intellectual property and transferred biological materials related to the PancreaSure™ test. The agreement included two non-refundable payments of \$0.3 million. Based on the terms of the agreement and the nature of the license, the Company determined that the performance obligations were satisfied upon the transfer of the licensed rights. Accordingly, the Company recognized \$0.6 million as license revenue during the year ended December 31, 2025. The license agreement also states that the Company shall earn a 3% royalty on any sales Immunovia has from products developed using the licensed intellectual property. Further, Immunovia agreed to pay the Company \$0.1 million for the delivery of the biological materials. As of December 31, 2025, the Company had not recognized any revenue due to the royalties or due to the biological materials.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

As of December 31, 2025 the Company had received payments of \$0.3 million due to the license agreement.

As of December 31, 2025 the Company had an outstanding accounts receivable balance of \$0.3 million due to the remaining payment from the customer due to the Company by March 31, 2026. As of December 31, 2025, the \$0.3 million receivable was reported as accounts receivable, net in the accompanying consolidated balance sheets.

During the years ended December 31, 2025 and 2024, the Company recognized total revenue of approximately \$0.8 million and \$2.5 million, respectively.

The Company's revenue was generated from the following geographic regions during the year ended December 31, 2025:

	European Union	Non-European Union (UK)	United States
Development services	100%	—%	—%
Other revenue	100%	—%	—%
Product sales	92%	8%	—%

	European Union	Non-European Union (UK)	United States	Total Revenue
Development services	\$ 1,654	\$ —	\$ —	\$ 1,654
Other revenue	587,882	—	—	587,882
Product sales	207,054	18,781	—	225,835
Total	\$ 796,590	\$ 18,781	\$ —	\$ 815,371

The Company's revenue was generated from the following geographic regions during the year ended December 31, 2024:

	European Union	Non-European Union (UK)	United States
Development services	100%	—%	—%
Product sales	65%	10%	25%

	European Union	Non-European Union (UK)	United States	Total Revenue
Development services	\$ 2,275,088	\$ —	\$ —	\$ 2,275,088
Product sales	162,071	23,842	63,115	249,028
Total	\$ 2,437,159	\$ 23,842	\$ 63,115	\$ 2,524,116

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

The Company had the following customer concentrations for its revenue during the years ended December 31, 2025 and 2024:

	For the Year Ended December 31, 2025			For the Year Ended December 31, 2024		
	Development Services	Product Sales	Other Revenue	Development Services	Product Sales	Other Revenue
Customer A	100%	92%	100%	100%	65%	—%
Customer B	—%	—%	—%	—%	25%	—%
Customer C	—%	3%	—%	—%	5%	—%
Customer D	—%	5%	—%	—%	5%	—%

Any revenues earned but not yet billed to the customer as of the date of the consolidated financial statements are recorded as either accounts receivable or contract assets in the accompanying consolidated financial statements, with the difference depending on whether or not the Company's right to consideration is conditional or unconditional. The Company had approximately \$0.3 million and \$0 in unbilled accounts receivable as of December 31, 2025 and 2024. Amounts recorded in contract assets are reclassified to accounts receivable in our consolidated financial statements when the right to consideration switches from conditional to unconditional. Accounts receivable was approximately \$0.3 million and \$0.03 million as of December 31, 2025 and 2024, respectively.

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

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 5).

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 5) 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.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

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.

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.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

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 losses for the years ended December 31, 2025 and 2024 are comprised of net loss, the effect of currency translation adjustments, and the change in pension benefit obligation.

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.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

Recently Adopted Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and are adopted by the Company as of the specified effective date.

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 has adopted the improvements to income tax disclosure requirements with no significant impact on its disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses*. This guidance will require additional disclosures and disaggregation of certain costs and expenses presented on the face of the income statement. The amendments are effective for annual reporting periods beginning after December 15, 2026 and interim reporting period beginning after December 15, 2027 with early adoption permitted. The Company is currently evaluating the impact of this new guidance to our 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, which primarily relate to Proclarix product as of December 31, 2025 and 2024, consisted of the following:

	December 31, 2025	December 31, 2024
Raw materials	\$ 103,431	\$ 57,446
Finished goods	46,530	6,633
Total	\$ 149,961	\$ 64,079

The Company recorded an impairment on the ENTADFI inventory in the amount of approximately \$0.4 million during the year ended December 31, 2024, which fully reserved all remaining inventory related to ENTADFI. There were no additional impairments recorded on inventory during the year ended December 31, 2025. Additionally, during the year ended December 31, 2025, the Company fully abandoned ENTADFI and disposed of the remaining inventory.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 4 — Balance Sheet Details (cont.)

Investor Receivable

The Company recorded a receivable of approximately \$50,000 pertaining to professional service fees paid by the Company on behalf of an investor in connection with the Series E financing. The receivable is non-interest bearing and is presented as investor receivable within the accompanying consolidated balance sheet.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Prepaid insurance	\$ 136,739	\$ 101,999
Prepaid professional fees	—	7,487
VAT taxes receivable	31,955	28,756
Prepaid other	170,552	33,894
Other Receivable	10,047	41,835
Total	\$ 349,293	\$ 213,971

Intangible Assets

Intangible assets acquired in connection with the ENTADFI and Proteomedix acquisitions were comprised of customer relationships, product rights for developed technology, and a trade name. These intangibles were fully impaired during the year ended December 31, 2024, resulting in a zero balance as of December 31, 2025 and 2024.

Changes in intangible assets recorded during the year ended December 31, 2024 consisted of the following:

	Trade name	Product rights for developed technology	Customer relationships	Total intangible assets, net
Balance at December 31, 2023	\$ 9,312,739	\$ 14,150,944	\$ 1,947,204	\$ 25,410,887
Measurement period adjustments related to the Proteomedix acquisition	(6,239,000)	(3,264,000)	(818,000)	(10,321,000)
Impairment	(2,676,441)	(9,912,392)	(987,607)	(13,576,440)
Amortization	(185,396)	(457,144)	(66,502)	(709,042)
Effect of Foreign Currency Translation	(211,902)	(517,408)	(75,095)	(804,405)
Balance at December 31, 2024	\$ —	\$ —	\$ —	\$ —

The finite lived intangible assets held by the Company, which includes trade name, customer relationships and product rights for developed technology, were being amortized over their estimated useful lives, which is 15 years. Amortization expense related to intangible assets was approximately \$0.7 million for the year ended December 31, 2024, of which approximately \$457,000 and \$252,000 was recorded as cost of revenue and selling, general, and administrative expenses, respectively, in the accompanying consolidated statements of operations and comprehensive loss. The Company did not record any additions, impairments, or other changes in intangible assets during the year ended December 31, 2025.

ENTADFI Intangible Asset Impairment

In 2024, the Company recorded impairment charges related to its ENTADFI asset group after determining that the carrying amount was not recoverable. As of June 30, 2024, the ENTADFI asset group was fully impaired and had no remaining carrying value.

Proteomedix Intangible Assets Impairment

During the year ended December 31, 2024, the Company recorded a full impairment charge related to the intangible assets acquired in connection with the PMX acquisition. As a result, the carrying value of these intangible assets was reduced to zero as of December 31, 2024.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 4 — Balance Sheet Details (cont.)

Goodwill

Goodwill consisted of the following as of December 31, 2025 and 2024:

Balance as of December 31, 2023	\$ 55,676,142
Measurement period adjustment related to the Proteomedix acquisition	8,393,843
Impairment loss	(32,347,000)
Foreign currency translation	(4,674,012)
Balance as of December 31, 2024	27,048,973
Impairment loss	(11,512,000)
Foreign currency translation	3,012,032
Balance as of December 31, 2025	\$ 18,549,005

Impairments for years ended December 31, 2025 and 2024

During the years ended December 31, 2025 and 2024, the Company recognized goodwill impairment losses of approximately \$11.5 million and \$32.3 million, respectively.

During the year ended December 31, 2025, the Company performed quantitative goodwill impairment analyses during each quarter as a result of sustained declines in the Company's stock price and market capitalization. The fair value of the reporting unit during the year ended December 31, 2025 was estimated primarily using a market capitalization approach, which was derived from the Company's fully-diluted market capitalization calculated using an indicative share price based on the December 31, 2025 closing price.

During the year ended December 31, 2024, the Company identified multiple indicators of goodwill impairment primarily related to declines in its stock price and market capitalization, changes in market conditions, and the anticipated timing of projected sales. As a result, the Company performed quantitative goodwill impairment assessments throughout 2024, which resulted in cumulative impairment charges of approximately \$32.3 million. These charges included impairments recognized in the first and second quarters of 2024 and an additional impairment recognized in the fourth quarter of 2024 following a measurement-period adjustment related to the Proteomedix acquisition.

During 2024, the Company also reassessed its reporting unit structure and determined that, effective April 30, 2024, it operated as a single reporting unit, which was considered in its impairment analyses. Fair value was estimated using a combination of the income approach, the market approach, and the Company's market capitalization, with valuation methodologies evolving during the year based on changes in facts and circumstances. In the first and second quarters of 2024, the Company estimated fair value using a combination of the income approach and market approach (market multiples), with results reconciled to the Company's market capitalization. In the third quarter of 2024, the Company shifted to an income approach, still reconciled to market capitalization, because previously selected guideline transactions and comparable-company inputs were no longer considered representative of the Company's circumstances. In the fourth quarter of 2024, the Company estimated fair value based on the Company's market capitalization.

Under the income approach, the Company estimated the fair value of the reporting unit based on the present value of estimated future cash flows, which the Company considers to be a Level 3 unobservable input in the fair value hierarchy. The Company prepared cash flow projections based on management's estimates of future revenue and operating costs, taking into consideration the historical performance and the current macroeconomic, industry, and market conditions. The Company based the discount rate on the weighted-average cost of capital considering Company-specific characteristics and changes in the reporting unit's projected cash flows. Under the market approach, the Company estimated the fair value of the reporting unit based on revenue market multiples derived from comparable companies with similar characteristics as the reporting unit, as well as an estimated control premium.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 4 — Balance Sheet Details (cont.)

Measurement period adjustment for year ended December 31, 2024

During 2024, the Company identified a measurement period adjustment relating from the Proteomedix acquisition resulting in an increase to the acquired goodwill of approximately \$8.4 million.

Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Accrued compensation	\$ 42,228	\$ 186,956
Accrued research and development	—	320,096
Accrued professional fees	201,208	161,981
Accrued franchise taxes	80,000	40,000
Accrued interest	—	139,409
Accrued license fees	—	14,705
Other accrued expenses	18,445	25,841
Total	<u>\$ 341,881</u>	<u>\$ 888,988</u>

Note 5 — Significant Agreements

Services Agreement

On July 21, 2023, the Company, entered into a Licensing and Services Master Agreement (“Master Services Agreement”) and a related statement of work with a vendor, pursuant to which the vendor was to provide to the Company commercialization services for the Company’s products, including recruiting, managing, supervising and evaluating sales personnel and providing sales-related services for such products, for fees totaling up to \$29.1 million over the term of the statement of work. The statement of work had a term through September 6, 2026, unless earlier terminated in accordance with the Master Services Agreement and the statement of work. On July 29, 2023, a second statement of work was entered into with the same vendor for certain subscription services providing prescription market data access to the Company. The fees under the second statement of work totaled approximately \$0.8 million, and the term was through July 14, 2025. On October 12, 2023, the Company terminated the Master Services Agreement and the statements of work. During 2023, the Company recognized a termination fee of approximately \$1.4 million included in selling, general and administrative expense. Subsequently during 2024, the Company agreed with the vendor to pay a reduced termination fee of approximately \$0.9 million and recorded net credits of \$0.5 million for the difference in the termination fee related to this contract during the year ended December 31, 2024, which was included in selling, general and administrative expense for the year then ended. During the year ended December 31, 2025, the Company settled the remaining balance of the termination fee and recognized a \$0.9 million gain on forgiveness of accounts payable in the accompanying consolidated statement of operations and comprehensive loss.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 5 — Significant Agreements (cont.)

Laboratory Corporation of America

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 of in the mid-six figures upon signing of the contract. Additionally, Proteomedix is entitled to royalty payments of between 5% and 10% on the net sales recognized by LabCorp of any Licensed Products plus milestone payments as follows:

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

The total milestone payments available under the terms of this contract are \$2.5 million. An additional \$0.5 million was paid to Proteomedix as an initial license fee in 2023.

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. There was no such activity under the agreement for the year ended December 31, 2025.

The license agreement and related royalty payment provisions expire during 2038, which approximates the expiration of the last patent covered by the license agreement. LabCorp has the right to terminate the license agreement for any reason by providing 90 days written notice to Proteomedix. Either party may terminate the license agreement due to a material breach of the terms of the license agreement with 40 days' notice, provided such breach is not cured within the foregoing 30-day period. Finally, Proteomedix may terminate the license agreement with 60 days' notice in the event LabCorp fails to make any undisputed payment due, provided that LabCorp does not remit the payment within the foregoing 60-day period.

As of December 31, 2025, the sale of Licensed Products by LabCorp under the license agreement has not commenced. The Company has sold product to LabCorp for their use in internal trials of the test.

On December 6, 2025, the Company entered into an amendment with LabCorp that adds in a clause for LabCorp to complete a research study on behalf of the Company. This amendment does not affect the licensing agreement or any conclusions therein. The Company engaged LabCorp to complete a study and will pay LabCorp for these services separately. Under the amendment, the Company is obligated to reimburse LabCorp for study-related services based on subject enrollment milestones, with total payments capped at \$0.3 million. Management currently estimates total study costs to be in the mid-five-figure range; however, actual costs may vary depending on enrollment levels and study execution.

Immunovia AB

On September 17, 2025, Proteomedix entered into a license agreement with Immunovia AB, pursuant to which Immunovia obtained exclusive rights to certain intellectual property and proprietary biological materials related to the PancreaSure™ test. In exchange for these rights, Immunovia paid Proteomedix a non-refundable upfront license fee of \$0.3 million. Based on the terms of the agreement and the nature of the license, the Company determined that the performance obligations were satisfied upon the transfer of the licensed rights. Accordingly, the Company recognized the \$0.6 million as license revenue during the year ended December 31, 2025. Additionally, the agreement provides for a second payment of \$0.3 million due by March 31, 2026.

Under the terms of the agreement, Immunovia is responsible for the development, manufacturing, and commercialization of the PancreaSure™ test in the United States. Proteomedix is also entitled to receive royalty payments based on net sales of the licensed product. The royalty structure includes a tiered percentage of net sales of 3%, depending on sales volume thresholds. Immunovia may deduct certain third-party costs related to the manufacture or sale of the licensed product from the royalty payments, subject to specified limits.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 5 — Significant Agreements (cont.)

The license agreement includes customary termination provisions, including termination for convenience with advance notice, and termination for material breach or non-payment. The agreement does not require Proteomedix to provide ongoing services or support following the initial transfer of rights and materials.

As of December 31, 2025, the Company received the initial nonrefundable license payment of \$0.3 million, and the sale of the Licensed Products by Immunovia under the license agreement has not commenced.

As of December 31, 2025 the Company had an outstanding accounts receivable balance of \$0.3 million due to the payment from the customer due to the Company by March 31, 2026. As of December 31, 2025, the Company's accounts receivable balances were reported as accounts receivable, net in the accompanying consolidated balance sheets.

Consulting Agreement

On June 17, 2025, the Company entered into a consulting agreement with a firm affiliated with Thomas Meier, PhD, (see Note 11) pursuant to which the consulting firm provides strategic and transactional advisory services, including services related to the Immunovia license agreement. Under the terms of the agreement, the consulting firm is eligible to earn success fees based on transaction proceeds and reimbursement of related expenses. During the year ended December 31, 2025, the Company recognized approximately \$0.03 million of expense related to success fees under this agreement, and approximately \$0.02 million was included in accounts payable as of December 31, 2025.

Note 6 — Notes Payable

Veru Notes Payable

As December 31, 2024, the Company had two non-interest-bearing notes payable outstanding with principal amounts of \$5.0 million and initial maturity dates of April 19, 2024 ("April Veru Note"), and September 30, 2024 ("September Veru Note" and together with the April Veru Note, the "Veru Notes"), respectively. In accordance with the Veru Notes, no principal payments are due until maturity; however, the Company may voluntarily prepay the Veru Notes with no penalty. Additionally, in an Event of Default, as defined in the Veru Notes, the unpaid principal amount of the Veru Notes will accrue interest at a rate of 10.0% per annum.

The Company imputed interest on the Veru 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.

On April 24, 2024, the Company entered into a forbearance agreement with Veru (the "Original Forbearance Agreement") due to the Company's failure to repay the principal balance on the \$5.0 million note payable that had a maturity date of April 19, 2024 (the "April Veru Note"). Pursuant to the Original Forbearance Agreement, Veru will forbear from exercising its rights and remedies under the April Veru Note as a result of this default, until March 31, 2025 (the "April 2024 Forbearance Period").

Interest will accrue on any unpaid principal balance of the April Veru Note at a rate of 10% per annum, commencing on April 20, 2024 through the date that the outstanding principal balance under the April Veru Note is paid in full. Any such accrued interest will become immediately due and payable upon the earlier of (i) certain events of default under the April Veru Note or the \$5.0 million note payable that matures on September 30, 2024 (the "September Veru Note"), (ii) a payment default under the September Veru Note and (iii) the final payment of any principal amount payable under the September Veru Note. No interest was to accrue under the September Veru Note during the April 2024 Forbearance Period unless an Event of Default (as defined in the Original Forbearance Agreement) occurs, in which case interest will accrue from and after the date on which such default occurs.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 6 — Notes Payable (cont.)

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

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

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

The Company determined that the Original Forbearance Agreement should be accounted for as a modification of the April Veru Note and the September Veru Note in accordance with ASC 470-50, *Debt - Modifications and Extinguishments* ("ASC 470"), as the change in cash flows expected under the April Veru Note and the September Veru Note was not substantial. A new effective interest rate was established based on the carrying value of the original Notes and the revised cash flows and no gain or loss was recorded.

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

The A&R Forbearance Agreement extends the due date for the April 2024 and September 2024 Veru Notes until the earlier to occur of (i) June 30, 2025 or (ii) the occurrence of any Event of Default. The Amended and Restated Forbearance Agreement also effected certain modifications to the payment terms in the Original Forbearance Agreement and amended certain terms of the September Veru Note as summarized below.

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

- Interest at the rate of 10% per annum shall accrue on any unpaid principal balance of the April Veru Note commencing on April 20, 2024 through the date that the outstanding principal balance under the April Veru Note is paid in full;
- Monthly payments equal to 25% (increased from 15% in the Original Forbearance Agreement) of (i) the monthly cash receipts of Proteomedix for the licensing or sale of any products or services, (ii) monthly cash receipts of the Company or any of its subsidiaries for the sales of Proclarix anywhere in the world, and (iii) monthly cash receipts of the Company or any of its subsidiaries for milestone payments or royalties from LabCorp cash receipts of the Company or any of its subsidiaries from certain sale or licensing revenues or payments (the "Ordinary Cash Revenue"), which increased amount began October 20, 2024 for cash receipts in September 2024;
- Payment of 20% (increased from 10% in the Original Forbearance Agreement) of the net proceeds from certain financing or other transactions outside the ordinary course of business completed by the Company or any of its subsidiaries during the April 2024 Forbearance Period, which increased amount will begin for any net proceeds received after September 19, 2024; and
- The remaining balance of the April Veru Note will be due at the end of the April 2024 Forbearance Period.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 6 — Notes Payable (cont.)

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

- As noted above, an extension of the maturity date to June 30, 2025;
- The accrual of interest at the rate of 10% per annum on any unpaid principal balance of the September Veru Note commencing on October 1, 2024 through the date that the outstanding principal balance under the September Veru Note is paid in full;
- Any amounts owed on the September Veru Note, including but not limited to unpaid principal and accrued interest, will be paid in cash or, upon the mutual written consent of Veru and the Company, in shares of the Company's Common Stock or a combination of cash and the Company's Common Stock;
- Following full repayment of all principal and interest under the April Veru Note, the Company will make the Required Payments first towards accrued and unpaid interest under the September Veru Note and then towards the remaining principal balance payable under the September Veru Note;
- If the aggregate unpaid principal outstanding under the April Veru Note and the September Veru Note and all accrued and unpaid interest thereon is repaid in cash on or before December 31, 2024, then the total principal balance under the September Veru Note that will be payable by the Company in satisfaction of its obligations under the September Veru Note will be reduced from \$5.0 million to \$3.5 million.

The Company determined the A&R Forbearance Agreement should be accounted for as a modification of both the April and September Veru Notes in accordance with ASC 470-50, *Debt - Modifications and Extinguishments* ("ASC 470"), as the change in cash flows expected under the April Veru Note and the September Veru Note was not substantial. A new effective interest rate was established based on the carrying value of the original Notes and the revised cash flows and no gain or loss was recorded.

On November 26, 2024, the Company entered into another Amended and Restated Forbearance Agreement with Veru (the "November Amended and Restated Forbearance Agreement" or "November A&R Forbearance Agreement"), which amends and restates certain terms of the Amended and Restated Forbearance Agreement. Pursuant to the November A&R Forbearance Agreement, Veru agreed to waive the due date for payment of applicable Cash Receipt Payments (as such term is defined in the A&R Forbearance Agreement) generated in October 2024 until the Company receives funds of at least \$97,000 pursuant to its equity line of credit facility with Keystone Capital Partners LLC. In exchange, the Company agreed to increase its payments to be made to Veru out of future financing and strategic transactions through June 30, 2025, from 20% to 25% of net proceeds generated from such transactions. All other terms of the A&R Forbearance Agreement with Veru remain the same. Management has evaluated and concluded that there is no accounting impact from the A&R Forbearance Agreement with Veru.

On March 31, 2025, Veru and the Company entered into a waiver agreement, pursuant to which Veru agreed to waive and extend the date for payment of the April Veru Note to April 14, 2025.

On April 23, 2025, Veru and the Company entered into a limited waiver agreement, pursuant to which Veru agreed to waive and extend the date for payment of the April Veru Note to June 30, 2025.

On June 30, 2025, Veru and the Company entered into a limited waiver agreement, pursuant to which Veru agreed to waive and extend the date for payment of the Veru Notes to July 31, 2025.

On July 31, 2025, Veru and the Company entered into a waiver agreement, pursuant to which Veru agreed to waive and extend the date for payment of the Veru Notes to August 14, 2025.

On August 7, 2025, Veru and the Company agreed to amend and restate the September Veru Note to increase the principal amount owed to Veru by \$100,000 to an aggregate principal amount of \$5.1 million and extend the maturity date to August 14, 2025. All other terms of the September Veru Note remained the same.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 6 — Notes Payable (cont.)

On August 14, 2025, Veru and the Company entered into a waiver agreement, pursuant to which Veru agreed to waive and extend the date for payment of the April Veru Note and the September Veru Note to August 31, 2025.

On August 28, 2025, Veru and the Company agreed to amend and restate the September Veru Note. Pursuant to the September Veru Note, the principal amount owed to Veru was increased by \$100,000 to an aggregate principal amount of \$5.2 million, and the maturity date was amended to September 19, 2025. All other terms of the September Veru Note remained the same.

On August 28, 2025, Veru and the Company also entered into a waiver agreement, pursuant to which Veru agreed to waive and extend the date for payment of the September Veru Note to September 19, 2025.

As of September 22, 2025, approximately \$8.8 million was payable to Veru under the Veru Notes and related amendments. On September 22, 2025, the Company and Veru entered into a Settlement Agreement and Release (the “Veru Settlement Agreement”), pursuant to which Veru agreed to accept a cash payment of approximately \$6.3 million (including interest accrued through receipt of the Settlement Amounts (as defined herein)), 3,125 shares of Series D Preferred Stock (as defined below) and 846,975 Series D Warrants (as defined below) from a Series D PIPE Financing (as defined below) entered between the Company and certain institutional investors on September 22, 2025 (such cash payment, shares of Series D Preferred Stock and Series D Warrants, collectively, the “Settlement Amounts”) in full satisfaction of all amounts due under the Veru Notes, as amended by all preceding amendments, forbearance agreements, and waivers, and Veru agreed that such acceptance constituted complete discharge of all obligations thereunder. The Settlement Agreement contains customary release provisions that upon timely delivery of the Settlement Amounts, Veru shall release all claims or actions against the Company. The transaction was accounted for as a debt extinguishment in accordance with ASC 405-20 and ASC 470-50. The Company derecognized the carrying amount of the Veru Notes and recognized a gain or loss on extinguishment equal to the difference between the reacquisition price—measured at the fair value of the cash and equity instruments transferred—and the net carrying value of the debt. The Company recognized a loss on extinguishment related to this transaction of \$3,516,811 recorded within loss on extinguishment of notes payable in the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2025.

On September 24, 2025, Veru confirmed receipt of all Settlement Amounts in satisfaction of all outstanding amounts, and all Veru Notes and related amendments were deemed cancelled and terminated, respectively, and of no further force or effect.

During the year ended December 31, 2025 and 2024, the Company recorded approximately \$0.8 million and \$1.4 million of associated interest expense, respectively, which includes accrued interest and amortization of the debt discount. The unamortized debt discount as of December 31, 2025 and 2024 was \$0 and \$5,000. As of December 31, 2025 and 2024, the Company has recorded accrued interest of approximately \$0 and \$0.1 million on the Notes, which is included in accrued expenses in the accompanying consolidated balance sheets.

There are no future minimum principal payments on the Veru Notes as of December 31, 2025 as the Veru Notes are fully paid off and extinguished in accordance with the Veru Settlement Agreement.

Related Party Debenture

On January 23, 2024, the Company issued a non-convertible debenture (the “Debenture”) to the PMX Investor, a related party, in the principal sum of \$5.0 million, in connection with the Subscription Agreement discussed in Note 7. The Debenture has an interest rate of 4.0% per annum, and the principal and accrued interest was originally payable in full upon the earlier of (i) the closing under the Subscription Agreement and (ii) June 30, 2024. Additionally, the \$5.0 million subscription amount under the Subscription Agreement shall be increased by the amount of interest payable under the Debenture.

On April 24, 2024, the maturity date of the related party debenture was extended to October 31, 2024, through the execution of an extension agreement (the “Extension Agreement”) between the Company and the PMX investor. No other terms of the Debenture were modified in connection with the Extension Agreement.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 6 — Notes Payable (cont.)

The Company considered the guidance of ASC 470-60, *Troubled Debt Restructuring by Debtors*, and concluded that the Extension Agreement should be accounted for as a troubled debt restructuring as the Company is experiencing financial difficulty and since the effective borrowing rate under the Extension Agreement is less than the effective borrowing rate under the original agreement, which indicates that a concession is deemed to have been granted. This did not result in a gain on restructuring as the future undiscounted cash outflows required under the Extension Agreement exceed the carrying value of the Debenture immediately prior to the extension. A new effective rate was established based on the carrying value of the original Debenture and the revised cash flows.

In connection with the issuance of the Debenture, the Company incurred approximately \$0.4 million in financing fees, which was recorded as a debt discount, and reflected as a reduction in the carrying amount of the Debenture. The debt discount is being amortized to interest expense through the maturity date. The Company did not incur any financing fees in connection with the Extension Agreement.

On September 24, 2024, the Company converted all unpaid principal and accrued interest due under the Debenture into 5,882 units, attributable to principal, and 158 units, attributable to accrued interest, upon the closing of the Subscription Agreement. Each unit consisted of 1 share of common stock and 0.30 pre-funded warrants at an exercise price of \$3.40 per share. As a result of the transaction, 6,040 shares of common stock were issued, and 1,812 pre-funded warrants were issued. As of December 31, 2024, there is no outstanding balance or accrued interest remaining on the Debenture. The remaining unamortized debt discount was immediately expensed upon settlement.

The Company recorded approximately \$0.5 million of interest expense on the Debenture during the year ended December 31, 2024 which includes accrued interest and amortization of the debt discount. There was no such interest expense during the year ended December 31, 2025.

Insurance Financing

During the years ended December 31, 2025 and 2024, the Company obtained financing for certain Director & Officer liability insurance policy premiums. The agreement assigns the lender a first priority lien on and security interest in the financed policies and any additional premium required in the financed policies.

During 2024, the total premiums, taxes and fees financed are approximately \$0.7 million, with an annual interest rate of 7.79%. In consideration of the premium payment by the lender to the insurance companies or the agent or broker, the Company unconditionally promised to pay the lender the amount financed plus interest and other charges permitted under the agreement. As of December 31, 2024, the company had paid off the insurance financing note payable. The Company paid the insurance financing through monthly installment payments of approximately \$78,000, the last payment for the note was paid on November 17, 2024.

During 2025, the total premiums, taxes and fees financed are approximately \$0.5 million, with an annual interest rate of 7.25%. In consideration of the premium payment by the lender to the insurance companies or the agent or broker, the Company unconditionally promised to pay the lender the amount financed plus interest and other charges permitted under the agreement. The Company paid the insurance financing through monthly installment payments of approximately \$52,768, with the last payment for the note occurring on November 17, 2025. As of December 31, 2025, the insurance financing is fully paid off and the insurance policy remains in effect until February 17, 2026.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 6 — Notes Payable (cont.)

Keystone Notes Payable

During the year ended December 31, 2025, the Company issued six subordinated promissory notes to Keystone Capital Partners, LLC, each with an original issue discount and payable upon the earlier of (i) receipt of sufficient proceeds from the Company's Equity Line of Credit ("ELOC") with the Investor or (ii) a specified maturity date. All notes are subordinated to the Company's existing debt obligations to Veru, do not initially bear interest, and are subject to a late charge of 15% per annum on any unpaid amounts past due.

- On February 12, 2025, the Company issued a note with an aggregate principal amount of \$117,647, including an original issue discount of \$17,647. The note matures on November 12, 2025, unless prepaid earlier upon receipt of sufficient capital from other securities offerings (the "February Keystone Note").
- On May 16, 2025, the Company issued a note with an aggregate principal amount of \$294,118, including an original issue discount of \$44,118. The note matures on February 16, 2026, subject to the same prepayment provisions (the "May Keystone Note").
- On June 5, 2025, the Company issued a note with an aggregate principal amount of \$147,059, including an original issue discount of \$22,059. The note matures on March 5, 2026, subject to the same prepayment provisions (the "June Keystone Note").
- On August 6, 2025, the Company issued a note with an aggregate principal amount of \$117,647, including an original issue discount of \$17,647. The note matures on March 6, 2026, subject to the same prepayment provisions (the "August 6 Keystone Note").
- On August 28, 2025, the Company issued two notes with an aggregate principal amount of \$58,824 each, including an original issue discount of \$8,824 each. The notes mature on May 28, 2026, subject to the same prepayment provisions (the "August 28 Keystone Notes").

On September 22, 2025, Keystone Capital Partners, LLC and the Company agreed to exchange the principal owed under the May Keystone Note, the June Keystone Note, the August 6 Keystone Note and the August 28 Keystone Notes for Series D Preferred Stock and Warrants in connection with the Series D PIPE Financing. The February Keystone Note was fully paid off as of October 10, 2025. The transaction was accounted for as a debt extinguishment in accordance with ASC 405-20 and ASC 470-50. The Company derecognized the carrying amount of the Keystone Notes and recognized a gain or loss on extinguishment equal to the difference between the reacquisition price, measured at the fair value of the cash and equity instruments transferred, and the net carrying value of the debt. The Company recognized a loss on extinguishment related to this transaction of \$1,867,908 recorded within loss on extinguishment of notes payable in the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2025.

During the year ended December 31, 2025, the Company recorded approximately \$0.1 million of amortization of the debt discount.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 7 — 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 Note 11), for the sale of 5,882 units, each comprised of 1 share of common stock and 0.30 pre-funded warrants (the “Units”) at \$850 per Unit. The Subscription Agreement includes a make-whole provision (the “Make-Whole Provision”) which requires the issuance of additional shares of common stock in the event that the 270-day volume weighted average price after the closing of the Subscription Agreement, is below \$850, and the PMX Investor still holds the common shares acquired upon closing of the Subscription Agreement 270 days after such closing. The Subscription Agreement would only close upon obtaining stockholder approval for certain transactions involving the Company’s Series B Preferred Stock. The Subscription Agreement was amended on January 23, 2024 to include a provision for interest on the \$5 million debenture, accruing at a rate of 4%, to be included in the calculation of the units to be issued upon the conversion. Stockholder approval was obtained on September 5, 2024, and as a result, the conversion and the issuance of 5,882 units, attributable to the Subscription Agreement, and 158 units, attributable to additional accrued interest under the debenture to the PMX Investor took place on September 24, 2024.

On June 24, 2025, the 270-day volume weighted average price after the closing of the Subscription Agreement was below \$850. In accordance with the Make-Whole Provision under the Subscription Agreement, the Company issued 241,514 shares of common stock (the “Make-Whole Shares”) to Altos Venture AG, following the determination that the 270-day volume weighted average price (“Issuer VWAP”) was below the \$850 threshold. The Company recorded common stock of \$2 and additional paid in capital of \$995,036 related to the issuance of the 241,514 shares in the accompanying consolidated balance sheet as of December 31, 2025.

The Subscription Agreement was accounted for as a liability in accordance with ASC 480, *Distinguishing Liabilities from Equity*, (“ASC 480”), as the make-whole provision could result in a variable number of shares being issued upon settlement. The related party subscription agreement liability was measured at fair value at the commitment date and remeasured 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.

During the year ended December 31, 2025, the subscription agreement liability - related party expired and was settled resulting in the recognition of \$2 in common stock and \$995,036 in additional paid in capital as of December 31, 2025.

The following table summarizes the activity for the related party subscription agreement liability, using unobservable Level 3 inputs, for the years ended December 31, 2025 and 2024:

	Subscription Agreement Liability
Balance at December 31, 2023	\$ 864,000
Change in fair value	3,259,000
Balance at December 31, 2024	4,123,000
Change in fair value	(3,127,962)
Settlement	(995,038)
Balance at December 31, 2025	\$ —

As of December 31, 2025 and 2024, the fair value of the related party subscription agreement liability was approximately \$0 and \$4,123,000, respectively. For the years ended December 31, 2025 and 2024, the Company recognized a (gain) loss in change in fair value of the related party subscription agreement liability of approximately \$(3,127,962) and \$3,259,000, respectively.

The fair value was determined using a Monte-Carlo option pricing model, and as of December 31, 2024, the Company utilized 100% 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 December 31, 2024:

	December 31, 2024
Exercise price	\$ 10
Term (years)	0.48
Expected stock price volatility	100%
Risk-free rate of interest	4.25%

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 8 — Warrant and derivative liabilities

Contingent warrant liabilities

The following table summarizes the activity for the contingent warrant liabilities, using unobservable Level 3 inputs, for the years ended December 31, 2025 and 2024:

	Contingent Warrant Liability
Balance at December 31, 2023	\$ 2,641
Fair value at issuance	1,296,196
Change in fair value	(1,250,466)
Gain on settlement of contingent warrant liability	(5,282)
Balance at December 31, 2024	\$ 43,089
Change in fair value	(16,499)
Balance at December 31, 2025	\$ 26,590

Series D derivative liabilities and warrant liabilities

On September 22, 2025, the Company completed a private placement transaction with institutional investors, resulting in the issuance of Series D convertible preferred stock and accompanying warrants to purchase shares of common stock. In connection with this transaction, the Company recorded warrant liabilities related to the Series D Warrants and derivative liabilities associated with certain embedded features in the Series D Preferred Stock. These instruments were classified as liabilities and measured at fair value in accordance with ASC 815 due to their settlement provisions and other contractual terms. Refer to Note 9 for further detail on the private placement transaction.

The Company measured its bifurcated embedded derivative liabilities and warrant liabilities as of December 31, 2025 and September 22, 2025, at fair value on a recurring basis using level 3 inputs. These financial instruments are measured using management's best estimate of fair value, where the inputs into the determination of fair value require significant management judgment to estimation. The derivative liabilities and warrant liabilities were both measured using Monte Carlo valuation models. Valuations based on unobservable inputs are highly subjective and require significant judgments. Changes in such judgments could have a material impact on fair value estimates.

As of December 11, 2025 the Company had entered a letter of intent with Realbotix ("LOI"), which contemplates a change of control transaction. A closing condition of the LOI is that no convertible securities of the Company will be outstanding prior to, or upon, closing (subject to approval of the preferred shareholders) which creates two distinct timing scenarios for the settlement of the preferred securities: prior to, or at closing, pursuant to the terms of the LOI or after closing in the event the transaction proposed by the LOI is not completed. Given the disparate timing conditions, the valuation included two scenarios in the Monte Carlo valuation analysis as of December 31, 2025 and December 23, 2025: Closing and No Closing. The Closing scenario includes settlement logic for the preferred securities based on the profit-maximizing outcome of the preferred shareholder at the hypothetical closing date. The No Closing scenario models the embedded derivatives as if there was no forced conversion event (similar to valuation analyses of the embedded derivatives as of their original issuance and September 30, 2025). The closing scenario resulted in higher warrant values primarily due to a higher implied equity value, a shorter expected time to liquidity, and changes to the post-transaction capital structure and holder economics relative to the no-closing scenario.

The table below shows the inputs used to determine the fair value of the derivative liabilities:

	As of		
	December 31, 2025	December 31, 2025	September 22, 2025
	Closing Scenario	Non-closing Scenario	
Expected term (years)	2.75	2.73	3.0
Expected volatility	150.00%	150.00%	150.00%
Expected dividend yield	0.00%	0.00%	0.00%
Risk-free interest rate	3.50%	3.50%	3.56%
Probability	40.00%	60.00%	N/A

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 8 — Warrant and derivative liabilities (cont.)

The table below shows the inputs used to determine the fair value of the warrant liabilities:

	As of		
	December 23, 2025	December 23, 2025	September 22, 2025
	Closing Scenario	Non-closing Scenario	
Expected term (years)	2.75	2.75	3.0
Expected volatility	150.00%	150.00%	150.00%
Expected dividend yield	0.00%	0.00%	0.00%
Risk-free interest rate	3.55%	3.50%	3.56%
Probability	40.00%	60.00%	N/A

The Limited Waiver Agreement executed on December 23, 2025 resulted in reclassification of the warrants to equity, the warrant liability was remeasured using inputs as of December 23, 2025, and no subsequent liability remeasurement was required through December 31, 2025.

The following table presents information about the Company's derivative liabilities and warrant liabilities that are measured at fair value on a recurring basis as of December 31, 2025 and September 22, 2025, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

	Valuation Level	December 31, 2025	September 22, 2025
Warrant liabilities	Level 3	\$ —	\$ 14,749,000
Derivative liabilities	Level 3	4,581,333	772,000
		<u>\$ 4,581,333</u>	<u>\$ 15,521,000</u>

The following table sets forth a summary of the change in the fair value of the derivative liabilities and warrant liabilities that are measured at fair value on a recurring basis for the year ended December 31, 2025:

	Derivative Liabilities	Warrant Liabilities
Balance, as of December 31, 2024	—	—
Fair value recognized upon issuance	\$ 772,000	\$ 14,749,000
Change in fair value	3,809,333	(10,377,638)
Reclassified to equity (See Note 9)	—	(4,371,362)
Balance, as of December 31, 2025	<u>\$ 4,581,333</u>	<u>\$ —</u>

Series E derivative liabilities and warrant liabilities

On October 1, 2025, the Company completed a private placement transaction with institutional investors, resulting in the issuance of Series E convertible preferred stock and accompanying warrants to purchase shares of common stock. In connection with this transaction, the Company recorded warrant liabilities related to the Series E Warrants and derivative liabilities associated with certain embedded features in the Series E Preferred Stock. These instruments were classified as liabilities and measured at fair value in accordance with ASC 815 due to their settlement provisions and other contractual terms. Refer to Note 9 for further detail on the private placement transaction.

The Company measures its bifurcated embedded derivative liability and warrant liability as of December 31, 2025 and issuance, at fair value on a recurring basis using level 3 inputs. These financial instruments are measured using management's best estimate of fair value, where the inputs into the determination of fair value require significant management judgment to estimation. The derivative liability and warrant liability were both measured using Monte Carlo valuation models. Valuations based on unobservable inputs are highly subjective and require significant judgments. Changes in such judgments could have a material impact on fair value estimates.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 8 — Warrant and derivative liabilities (cont.)

As of December 11, 2025 the Company had entered a letter of intent with Realbotix (“LOI”), which contemplates a change of control transaction. A closing condition of the LOI is that no convertible securities of the Company will be outstanding prior to, or upon, closing (subject to approval of the preferred shareholders) which creates two distinct timing scenarios for the settlement of the preferred securities: prior to, or at closing, pursuant to the terms of the LOI or after closing in the event the transaction proposed by the LOI is not completed. Given the disparate timing conditions, the valuation included two scenarios in the Monte Carlo valuation analysis as of December 31, 2025 and December 23, 2025: Closing and No Closing. The Closing scenario includes settlement logic for the preferred securities based on the profit-maximizing outcome of the preferred shareholder at the hypothetical closing date. The No Closing scenario models the embedded derivatives as if there was no forced conversion event (similar to valuation analyses of the embedded derivatives as of their original issuance and September 30, 2025). The closing scenario resulted in higher warrant values primarily due to a higher implied equity value, a shorter expected time to liquidity, and changes to the post-transaction capital structure and holder economics relative to the no-closing scenario.

The table below shows the inputs used to determine the fair value of the derivative liabilities:

	As of		
	December 31, 2025	December 31, 2025	October 1, 2025
	Closing Scenario	Non-closing Scenario	
Expected term (years)	2.73	2.75	3.0
Expected volatility	150.00%	150.00%	150.00%
Expected dividend yield	0.00%	0.00%	0.00%
Risk-free interest rate	3.50%	3.50%	3.53%
Probability	40.00%	60.00%	N/A

The table below shows the inputs used to determine the fair value of the warrant liabilities:

	As of		
	December 23, 2025	December 23, 2025	October 1, 2025
	Closing Scenario	Non-closing Scenario	
Expected term (years)	2.77	2.77	3.0
Expected volatility	150.00%	150.00%	150.00%
Expected dividend yield	0.00%	0.00%	0.00%
Risk-free interest rate	3.55%	3.50%	3.53%
Probability	40.00%	60.00%	N/A

The Limited Waiver Agreement executed on December 23, 2025 resulted in reclassification of the warrants to equity, the warrant liability was remeasured using inputs as of December 23, 2025, and no subsequent liability remeasurement was required through December 31, 2025.

The following table presents information about the Company’s derivative liabilities and warrant liabilities that are measured at fair value on a recurring basis as of December 31, 2025 and October 1, 2025, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

	Valuation Level	December 31, 2025	October 1, 2025
Warrant liabilities	Level 3	\$ —	\$ 6,516,000
Derivative liabilities	Level 3	2,404,014	865,000
		<u>\$ 2,404,014</u>	<u>\$ 7,381,000</u>

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 8 — Warrant and derivative liabilities (cont.)

The following table sets forth a summary of the change in the fair value of the derivative liabilities and warrant liabilities that are measured at fair value on a recurring basis for the year ended December 31, 2025:

	Derivative Liabilities	Warrant Liabilities
Balance, as of December 31, 2024	—	—
Fair value recognized upon issuance	\$ 865,000	\$ 6,516,000
Change in fair value	1,539,014	(4,486,847)
Reclassified in equity (See Note 9)	—	(2,029,153)
Balance, as of December 31, 2025	<u>\$ 2,404,014</u>	<u>\$ —</u>

Note 9 — Convertible Redeemable Preferred Stock and Stockholders' Equity

Authorized Capital

As of December 31, 2025 and 2024, 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.

At December 31, 2025 and 2024, the Company had designated 1,150,000 shares, 10,000 shares, 2,700,000 shares, and 10,000 shares of Series Seed Preferred Stock, Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock, respectively. At December 31, 2025, the Company had designated 32,000 shares and 10,000 shares of Series D and E Preferred Stock, respectively.

Preferred Stock

Series Seed Convertible Preferred Stock

The Company has 1,150,000 shares of preferred stock designated as Series Seed Preferred Stock ("Series Seed") and there are no shares of Series Seed outstanding as of December 31, 2025 and 2024.

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.

On September 24, 2024, Veru converted all 3,000 shares of Series A Convertible Preferred Stock into 1,679 shares of the Company's common stock per the stated conversion ratio. There were no shares of Series A Convertible Stock outstanding as of December 31, 2025 and 2024.

Series B Convertible Preferred Stock

In connection with the PMX acquisition on December 15, 2023, the Company issued 2,696,729 shares of Series B Convertible Preferred Stock, which were initially convertible into approximately 79,315 shares of common stock, subject to stockholder approval on September 5, 2024. All Series B Preferred Stock was fully converted into common stock on September 24, 2024. As of December 31, 2024 and 2025, no Series B Preferred Stock remains outstanding.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

Series C Convertible Preferred Stock

On October 1, 2024, the Board of Directors authorized the Company to create a series of 10,000 shares of preferred stock designated as "Series C Convertible Preferred Stock", with a par value of \$0.00001, pursuant to the certificate of designations. At any time after the initial issuance date of Series C convertible Preferred Stock, each Preferred Share shall be convertible into validly issued, fully paid and non-assessable shares of Common Stock. The holders of Series C Preferred Stock are entitled to dividends, on an as-if converted basis, equal to and in the same form as dividends actually paid on shares of Common Stock, when and if actually paid. In addition, from and after the occurrence and during the continuance of any Triggering Event, dividends ("Default Dividends") will accrue on the Stated Value of each Preferred Share at a rate of fifteen percent (15.0%) (the "Default Rate") per annum. Each holder is entitled to convert any portion of the outstanding Preferred Shares held by such holder into validly issued, fully paid and non-assessable Conversion shares at the Conversion Rate, which can be determined by dividing (x) the Conversion Amount of such Preferred Share by (y) the Conversion Price, \$4.5056, subject to adjustment as provided in the Certificate of Designations.

After the Stockholder Approval Date, if a Triggering Event occurs and is continuing at any time after the earlier of the holders' receipt of a Triggering Event Notice and such holder becoming aware of such Triggering Event (such earlier date, the "Alternate Conversion Right Commencement Date") and ending on the twentieth (20th) Trading Day after the later of (x) the date of such Triggering Event is cured and (y) such holder's receipt of a Triggering Event Notice (such ending date, the "Alternate Conversion Right Expiration Date"), and each such period, an "Alternate Conversion Right Period", such holder may, at such holder's option, by delivery of a Conversion Notice to the Company (the date of any such Conversion Notice, each an "Alternate Conversion Date"), convert all, or any number of Preferred Shares held by such holder into shares of Common Stock at the Alternate Conversion Price (each, an "Alternate Conversion"). Alternate Conversion Price means, with respect to any Alternate Conversion that price will be the lowest of (i) the applicable Conversion Price as in effect on the applicable Conversion Date of the applicable Alternate Conversion, and (ii) the greater of (x) the Floor Price and (y) 80% of the lowest VWAP of the Common Stock during the five (5) consecutive Trading Day period ending and including the Trading Day immediately preceding the delivery or deemed delivery of the applicable Conversion Notice (such period, the "Alternate Conversion Measuring Period").

At any time, the Company has the right to redeem in cash all, but not less than all, of the Preferred Shares then outstanding at a price (the "Company Optional Redemption Price") equal to 125% of the greater of (i) the Conversion Amount being redeemed and (ii) the product of (1) the Conversion Rate with respect to the Conversion Amount being redeemed multiplied by (2) the greatest closing sale price of the Company's Common Stock on any Trading Day during the period commencing on the date immediately preceding the date the Company notifies the holders of its elections to redeem and the date the Company makes the entire payment required. Upon the occurrence of a Bankruptcy Triggering Event, the Company will immediately redeem, in cash, each of the Preferred Shares then outstanding at a redemption price equal to the greater of (i) the product of (A) the Conversion Amount to be redeemed multiplied by (B) 125% and (ii) the product of (X) the Conversion Rate with respect to the Conversion Amount in effect immediately following the date of initial public announcement of such Bankruptcy Triggering Event multiplied by (y) the product of (1) 125% multiplied by (2) the greatest closing sale price of the Common Stock on any Trading Day during the period commencing on the date immediately preceding such Bankruptcy Triggering Event and ending on the date the Company pays the entire payment required. The holders of the Series C Preferred Stock are entitled to be paid a cash amount equal to 30% of the gross proceeds in the event of any sale of common stock under the ELOC in accordance with the terms stated below within the ELOC securities purchase agreement.

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

On July 16, 2025, the Company exercised its voluntary Series C Preferred Stock adjustment right to lower the conversion price of the Series C Preferred Stock to \$3.50, and holders of 1,920 shares of Series C Preferred Stock agreed to convert their shares into shares of Common Stock. During the year ended December 31, 2025, 1,369 shares of Series C Preferred Stock were redeemed for an aggregate amount of \$1.71 million, 1,920 shares of Series C Preferred Stock were converted into common stock and 203 shares of Series C Preferred Stock were exchanged into 244 shares of Series D Preferred Stock (as defined below). There were no redemptions or conversions of the Series C Preferred Stock during the year ended December 31, 2024. As of December 31, 2025, 7 shares of Series C Preferred Stock remain outstanding, with a carrying value of \$1.7 thousand, as reflected in the accompanying consolidated balance sheet. As of December 31, 2024, 3,499 shares of Series C Preferred stock were outstanding with a carrying value of \$1.1 million, as reflected in the accompanying consolidated balance sheet.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

Series D Preferred Stock

On September 22, 2025, the Company entered into a securities purchase agreement (the "Series D Securities Purchase Agreement" and the financing contemplated therein, the "Series D PIPE Financing") with eleven institutional investors, and sold or exchanged debt, to such investors (collectively, the "Series D PIPE Investors") an aggregate of 16,099 shares of Series D convertible preferred stock, par value \$0.00001 per share ("Series D Preferred Stock"), which includes an issuance of 500 shares of Series D Preferred Stock to the lead investor in consideration for the Series D PIPE Investors' irrevocable commitment to purchase shares of the Series D Preferred Stock, and warrants (the "Series D Warrants") to purchase 4,362,827 shares of Common Stock, (the Series D Preferred Stock together with the Series D Warrants, the "Series D PIPE Securities"), for an aggregate purchase price of approximately \$12.9 million and net cash proceeds of \$9.3 million. The exercise price of the Series D Warrants is \$3.6896, and the Series D Warrants are exercisable beginning on the issuance date and expire on the third anniversary of the issuance date.

Concurrently with entering into the Securities Purchase Agreement, the Company also entered into a registration rights agreement with the Series D PIPE Investors, pursuant to which it has agreed to provide the Series D PIPE Investors with certain registration rights related to the shares of Common Stock underlying the shares of Series D Preferred Stock and Series D Warrants.

In connection with the Series D financing entered into on September 22, 2025, the Company utilized the proceeds to extinguish the outstanding Veru and Keystone notes payable upon the transfer of the settlement considerations. The extinguishment was achieved through a combination of cash payment and the issuance of Series D Preferred Stock and Series D Warrants (See Note 6). The transaction was accounted for as a debt extinguishment in accordance with ASC 405-20 and ASC 470-50. The Company derecognized the carrying amounts of the notes payable and recognized a gain or loss on extinguishment equal to the difference between the reacquisition price, measured at the fair value of the cash and equity instruments transferred, and the net carrying value of the debt. The Company recognized a loss on extinguishment related to this transaction of \$5,384,719 recorded within loss on extinguishment of notes payable in the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2025.

The Series D Preferred Stock was determined to be more akin to an equity-like host than a debt-like host and was classified as permanent equity as it was not redeemable in any manner that would require classification outside of permanent equity pursuant to ASC 480-10-S99. The Series D Preferred Stock was recorded on the accompanying consolidated balance sheet at its par value. Certain embedded share-settled redemption features within the Series D Preferred Stock were bifurcated and accounted for separately as derivative liability.

The Series D Warrants and certain embedded share-settled redemption features of the Series D Preferred Stock issued were determined to be liability-classified instruments pursuant to ASC 480 and ASC 815. The embedded features of the Series D Preferred Stock were bifurcated and accounted for separately as derivative liabilities. The Company measured the warrant liabilities and bifurcated derivative liabilities at fair value on a recurring basis using Level 3 inputs as of September 22, 2025 (the issuance date), December 23, 2025 (amended warrants date), and December 31, 2025 (derivative liabilities fair value date), respectively. The fair value of the derivative liabilities was \$772,000 and \$4,581,333 as of September 22, 2025 and December 31, 2025, respectively. The fair value of the warrant liabilities was \$14,749,000 and \$4,371,362 as of September 22, 2025 and December 23, 2025, respectively. See Note 8 for further information regarding the valuation methodology and assumptions used in determining the fair value of the warrant and derivative liabilities.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

In connection with the Series D PIPE Financing, the Company incurred direct and incremental expenses of \$775,000, comprised of legal fees and success fees, were expensed immediately. In addition to these issuance costs, the Company recognized a significant loss on issuance due to the fair value allocation requirements under US GAAP. Specifically, because the Series D Warrants and certain embedded features of the Series D Preferred Stock were determined to be liability-classified instruments pursuant to ASC 480 and ASC 815, they were initially measured at fair value upon issuance. The aggregate fair value of the Warrants \$14,749,000 and the bifurcated derivative liabilities related to the Preferred Stock \$772,000, as determined by a third-party valuation specialist using a Monte Carlo simulation, exceeded the total gross proceeds received in the Series D PIPE Financing of \$12,977,671. As required by the guidance in ASC 470-20-25-2, when the fair value of financial liabilities required to be measured at fair value exceeds the net proceeds received, the excess is recognized as a loss in earnings at issuance. Accordingly, the Company recognized a loss on issuance of \$2,543,329, representing the excess of the fair value of the liability-classified instruments over the proceeds allocated to the transaction.

The Series D Preferred Stock has no voting rights. The Series D Preferred Stock are convertible into common stock at the election of the holders of the Series D Preferred Stock at any time at an initial conversion price of \$3.6896 per share. The conversion price is subject to customary adjustments for stock dividends, stock splits, reclassifications, stock combinations and the like (subject to certain exceptions), anti-dilution provisions, and a floor price of \$0.74.

The Series D Preferred Stock is not redeemable by the holder except in the event of 1) a liquidation, dissolution, or winding up, or 2) the Series D Preferred Stock is redeemable for common stock of the Company upon the occurrence of a change in control. Holders of the Series D Preferred Stock shall be entitled to receive dividends as authorized and declared by the Company's Board of Directors, payable in cash, securities, or in other assets as determined by the Company's Board of Directors.

In the event of the Company's liquidation, dissolution, or winding up, holders of the Series D Preferred Stock will be entitled to receive out of the assets, whether capital or surplus, an amount equal to the stated value of the Series D Preferred Stock, plus any accrued and unpaid dividends thereon and any other fees or liquidated damages owed before any distribution or payment shall be made to the holders of any junior securities.

During the year ended December 31, 2025, the Company issued 16,343 in connection with the Series D financing, which includes the 16,099 initially issued and an additional 244 shares that were exchanged from Series C Preferred Stock to Series D Preferred Stock, and converted approximately 18 Series D Preferred Stock into common shares. As of December 31, 2025, 16,325 shares of Series D Preferred Stock remain outstanding.

Series E Preferred Stock

On October 1, 2025, Onconetix entered into, and sold to institutional investor(s) (collectively, the "PIPE Investors"), pursuant to a securities purchase agreement (the "Securities Purchase Agreement") an aggregate of 7,813 shares of Series E convertible preferred stock, par value \$0.00001 per share ("Series E Preferred Stock"), which are convertible into common stock of the Company, \$0.00001 par value per share (the "Common Stock") and warrants to purchase 2,025,223 shares of Common Stock (the "Warrants" and, together with the Series E Preferred Stock, the "PIPE Securities"), for an aggregate purchase price of approximately \$6.25 million and net cash proceeds of \$6.2 million. Such investment is referred to as the "PIPE Financing". The exercise price of the Series E Warrants is \$3.8576, and the Series E Warrants are exercisable beginning on the issuance date and expire on the third anniversary of the issuance date.

Concurrently with entering into the Securities Purchase Agreement, the Company also entered into a registration rights agreement with the Series E PIPE Investors, pursuant to which it has agreed to provide the Series E PIPE Investors with certain registration rights related to the shares of Common Stock underlying the shares of Series E Preferred Stock and Series E Warrants.

The Series E Preferred Stock was determined to be more akin to an equity-like host than a debt-like host and was classified as permanent equity as it was not redeemable in any manner that would require classification outside of permanent equity pursuant to ASC 480-10-S99. The Series E Preferred Stock was recorded on the accompanying consolidated balance sheet at its par value. Certain embedded share-settled redemption features within the Series E Preferred Stock were bifurcated and accounted for separately a derivative liability.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

The Series E Warrants and certain embedded share-settled redemption features of the Series E Preferred Stock issued were determined to be liability-classified instruments pursuant to ASC 480 and ASC 815. The embedded features of the Series E Preferred Stock were bifurcated and accounted for separately as derivative liabilities. The Company measured the warrant liabilities and bifurcated derivative liabilities at fair value on a recurring basis using Level 3 inputs as of October 1, 2025 (the issuance date), December 23, 2025 (amended warrants date), and December 31, 2025 (derivative liabilities fair value date). The fair value of the derivative liabilities was \$865,000 and \$2,404,014 as of October 1, 2025 and December 31, 2025, respectively. The fair value of the warrant liabilities was \$6,516,000 and \$2,029,153 as of October 1, 2025 and December 23, 2025, respectively. See Note 8 for further information regarding the valuation methodology and assumptions used in determining the fair value of the warrant and derivative liabilities.

In connection with the Series E PIPE Financing, the Company incurred direct and incremental expenses of \$60,000, comprised of legal fees and success fees, were expensed immediately. In addition to these issuance costs, the Company recognized a significant loss on issuance due to the fair value allocation requirements under US GAAP. Specifically, because the Series E Warrants and certain embedded features of the Series E Preferred Stock were determined to be liability-classified instruments pursuant to ASC 480 and ASC 815, they were initially measured at fair value upon issuance. The aggregate fair value of the Warrants \$6,516,000 and the bifurcated derivative liabilities related to the Preferred Stock \$865,000, as determined by a third-party valuation specialist using a Monte Carlo simulation, exceeded the total gross proceeds received in the Series E PIPE Financing of \$6,250,000. As required by the guidance in ASC 470-20-25-2, when the fair value of financial liabilities required to be measured at fair value exceeds the net proceeds received, the excess is recognized as a loss in earnings at issuance. Accordingly, the Company recognized a loss on issuance of \$1,131,000, representing the excess of the fair value of the liability-classified instruments over the proceeds allocated to the transaction.

The Series E Preferred Stock has no voting rights. The Series E Preferred Stock are convertible into common stock at the election of the holders of the Series E Preferred Stock at any time at an initial conversion price of \$3.8576 per share. The conversion price is subject to customary adjustments for stock dividends, stock splits, reclassifications, stock combinations and the like (subject to certain exceptions), anti-dilution provisions, and a floor price of \$0.7715.

The Series E Preferred Stock is not redeemable by the holder except in the event of 1) a liquidation, dissolution, or winding up, or 2) the Series E Preferred Stock is redeemable for common stock of the Company upon the occurrence of a change in control. Holders of the Series E Preferred Stock shall be entitled to receive dividends as authorized and declared by the Company's Board of Directors, payable in cash, securities, or in other assets as determined by the Company's Board of Directors.

In the event of the Company's liquidation, dissolution, or winding up, holders of the Series E Preferred Stock will be entitled to receive out of the assets, whether capital or surplus, an amount equal to the stated value of the Series E Preferred Stock, plus any accrued and unpaid dividends thereon and any other fees or liquidated damages owed before any distribution or payment shall be made to the holders of any junior securities.

During the year ended December 31, 2025, the Company issued 7,813 in connection with the Series E financing. As of December 31, 2025, 7,813 shares of Series E Preferred Stock remain outstanding.

Warrant Waiver Amendment Reclassification

On December 23, 2025, the Company executed a Limited Waiver Agreement (the "Limited Waiver") effective October 1, 2025, that amended the September 2025 Series D and October 2025 Series E investor warrants of an aggregate of 6,388,050 warrants (the "Amended Warrants"), including removal of the issuer-specific cash settlement upon certain Fundamental Transactions and a change to treat holders *pari passu* with common shareholders. Management concluded the Amended Warrants no longer embody an obligation to transfer assets under ASC 480 and, after evaluating exercise/settlement terms (including anti-dilution, buy-in, authorized-share-failure, and beneficial-ownership caps), determined they are indexed to the Company's stock and meet equity-classification conditions under ASC 815-40. Accordingly, the warrants were remeasured at fair value and reclassified to equity on December 23, 2025. Because the amendment moved the instruments from liability to equity, the Company recognized a gain of approximately \$14.9 million for the change in fair value on December 23, 2025, and reclassified \$6.4 million (aggregate fair value) to additional paid-in capital. The reclassification resulted in a non-cash adjustment to the Company's balance sheet, reducing warrant liabilities and increasing additional paid-in capital. No subsequent remeasurement of the Warrants will be required so long as they remain equity-classified. After reclassification to equity, the Amended Warrants are not remeasured.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

October 2024 Securities Purchase Agreement and ELOC

On October 2, 2024, the Company entered into a Securities Purchase Agreement (the "Series C Securities Purchase Agreement") with six institutional and accredited investors. The Company sold an aggregate of i) 3,499 Series C Preferred Stock, par value \$0.00001 per, and (ii) a warrants to purchase 6,963 shares of common stock (the "Series C PIPE Warrants"), for aggregate cash proceeds of \$2,000,000. The Series C Warrants have an exercise price of \$372.30 per share, subject to adjustment therein, and expire on the third anniversary of the initial exercisability date. The warrants issued with the Series C Redeemable Preferred Stock are accounted for as liabilities in accordance with ASC 815.

Concurrently, on October 2, 2024, the Company entered into a Common Stock Equity Line of Credit Purchase Agreement (the "ELOC Purchase Agreement" and the equity line of credit, the "ELOC") with an institutional investor, whereby the Company may sell up to \$25,000,000 of the Company's new issued Common Stock. Pursuant to the ELOC Purchase Agreement, the investor shall purchase from the Company up to the lesser of (i) \$25.0 million in shares of our Common Stock and (ii) 19,512 shares, representing 19.99% of the total number of shares of Common Stock outstanding immediately prior to the execution of the ELOC Purchase Agreement. Pursuant to the ELOC Purchase Agreement, 30% of the gross proceeds to the Company from any sale of common stock thereunder must be applied towards the redemption of the Series C Redeemable Preferred Stock.

Based on the terms of the Series C Redeemable Preferred Stock and the Company's Certificate of Designation, and in accordance with ASC 480, the Series C Redeemable Preferred Stock is accounted for as mezzanine equity due to the contingent redemption feature upon any sale of common stock under the ELOC Purchase Agreement. The initial cash proceeds of \$2,000,000 were allocated between the Series C Preferred Stock and derivative liability warrants, with the amount initially recorded in mezzanine equity based on the guidance in ASC 815 (i.e. the value of the derivative liability warrant is allocated its full fair value, and the residual is allocated to the Series C Redeemable Preferred Stock). The derivative liability warrants were measured at fair value at inception in the amount of \$1,138,476 and the Series C Redeemable Preferred stock was measured at residual value of \$861,524. The Series C Redeemable Preferred Stock is subsequently measured at redemption value as they occur, with the difference between the basis per share of \$246.22 and redemption value per share recorded as a deemed dividend in the statements of operations.

During the year ended December 31, 2024, the Company received proceeds of \$935,625 and recorded approximately \$250,000 of shareholder receivable under the ELOC. In addition, the Company recorded a deemed dividend in the amount of \$206,404 in the consolidated statement of operations for the year ended December 31, 2024.

During the year ended December 31, 2025, the Company received proceeds of \$6,391,655 under the ELOC and recorded a deemed dividend in the amount of \$1,498,595 in the consolidated statement of operations.

Common Stock

As of December 31, 2025 and 2024 there were 1,560,153 and 138,422 shares of common stock issued, respectively, and 1,560,001 and 138,270 shares of common stock outstanding, respectively.

Warrant Inducements:

July 2024 Inducement

On July 11, 2024, the Company entered into common stock preferred investment options exercise inducement offer letters (the "Inducement Letters") with certain holders of existing preferred investment options to purchase shares of the Company's common stock at exercise prices of \$8,656.40 and \$3,706.00 per share, issued on August 11, 2022 and August 2, 2023, respectively (collectively, the "Existing PIOs"), pursuant to which the holders agreed to exercise for cash their Existing PIOs to purchase an aggregate of 2,193 shares of the Company's common stock, at a reduced exercise price of \$510 per share, in consideration for the Company's agreement to issue new preferred investment options (the "Inducement PIOs") to purchase up to an aggregate of 6,580 shares of the Company's common stock. Of the 6,580 PIOs issued, 2,193 have a contractual term of 5 years, while the remaining 4,387 have a contractual term of 2 years. Aside from the contractual terms, the Inducement PIOs have substantially the same terms as the Existing PIOs.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

On July 11, 2024, the Company consummated the transaction contemplated by the Inducement Letters upon unanimous written consent of the Board of Directors (the "Warrant Inducement"). The Company received aggregate net proceeds of approximately \$0.9 million from the Warrant Inducement, after deducting placement agent fees and other offering expenses payable by the Company.

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") within 30 days after the date of the Inducement Letter and to use commercially reasonable efforts to cause such Resale Registration Statement to be declared effective by the SEC within 60 days following the date of the Inducement Letter (or within 90 days following the date of the Inducement Letter in the case of full review of the Resale Registration Statement by the SEC).

The Company engaged H.C. Wainwright & Co., LLC ("Wainwright") to act as its exclusive placement agent in connection with the transactions summarized herein 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 paid Wainwright for non-accountable expenses in the amount of \$35,000. The Company also issued to Wainwright or its designees warrants (the "Placement Agent Warrants"), and as such shares of common stock issuable thereunder, (the "Placement Agent Warrant Shares") to purchase (i) 154 shares of common stock which have the same terms as the Inducement PIOs except for an exercise price equal to \$637.50 per share and a term of five (5) years following the date of stockholder approval and (ii) upon any exercise for cash of the Inducement PIOs, 7.5% of the aggregate exercise price and that number of shares of common stock equal to 7.0% of the aggregate number of such shares of common stock underlying the Inducement PIOs that have not been exercised, which will have substantially the same terms as the Placement Agent Warrants.

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 \$0.9 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 \$1.9 million as an equity issuance cost.

In addition, the change in fair value of the contingent warrant liability associated with 44 of the August 2022 Contingent Warrants and 88 of the August 2023 Contingent Warrants was decreased to \$0 upon the agreement with Wainwright that all prior contingent warrants were no longer issuable or due upon the Warrant Inducement Transaction. The fair value of the contingent warrant liability of approximately \$2,700 was derecognized as of the settlement date, with the corresponding amount, representing the fair value of the Wainwright Inducement Warrants, was recognized as additional paid-in capital.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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

The Company evaluated the terms of the 461 Inducement Contingent Warrants (equivalent to 7.0% of the aggregate number of such shares of common stock underlying the Inducement PIOs that have not been exercised), which are issuable upon a future inducement, 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 \$158,000 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 statements of operations. The fair value was determined using a Monte-Carlo option pricing model, and as of December 31, 2025 and 2024

Treasury Stock

On November 10, 2022, the Board approved a stock repurchase program (the "Repurchase Program") to allow the Company to repurchase up to 125,000 shares of common stock with a maximum price of \$1.00 per share, with discretion to management to make purchases subject to market conditions. On November 18, 2022, the Board approved an increase to the maximum price to \$2.00 per share. There was no expiration date for this program and prices are not adjusted for the reverse stock split to comply with the program.

There were no repurchases of common stock during the years ended December 31, 2025 and 2024.

On November 13, 2024, the Board terminated the Repurchase Program.

At the Market Offering Agreement

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

As of December 31, 2025 and 2024, no shares have been sold under the ATM Offering, and the Company wrote off approximately \$0.3 million of deferred offering costs in its consolidated balance sheets as of December 31, 2024.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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 years ended December 31, 2025 and 2024:

	Number of Shares	WA Average Exercise Price	WA Remaining Contractual Life (in years)
Outstanding as of December 31, 2023	2,323	\$ 5,712.00	4.30
Granted	15,509	390.15	—
Exercised	(4,014)	2,935.05	—
Cancelled	—	—	—
Outstanding as of December 31, 2024	13,818	\$ 568.38	2.92
Granted	6,388,057	3.86	—
Exercised	—	—	—
Cancelled	—	—	—
Outstanding as of December 31, 2025	6,401,875	4.97	2.73
Warrants vested and exercisable as of December 31, 2025	6,401,875	\$ 4.97	2.73

As of December 31, 2025, the Company had outstanding warrants, which are exercisable into 6,401,875 shares of common stock. The shares of common stock underlying the warrants outstanding had an exercise price of \$4.97 per share.

Contingent Warrant Liabilities

As of December 31, 2025, the fair value of contingent warrant liabilities includes the Series C Warrants of \$6,300 and those issuable upon exercise of the Inducement PIOs of approximately \$20,290 totaling \$26,590 included as contingent warrant liabilities in the accompanying consolidated balance sheets.

As of December 31, 2024, the fair value of contingent warrant liabilities includes the Series C Warrants of \$32,982 and those issuable upon exercise of the Inducement PIOs of approximately \$10,200 totaling \$43,089 included as contingent warrant liabilities in the accompanying consolidated balance sheets.

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. On February 23, 2022 the Company's board of directors adopted the Company's 2022 Equity Incentive Plan (the "2022 Plan"), which is the successor and continuation of the Company's 2019 Plan. Under the 2022 Plan, the Company may grant stock options, restricted stock, restricted stock units, stock appreciation rights, and other forms of awards to employees, directors, and consultants of the Company. In May 2023, the number of shares of common stock reserved for issuance under the 2022 Plan was increased to 926, and in September 2024, the number of shares of common stock reserved for issuance under the 2022 Plan was increased to 17,058. Stock-based awards granted during the years ended December 31, 2025 and 2024 were all granted under the 2022 Plan. As of December 31, 2025, there are 7,899 shares available for issuance under the 2022 Plan.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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 years ended December 31, 2025 and 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2023	560	\$ 5,542.00	8.4
Granted	—	—	—
Forfeited / cancelled	(394)	2,409.75	—
Exercised	(4)	42.50	—
Outstanding as of December 31, 2024	162	\$ 13,258.74	7.9
Granted	—	—	—
Forfeited / cancelled	(139)	14,582.00	—
Exercised	—	—	—
Outstanding as of December 31, 2025	23	5,700.95	6.8
Options vested and exercisable as of December 31, 2025	20	\$ 5,871.67	6.8

There were no stock options granted during the years ended December 31, 2025 and 2024.

The aggregate fair value of stock options that vested during the year ended December 31, 2025 and 2024, was approximately \$0.01 million and \$0.7 million, respectively.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

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 143, of which 44, 22, and 44 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 7 shares of restricted stock, granted to the Company's non-executive Board members, with full vesting on May 31, 2024. On February 14, 2024, in connection with the appointment of a non-executive Board member, the Company issued 1 share of restricted stock, which vested in full on June 14, 2024. Furthermore, on September 26, 2024, the Company issued its Board members a total of 195 restricted stock, with full vesting August 31, 2025. On February 24, 2025, in connection with the appointment of an executive Board member, the Company issued 20 shares of restricted stock with full vesting August 31, 2025. Subsequently, the Company modified the vesting date of 137 shares previously issued to the Board members to provide for full vesting August 31, 2026. On August 15, 2025, the Company issued its Board members a total of 2,472 restricted stock, with full vesting August 16, 2026.

The following summarizes activity related to the Company's restricted stock awards granted under the 2022 Plan for the year ended December 31, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2023	75	\$ 3,502.00
Granted	8,236	35.70
Vested	(8,097)	52.70
Forfeited	(3)	3,479.05
Nonvested as of December 31, 2024	211	\$ 522.75
Granted	2,492	2.99
Vested	—	—
Forfeited	(751)	119.50
Nonvested as of December 31, 2025	1,952	\$ 14.31

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.

Generally, options issued under the PMX Option Plan have a term of not more than 11 years and provide for a four-year vesting period. Stock options issued under the PMX Option Plan are measured at fair value using the Black-Scholes option pricing model.

On April 16, 2024, the board of directors of Proteomedix approved a two-year extension of 144 vested stock options that were set to expire in April 2024. The extended expiration date for these options is April 18, 2026. The Company recorded approximately \$18,000 of expense associated with this modification during the year ended December 31, 2024.

There was no activity under the PMX Option Plan for the years ended December 31, 2025 and 2024. In October 2024, 684 stock options were converted to shares with a weighted average exercise price of \$294.10. As of December 31, 2025 and 2024, there were no outstanding stock options.

Stock-Based Compensation

Stock-based compensation expense for the years ended December 31, 2025 and 2024 was as follows:

	For the Years Ended December 31,	
	2025	2024
Selling, general and administrative	\$ 74,267	\$ 483,226
Research and development	—	(44,573)
Total	\$ 74,267	\$ 438,653

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 10 — Commitments and Contingencies

Office Lease

Proteomedix leases office and lab space in Zurich Switzerland. On April 1, 2024, the original lease was amended to add additional office and laboratory space. The lease amendment was accounted for as a separate lease, resulting in an additional right-of-use asset and lease liability of approximately \$88,000.

In May 2025, Proteomedix entered into a lease amendment to reduce its leased premises. Effective June 30, 2025, the Company terminated the April 2024 lease amendment, which included office space and laboratory space. Additionally, a partial termination of a prior lease amendment further reduced the office space.

This lease expired on December 31, 2025, and was renewed for a successive two-year term, resulting in an additional right-of-use asset and lease liability of approximately \$49,000. The lease, as renewed, requires payments of approximately \$24,000 over the next twelve months. The lease will automatically renew for successive two-year terms, unless terminated. Either party may terminate the lease with twelve months' written notice.

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, 2025, the Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims.

Termination of Ocuvox Merger Agreement

On July 16, 2025, the Company entered into an Agreement and Plan of Merger with (i) Onconetix Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of the Company, and (ii) Ocuvox Therapeutics, Inc., a Delaware corporation ("Ocuvox", and such agreement, the "Merger Agreement"). Pursuant to the Merger Agreement, Merger Sub will merge with and into Ocuvox, with Ocuvox surviving the merger as a direct, wholly owned subsidiary of the Company (the "Merger").

Effective September 24, 2025, pursuant to the terms of the Merger Agreement, the Company and Ocuvox entered into a Termination and Release Agreement (the "Termination Agreement") pursuant to which they agreed to terminate the Merger Agreement and the transactions contemplated thereby. The Termination Agreement also provides for a mutual release of claims among the Company, Ocuvox and their affiliates and in consideration of the foregoing, the Company agreed to pay to Ocuvox, an amount equal to \$302,343.55 (the "Termination Payment"), which represents all amounts payable by the Company to Ocuvox pursuant to the terms of the Merger Agreement. The termination payment is recorded within selling, general, and administrative expenses in the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2025.

As of September 24, 2025, Ocuvox confirmed receipt of the Termination Payment, and as a result the Merger Agreement is of no further force and effect.

Registration Rights Agreements

In connection with private placements consummated in April 2022 and August 2022, the Company entered into Registration Rights Agreements with the purchasers. Upon the occurrence of any Event (as defined in each Registration Rights Agreement), which, among others, prohibits the purchasers from reselling the securities for more than ten consecutive calendar days or more than an aggregate of fifteen calendar days during any 12-month period, and should the registration statement cease to remain continuously effective, the Company would be obligated to pay to each purchaser, on each monthly anniversary of each such Event, an amount in cash, as partial liquidated damages and not as a penalty, equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such purchaser in the private placements. As of December 31, 2025 and 2024, and as a result of the consummation of the remaining warrants associated with the April 2022 and August 2022 private placements, the Company has no further obligations pertaining to the Registration Rights Agreements.

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. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is not estimable at this time.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 11 — Related Party Transactions

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, 2025. During the year ended December 31, 2024, the Company issued a non-convertible debenture in the principal amount of \$5.0 million to the PMX Investor, in connection with the Subscription Agreement and has settled the principal and accrued interest through the issuance of shares (see Note 6).

On February 6, 2024, the Company appointed Thomas Meier, PhD, as a member of the Company's board of directors. Dr. Meier provides consulting services to Proteomedix, through a consulting agreement that was effective January 4, 2024. The Company recorded approximately \$0 and \$58,000 in related expenses during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, no amounts related to this agreement were included in accounts payable.

On June 17, 2025, the Company entered into a separate consulting agreement with a firm affiliated with Dr. Meier. The agreement provides for the payment of certain success fees and reimbursement of related expenses. Under its terms, Dr. Meier is entitled to earn up to 10% of success fees for transactions greater than \$9 million earned by the affiliated firm, payable only upon receipt of such proceeds. The Company recorded approximately \$33,000 and \$0 in related expenses during the years ended December 31, 2025 and 2024. As of December 31, 2025 and 2024, approximately \$16,500 and \$0 related to this agreement was included in accounts payable.

Note 12 — Income Taxes

The components of loss before income taxes are as follows:

	For the Years Ended	
	December 31,	
	2025	2024
U.S.	\$ (14,454,877)	\$ (58,988,309)
Foreign	423,060	(747,894)
Total loss before income taxes	\$ (14,031,817)	\$ (59,736,203)

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 provision (benefit) recorded for the years ended December 31, 2025 and December 31, 2024 related to the Company's deferred foreign taxes. Generally, the Company's federal returns from 2020 on and state returns from 2019 on, and foreign returns from 2019 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.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 12 — Income Taxes (cont.)

At December 31, 2025, the Company had a net operating loss (“NOL”) carryforward for federal, foreign, and state income tax purposes totaling approximately \$55.2 million, \$14.2 million, and \$36.0 million, respectively, available to reduce future taxable income. The federal NOL and certain state NOLs of \$25.1 million are carried forward indefinitely subject to a limitation of 80% of taxable income. Foreign NOLs and state NOLs of approximately \$14.2 million and \$11.0 million, respectively will begin to expire in 2025 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, 2025. 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,	
	2025	2024
Deferred tax assets:		
Net-operating loss carryforward	\$ 15,628,885	\$ 13,309,416
Intangibles	3,530,546	3,887,855
Capitalized research and development	214,455	1,001,916
Stock-based compensation	371,669	645,113
Deposit on WraSer APA	83,296	854,896
Accrued compensation	—	55,193
License agreement	41,085	45,493
Other	251,723	667,065
Gross deferred tax assets	20,121,659	20,466,947
Valuation allowance	(20,111,374)	(20,441,833)
Deferred tax assets, net of allowance	\$ 10,285	\$ 25,114
Deferred tax liabilities:		
Intangible assets	—	—
Fixed assets	(701)	(1,378)
Other	(9,584)	(23,736)
Total deferred tax liabilities	\$ (10,285)	\$ (25,114)
Net deferred tax liability	\$ —	\$ —

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 federal and state deferred tax assets, as well as a portion of its foreign deferred tax assets in each of the years ended December 31, 2025 and 2024, 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, 2025 and 2024, the valuation allowance decreased by approximately \$0.3 million and \$4.7 million, respectively.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 12 — Income Taxes (cont.)

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2025 and 2024, due to the following:

	For the Years Ended December 31,			
	2025		2024	
US federal statutory income tax rate	\$	(2,946,792)	21.00%	\$ (12,488,416) 21.00%
Domestic state and local taxes, net of federal effect				
Income tax effect		362,123	(2.58)%	(339,155) 0.57%
State rate adjustment		117,931	(0.84)%	— 0.00%
Foreign tax effects:				
Switzerland				
Expiration of Swiss NOLs		578,270	(4.12)%	— 0.00%
Foreign rate differential		11,765	(0.08)%	7,205 (0.01)%
Currency translation adjustment		—	0.00%	49,773 (0.08)%
Statutory to GAAP adjustments		(253,552)	1.81%	— 0.00%
Change in Swiss valuation allowance		(283,805)	2.02%	710,982 (1.20)%
Tax credits:				
Research credits		—	0.00%	(37,810) 0.06%
Nontaxable or nondeductible items:				
Goodwill impairment		2,417,520	(17.23)%	6,792,870 (11.42)%
Stock compensation		57	0.00%	29,088 (0.05)%
Warrant liability fair value adjustment		(3,125,007)	22.27%	— 0.00%
Loss on extinguishment of debt		1,130,791	(8.06)%	— 0.00%
Loss on issuance of preferred stock		771,609	(5.50)%	— 0.00%
Acquisition related costs		—	0.00%	10,500 (0.02)%
Subscription agreement liability		466,281	(3.32)%	684,390 (1.15)%
Other permanent items		41,211	(0.29)%	(244,395) 0.41%
Other adjustments				
Return to provision adjustments:				
WraSer deposit receivable write-off		769,517	(5.48)%	— 0.00%
Other return to provision adjustments		(20,569)	0.15%	— 0.00%
Other, net		9,829	(0.07)%	(253,362) 0.43%
Change in domestic valuation allowance		(46,654)	0.33%	4,033,150 (6.78)%
Income tax provision (benefit)	\$	525	0.01%	\$ (1,045,180) 1.75%

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,	
	2025	2024
Beginning balance	\$ 26,462	\$ 17,010
Decreases related to prior year tax positions	(8,749)	—
Increases related to current year tax positions	—	9,452
Ending balance	<u>\$ 17,713</u>	<u>\$ 26,462</u>

At December 31, 2025 and 2024, the Company's unrecognized tax benefits were \$17,713 and \$26,462, respectively. 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 expense and penalties related to uncertain tax positions as a component of income tax expense. As of December 31, 2025 and 2024, there were no accrued interest and penalties associated with uncertain tax positions.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 13 — Net Loss Per Share

Basic net loss per share is computed by dividing the net income or loss applicable to common shares by the weighted average number of common shares outstanding during the period. The weighted average number of shares of common stock outstanding includes pre-funded warrants because their exercise requires only nominal consideration for delivery of shares; it does not include any potentially dilutive securities or any unvested restricted shares of common stock. Certain restricted shares, although classified as issued and outstanding at December 31, 2025, 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.

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

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

	For the Years Ended December 31,	
	2025	2024
Options to purchase shares of common stock	23	161
Warrants	6,401,875	13,827
Unvested shares of restricted stock	1,952	211
Common stock issuable upon conversion of Series C Redeemable Preferred Stock	1,897	9,136
Common stock issuable upon conversion of Series D Redeemable Preferred Stock	4,424,080	—
Common stock issuable upon conversion of Series E Redeemable Preferred Stock	2,025,223	—
Total	12,855,050	23,335

Note 14 — Defined Benefit Plan

Proteomedix sponsors a defined benefit pension plan (the "Swiss Plan") covering certain eligible employees. The Swiss Plan provides retirement benefits based on years of service and compensation levels. As of December 31, 2025, the Proteomedix defined benefit pension plan was fully terminated and settled. As a result of this settlement, all curtailment and settlement gains have been recognized in the current period. Accordingly, the projected benefit obligation is zero, and there are no remaining assets or liabilities associated with the defined benefit plan as of the reporting date.

The following significant actuarial assumptions were used in calculating the benefit obligation and the net periodic benefit cost as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Discount rate	1.10%	1.00%
Expected long-term rate of return on plan assets	1.10%	1.00%
Rate of compensation increase	1.50%	1.50%

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 years ended December 31, 2025 and 2024 are as follows:

	For the year ended December 31, 2025	For the year ended December 31, 2024
Service cost	\$ 56,867	\$ 97,964
Interest cost	14,992	30,032
Expected return on plan assets	(13,250)	(23,343)
Amortization of net gain	(21,850)	(15,346)
Curtailment gain recognized	(146,804)	—
Settlements gain	(795,594)	—
Total	\$ (905,639)	\$ 89,307

During the years ended December 31, 2025 and 2024, Proteomedix made pension contributions of approximately \$45,000 and \$89,404, respectively.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 14 — Defined Benefit Plan (cont.)

The components of change in pension benefit obligation plan for the years ended December 31, 2025 and 2024 are as follows:

	For the year ended December 31, 2025	For the year ended December 31, 2024
Net loss (gain)	\$ (227,818)	\$ (190,064)
Prior service cost (credit)	—	(63,292)
Amortization of prior service credit	3,607	—
Amortization of net gain	18,243	15,346
Effect of curtailment	65,812	—
Effect of settlement	795,594	—
Total recorded during the period	<u>\$ 655,438</u>	<u>\$ (238,010)</u>

As of December 31, 2025, these amounts were fully removed from Accumulated Other Comprehensive Income as a part of the pension settlement and recognized in retained earnings through the net periodic benefit cost above.

As of December 31, 2025 and 2024, the funded status of the plan and the amounts recognized in the accompanying consolidated balance sheet are as follows:

	December 31, 2025	2024
Projected benefit obligation	\$ —	\$ 2,593,360
Fair value of plan assets	—	2,312,481
Overfunded (underfunded) status	<u>\$ —</u>	<u>\$ (280,879)</u>

A reconciliation of the beginning and ending balances of the accumulated benefit obligation is provided in the table below:

As of December 31, 2024	\$ 2,593,360
Service cost	56,868
Interest cost	14,992
Actuarial (gain) loss	(516,774)
Benefits paid	(10,531)
Ordinary contributions paid by employees	44,961
Settlements	(2,095,733)
Curtailments	(87,143)
Projected benefit obligation as of December 31, 2025	<u>—</u>
Actuarial (gain)/loss due to assumption changes	—
Actuarial (gain)/loss due to plan experience	—
Accumulated benefit obligation as of December 31, 2025	<u>\$ —</u>

A reconciliation of the beginning and ending balances of the plan assets is provided in the table below:

As of December 31, 2024	\$ 2,312,481
Actual return on plan assets	(296,139)
Contributions paid by employer	44,961
Ordinary contributions paid by employees	44,961
Benefits paid	(10,531)
Settlements	(2,095,733)
As of December 31, 2025	<u>\$ —</u>

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 15 — Segment Information

The Company conducts its business activities and reports financial results as one business segment. The presentation of financial results as one reportable segment is consistent with the way the Company operates its business and is consistent with the manner in which the Chief Operating Decision Maker ("CODM") evaluates performance and makes resource and operating decisions for the business. The Company's CODM is the Chief Executive Officer. Furthermore, the Company notes that monitoring financial results as one reportable segment helps the CODM manage costs on a consolidated basis, consistent with the integrated nature of the operations. The CODM uses net loss, as reported on the Consolidated Statements of Operations and Comprehensive Loss, in evaluating performance of the Company and determining how to allocate resources of the Company as a whole. As the CODM evaluates performance on a consolidated basis, all required financial segment information is included in the consolidated financial statements.

Geographic Information

The distribution of revenue by geographical area was as follows:

	Years Ended December 31,	
	2025	2024
United States	\$ —	\$ 63,115
United Kingdom	18,781	23,842
Switzerland	796,590	2,437,159
Total	\$ 815,371	\$ 2,524,116

Note 16 — Subsequent Events

Realbotix Corp. Share Exchange Agreement

On February 11, 2026, we entered into a Share Exchange Agreement (the "Share Exchange Agreement"), by and among (i) Onconetix, (ii) Realbotix Corp., a company existing under the laws of the Province of Ontario ("Parent"), (iii) Simulacra Corporation, a Delaware corporation and a wholly-owned subsidiary of Parent (the "Seller") and (iv) Realbotix, LLC, a Delaware limited liability company and wholly owned subsidiary of the Seller (the "Realbotix").

Pursuant to the Share Exchange Agreement, subject to the terms and conditions set forth therein, the Seller agreed to contribute and transfer to us, and we agreed to acquire and accept, all of the issued and outstanding equity interests of Realbotix in exchange for newly issued shares of Common Stock. (the "Share Exchange" and the other transactions contemplated by the Share Exchange Agreement, the "Realbotix Transactions").

Under the terms of the Share Exchange Agreement, the percentage ownership of Buyer's fully diluted shares to be received by the Seller upon closing will vary based on Buyer's net cash at closing, ranging from 75% to 90% of Buyer's fully diluted shares. The transaction is subject to multiple closing conditions, including, among others, minimum net cash requirements, completion of financing arrangements, receipt of required regulatory and stockholder approvals, delivery of audited financial statements, and the absence of any legal prohibition to consummation of the transaction. The Share Exchange Agreement also includes customary representations, warranties, covenants, and termination provisions, including potential termination fees and reimbursement of transaction expenses under certain circumstances.

As of the date the financial statements were issued, the Share Exchange had not been consummated, and no amounts related to the transaction have been recognized in the accompanying financial statements. The Company will account for the transaction, if and when consummated, in the period in which the closing occurs.

ONCONETIX, INC.
Notes to Consolidated Financial Statements

Note 16 — Subsequent Events (cont.)

Investor Relations and Advisory Agreement

On February 11, 2026, in connection with the pending Realbotix transaction, the Company entered into a six-month business advisory and investor relations agreement with MDM Worldwide Solutions, Inc. Under the agreement, the Company will pay MDM \$50,000 per month for the first four months and \$10,000 per month for the remaining two months, with additional fees for special projects subject to mutual agreement.

Reverse Stock Split

On February 3, 2026, the Company held a special meeting of stockholders (the “Special Meeting”), whereby its stockholders approved an amendment to the Company’s Amended and Restated Certificate of Incorporation to effect a reverse stock split of all of the outstanding shares of Common Stock at a ratio in the range of 1-for-2 to 1-for-50, at any time prior to the one-year anniversary date of the Special Meeting, with such ratio to be determined by the Board without further approval or authorization of the Company’s stockholders.

Director & Officer Insurance Policy

On February 17, 2026, the Company entered into a twelve-month insurance policy for its Board of Directors and Officers with total premiums of \$330,000, for which a note payable of \$247,197 was issued to finance such policy. The principal of the note is expected to be paid off through ten monthly payments of \$25,693 starting on March 17, 2026.

Series D and Series E Preferred Stock Conversions

As of March 11, 2026, at the election of their holders, 1,916 shares of Series D Preferred Stock had converted into 1,852,715 shares of common stock and 132 shares of Series E Preferred Stock had converted into 176,363 shares of common stock.

Exhibit No.	Description
2.1	<u>Share Exchange Agreement, dated February 11, 2026, by and among Onconetix, Inc., Realbotix, LLC, Realbotix Corp, and Simulacra Corporation</u> ⁽²⁸⁾
3.1	<u>Amended and Restated Certificate of Incorporation filed.</u> ⁽³⁾
3.2	<u>Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation</u> ⁽¹¹⁾
3.3	<u>Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation.</u> ⁽¹⁹⁾
3.4	<u>Fourth Amended and Restated Bylaws of the Company.</u> ⁽¹⁹⁾
3.5	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation</u> ⁽¹²⁾
3.6	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation</u> ⁽¹⁴⁾
3.7	<u>Certificate of Amendment, dated June 11, 2025</u> ⁽⁴⁾
3.8	<u>Certificate of Designations authorizing the issuance of the Series C Preferred Stock</u> ⁽¹⁵⁾
3.9	<u>Certificate of Correction to Certificate of Designations authorizing the issuance of the Series C Preferred Stock</u> ⁽⁶⁾
3.10	<u>Certificate of Designation of Series D Preferred Stock.</u> ⁽⁷⁾
3.11	<u>Certificate of Designation of Series E Preferred Stock</u> ⁽⁹⁾
4.1	<u>Specimen Common Stock Certificate.</u> ⁽¹⁾
4.2	<u>Description of Registered Securities*</u>
4.3	<u>Form of Inducement PIO</u> ⁽¹⁰⁾
4.4	<u>Form of Altos Warrants</u> ⁽¹⁴⁾
4.5	<u>Form of Warrant</u> ⁽¹⁵⁾
4.7	<u>Form of Warrant (Series C)</u> ⁽¹⁵⁾
4.8	<u>Form of Warrant (Series D)</u> ⁽⁷⁾
4.9	<u>Form of Warrant (Series E)</u> ⁽²³⁾
4.10	<u>Form of Warrant Waiver*</u>
10.1	<u>2019 Equity Incentive Plan.</u> ⁽¹⁾
10.2	<u>2022 Equity Incentive Plan.</u> ⁽⁸⁾
10.3	<u>2019 Equity Incentive Plan Form of Stock Option Grant Agreement.</u> ⁽¹⁾
10.4	<u>2022 Equity Incentive Plan Form of Incentive Stock Option Agreement (Employee).</u> ⁽²⁴⁾
10.5	<u>2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Consultant).</u> ⁽²⁴⁾
10.6	<u>2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Non-Employee Director).</u> ⁽²⁴⁾
10.7	<u>2022 Equity Incentive Plan Form of Nonstatutory Stock Option Agreement (Employee).</u> ⁽²⁴⁾
10.8	<u>Form of Employment Agreement with Neil Campbell.</u> ⁽¹³⁾
10.9	<u>Form of Employment Agreement with Bruce Harmon.</u> ⁽¹³⁾
10.10	<u>Form of Employment Agreement with Ralph Schiess.</u> ⁽²⁾
10.11	<u>Amendment to Employment Agreement, dated October 15, 2020, by and between Proteomedix and Ralph Schiess.</u> ⁽²⁾
10.12	<u>Amendment to Employment Agreement by and between Proteomedix and Ralph Schiess.</u> ⁽²⁾
10.13	<u>Form of Employment Agreement with Christian Brühlmann.</u> ⁽²⁾
10.14	<u>Amendment to Employment Agreement, dated October 16, 2020, by and between Proteomedix and Christian Brühlmann.</u> ⁽²⁾
10.15	<u>Amendment to Employment Agreement by and between Proteomedix and Christian Brühlmann.</u> ⁽²⁾
10.16	<u>Form of Indemnification Agreement for Directors and Officers.</u> ⁽¹³⁾
10.17	<u>Asset Purchase Agreement, dated April 19, 2023, between the Company and Veru Inc.</u> ^{(11)†}
10.18	<u>Amendment to Asset Purchase Agreement, dated September 29, 2023, between the Company and Veru Inc.</u> ⁽²⁶⁾
10.19	<u>Form of Non-Competition and Non-Solicitation Agreement, dated April 19, 2023.</u> ⁽¹¹⁾
10.20	<u>Form of Lock-Up Agreement, dated December 15, 2023, by and among the Company and certain stockholders of Proteomedix.</u> ⁽¹⁹⁾

10.21	<u>Form of Non-Competition and Non-Solicitation Agreement, dated December 15, 2023, by and among the Company and certain stockholders of Proteomedix.</u> ⁽¹⁹⁾
10.22	<u>Form of Stockholder Support Agreement, dated December 15, 2023, by and among the Company, Proteomedix, and certain stockholders of Proteomedix.</u> ⁽¹⁹⁾
10.23	<u>Form of Subscription Agreement, dated December 15, 2023, by and among the Company, Proteomedix, and the Investor.</u> ⁽¹⁹⁾
10.24	<u>Note, dated February 12, 2025</u> ⁽¹⁶⁾
10.25	<u>Note, dated May 16, 2025</u> ⁽¹⁷⁾
10.26	<u>Note, dated June 5, 2025</u> ⁽⁴⁾
10.27	<u>Form of Lock-Up Agreement, dated July 16, 2025, by and among the Company and the holders thereto</u> ⁽¹⁸⁾
10.28	<u>Form of Company Support Agreement, dated July 16, 2025, by and among the Company, OcuveX and certain OcuveX stockholders</u> ⁽¹⁸⁾
10.29	<u>Form of Termination Agreement effective as of September 24, 2025, by and between the Company and OcuveX Therapeutics, Inc.</u> ⁽⁷⁾
10.30	<u>Form of Conversion Price Reduction Consent</u> ⁽¹⁸⁾
10.31	<u>Promissory Note, dated August 6, 2025, by and between Keystone Capital Partners, LLC and the Company</u> ⁽²⁰⁾
10.32	<u>Amended and Restated Promissory Note, dated August 7, 2025, by and between Veru, Inc. and the Company</u> ⁽²⁰⁾
10.33	<u>Settlement Agreement and Release, dated September 22, 2025, by and between the Company and Veru, Inc.</u> ⁽⁷⁾
10.34	<u>Promissory Note, dated August 28, 2025, by and between Keystone Capital Partners, LLC and the Company</u> ⁽²¹⁾
10.35	<u>Promissory Note, dated August 28, 2025, by and between KCP Fund I, LLC and the Company</u> ⁽²¹⁾
10.36	<u>Second Amended and Restated Promissory Note, dated August 28, 2025, by and between Veru, Inc. and the Company</u> ⁽²¹⁾
10.37	<u>Waiver, dated August 28, 2025, by and between Veru, Inc. and the Company</u> ⁽²¹⁾
10.38	<u>License Agreement, dated September 17, 2025, by and between Immunovia AB and Proteomedix AG</u> ⁽²²⁾
10.39	<u>Form of Securities Purchase Agreement dated September 22, 2025 relating to the sale of the Series D Preferred Stock and Warrants</u> ⁽⁷⁾
10.40	<u>Form of Registration Rights Agreement dated as of September 22, 2025 relating to the resale of the shares of Common Stock underlying the Series D Preferred Stock and Warrants</u> ⁽⁷⁾
10.41	<u>Form of Securities Purchase Agreement dated October 1, 2025 relating to the sale of the Series E Preferred Stock and Warrants</u> ⁽²³⁾
10.42	<u>Form of Registration Rights Agreement dated as of October 1, 2025 relating to the resale of the shares of Common Stock underlying the Series E Preferred Stock and Warrants</u> ⁽²³⁾
10.43	<u>Master Research Services Agreement, dated October 1, 2022, by and between Proteomedix AG and Immunovia, AB</u> ⁽⁵⁾
10.44	<u>Collaboration Agreement, dated July 19, 2021, by and between Proteomedix AG and New Horizon Health Limited</u> ⁽⁵⁾
10.45	<u>Amendment No. 1, dated June 26, 2023, to Collaboration Agreement, dated July 19, 2021, by and between Proteomedix AG and New Horizon Health Limited</u> ⁽⁵⁾
10.46	<u>Form of Inducement Letter</u> ⁽¹⁰⁾
10.47	<u>License Agreement, dated March 27, 2023, between Proteomedix and Laboratory Corporation of America Holdings.</u> ^{(2)†#}
10.48	<u>First Amendment to License Agreement between Proteomedix AG and Laboratory Corporation of America Holdings, dated December 6, 2025</u> ^{†(27)}
10.49	<u>License Agreement, dated September 17, 2025, by and between Immunovia AB and Proteomedix AG</u> ⁽²²⁾
14	<u>Code of Ethics.</u> ⁽²⁵⁾
19	<u>Insider Trading Policy, adopted August 7, 2023</u> ⁽²⁾
21	<u>List of Subsidiaries.</u> *
23.1	<u>Consent of Malone Bailey</u> *
31.1	<u>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.</u> *
32.1	<u>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.</u> **
97	<u>Policy Related to Recovery of Erroneously Awarded Compensation, adopted January 17, 2024.</u> ⁽²⁾
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 Annual Report on Form 10-K, filed with the SEC on April 11, 2024.
 - (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 Current Report on Form 8-K, filed with the SEC on June 11, 2025.
 - (5) Incorporated by reference to the Company’s Registration Statement on Form S-1/A filed with the SEC on June 5, 2024.
 - (6) Incorporated by reference to the Company’s Quarterly Report on Form 10-Q, filed with the SEC on June 12, 2025.
 - (7) Incorporated by reference to the Company’s Current Report on Form 8-K, filed with the SEC on September 26, 2025.
 - (8) Incorporated by reference to the Company’s Registration Statement on Form S-1/A, filed with the SEC on January 6, 2022.
 - (9) Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on October 3, 2025.
 - (10) Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on July 11, 2024.
 - (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 September 20, 2024.
 - (13) Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on October 10, 2023.
 - (14) Incorporated by reference to the Company’s Current Report on Form 8-K, filed with the SEC on September 24, 2024.
 - (15) Incorporated by reference to the Company’s Current Report on Form 8-K, filed with the SEC on October 3, 2024.
 - (16) Incorporated by reference to the Company’s Current Report on Form 8-K, filed with the SEC on February 18, 2025.
 - (17) Incorporated by reference to the Company’s Current Report on Form 8-K, filed with the SEC on May 22, 2025.
 - (18) Incorporated by reference to the Company’s Current Report on Form 8-K, filed with the SEC on July 16, 2025.
 - (19) Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on December 21, 2023.
 - (20) Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on August 12, 2025.
 - (21) Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on September 4, 2025.
 - (22) Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on September 22, 2025.
 - (23) Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on October 3, 2025.
 - (24) Incorporated by reference to the Company’s Registration Statement on Form S-1/A filed with the SEC on January 6, 2022.
 - (25) Incorporated by reference to the Company’s Registration Statement on Form S-1/A, filed with the SEC on November 5, 2021.
 - (26) Incorporated by reference to the Company’s Current Report on Form 8-K filed with the SEC on October 3, 2023.
 - (27) Incorporated by reference to the Company’s Current Report on Form 8-K, filed with the SEC on December 10, 2025.
 - (28) Incorporated by reference to the Company’s Current Report on Form 8-K, filed with the SEC on February 12, 2026.

Item 16. Form 10-K Summary.

We have elected not to include a summary pursuant to this Item 16.

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: March 13, 2026

By: /s/ Karina Fedasz

Karina Fedasz
Interim Chief Executive Officer and Interim Chief
Financial 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 March 13, 2026.

Signature	Title
<u>/s/ Karina Fedasz</u> Karina Fedasz	Interim Chief Executive Officer and Interim Chief Financial Officer
<u>/s/ Andrew Oakley</u> Andrew Oakley	Non-Executive Chairman of the Board
<u>/s/ Thomas Meier</u> Thomas Meier	Director
<u>/s/ Timothy Ramdeen</u> Timothy Ramdeen	Director
<u>/s/ Sarah Romano</u> Sarah Romano	Director