UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended: **December 31, 2024**

OR

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

For the transition period from _____ to _____

Commission file number: 001-34673

CORMEDIX INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**20-5894890**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
300 Connell Drive, Suite 4200, Berkeley Heights, NJ	**07922**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(908) 517-9500**

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

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, $0.001 Par Value	CRMD	Nasdaq Global Market

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 Section 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 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 news 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. 7262(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 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 ☒

The aggregate market value of the registrant's voting common equity held by non-affiliates of the registrant, based upon the closing price of the registrant's common stock on the last business day of the registrant's most recently completed second fiscal quarter was approximately $236.8 million.

The number of outstanding shares of the registrant's common stock was 65,181,771 as of March 23, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive Proxy Statement to be issued in conjunction with the registrant's 2025 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Annual Report. Except as expressly incorporated by reference, the registrant's Proxy Statement shall not be deemed to be a part of this Annual Report on Form 10-K.

CORMEDIX INC.
2024 Form 10-K Annual Report
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Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are subject to risks and uncertainties. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "will," "plan," "project," "seek," "should," "target," "will," "would," and similar expressions or variations intended to identify forward-looking statements. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or CorMedix's prospects should be considered forward-looking statements. Readers are cautioned that actual results may differ materially from projections or estimates due to a variety of important factors, and readers are directed to the Risk Factors identified in the Risk Factor Summary and section titled "Item 1A. Risk Factors" of this Annual Report on Form 10-K and in CorMedix's other filings with the Securities and Exchange Commission (the "SEC") copies of which are available free of charge at the SEC's website at www.sec.gov or upon request from CorMedix. CorMedix may not actually achieve the goals or plans described in its forward-looking statements, and such forward-looking statements speak only as of the date of this Annual Report on Form 10-K. Investors should not place undue reliance on these statements. CorMedix assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

PART I

Item 1. Business

Overview

CorMedix Inc. (collectively, with our wholly owned subsidiaries, referred to herein as "we," "us," "our" or the "Company") is a biopharmaceutical company focused on developing and commercializing therapeutic products for life-threatening diseases and conditions.

Our primary focus is commercializing our lead product, DefenCath® (taurolidine and heparin), in the U.S. The name DefenCath is the U.S. proprietary name approved by the U.S. Food and Drug Administration ("FDA"). CorMedix launched the product commercially in April 2024 in the inpatient setting and July 2024 in the outpatient hemodialysis setting.

DefenCath is an FDA approved antimicrobial catheter lock solution ("CLS") (a formulation of taurolidine 13.5 mg/mL, and heparin 1000 USP Units/mL) indicated to reduce the incidence of catheter-related bloodstream infections ("CRBSI") in adult patients with kidney failure receiving chronic hemodialysis through a central venous catheter ("CVC"). It is indicated for use in a limited and specific population of patients. CRBSIs, a clinically confirmed subset of the epidemiological surveillance term, central line associated bloodstream infection ("CLABSI"), can lead to treatment delays and increased costs to the healthcare system when they occur due to extended and often repeat hospitalizations, need for IV antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the CVC, related treatment costs, as well as increased mortality. We believe DefenCath can address a significant unmet medical need.

Following the submission of a duplicate New Technology Add-On Payment ("NTAP") application to Centers for Medicare and Medicaid Services ("CMS"), CMS issued the Inpatient Prospective Payment System ("IPPS") 2024 proposed rule that includes a NTAP per hospital stay for DefenCath. This NTAP represents reimbursement to inpatient facilities of 75% of the wholesaler acquisition cost ("WAC") price per 3 mL vial, and an average utilization of 19.5 vials per hospital stay. The final IPPS rule amended as of October 1, 2024 to reflect the current WAC of $249.99 per 3ml vial resulting in a potential maximum NTAP of $3,656.10.

On November 15, 2023, we announced that the FDA approved the new drug application ("NDA") for DefenCath to reduce the incidence of CRBSI in adult patients with kidney failure receiving chronic hemodialysis through a CVC. DefenCath is the first and only FDA-approved antimicrobial CLS in the U.S. and was shown to reduce the risk of CRBSI by up to 71% in a Phase 3 clinical study. As a result of the November 2023 FDA approval, CorMedix launched the product commercially in April 2024 in the inpatient setting and July 2024 in the outpatient hemodialysis setting.

DefenCath is listed in the Orange Book as having new chemical entity ("NCE") exclusivity (5 years) expiring on November 15, 2028, and the Generating Antibiotic Incentives Now ("GAIN") exclusivity extension of the NCE exclusivity (an additional 5 years) expiring on November 15, 2033. The GAIN exclusivity extension of 5 years is the result of the January 2015 designation of DefenCath as a Qualified Infectious Disease Product ("QIDP").

On January 25, 2024, CMS determined that DefenCath should be classified as a renal dialysis service that is subject to the Medicare end-stage renal disease prospective payment system ("ESRD PPS"). The ESRD PPS provides bundled payment for renal dialysis services, but also affords a transitional drug add-on payment adjustment, or TDAPA, which provides temporary, additional payments for certain new drugs and biologicals. We submitted an application for TDAPA on January 26, 2024, and received confirmation that our application was approved on April 18, 2024 for a July 1, 2024 implementation. We also submitted a Healthcare Common Procedure Coding System ("HCPCS") application for a J-code to CMS on December 8, 2023, for DefenCath, which is relevant to billing and the TDAPA application. The HCPCS J-code for DefenCath was published by CMS on April 2, 2024. TDAPA reimbursement is calculated based on 100 percent ASP (or 100 percent of wholesale acquisition price or manufacturers' list price, respectively, if such data is unavailable). TDAPA and post-TDAPA add-on payment adjustments for DefenCath apply for five years (with such add-on payments applying to all ESRD PPS payments for years three through five). CMS confirmed a July 1, 2024 implementation date for HCPCS and TDAPA.

We announced on June 6, 2024 that CMS determined that DefenCath qualified for pass-through status under the hospital Out-Patient Prospective Payment System ("OPPS"). Pass-through status provides for separate payment under Medicare Part B for the utilization of DefenCath in the outpatient ambulatory setting for a period of at least two years, and up to a maximum of three years. While vascular access for hemodialysis can be initiated in an inpatient setting, ambulatory surgical centers or vascular access centers offer a less-invasive, outpatient-based alternative for patients. We estimate that up to 100,000 hemodialysis-central venous catheter ("HD-CVC") placements occur each year, and pass-through status offers providers a separate reimbursement mechanism in this setting of care administration of DefenCath.

Subsequent to the launch of DefenCath in April 2024, we announced U.S.-based multi-year commercial supply agreements consisting of a large and several mid-sized dialysis organizations. Each provider has customized an implementation plan to provide access to patients based on a variety of clinical and other factors. We believe the currently contracted customer base represents roughly 60% of the outpatient dialysis centers in the U.S., in terms of the total addressable patient market.

Market Opportunity

Central Venous Catheters ("CVC") or 'central lines' are an important and frequently used method for accessing the vasculature for hemodialysis (a form of dialysis where the patient's blood is circulated through a dialysis filter), administering chemotherapy and basic fluids in cancer patients and for cancer chemotherapy, administering long term antibiotic therapy, and administering total parenteral nutrition (complete or partial dietary support via intravenous nutrients).

Bloodstream infections resulting from the use of central venous catheters known as CLABSIs can result in significant morbidity and increased rates of hospital admissions, readmissions and mortality. One of the major and common risk factors for all patients requiring CVCs is the risk of acquiring a CLBSI and the clinical complications associated with them. The total annual cost for treating outpatient derived CRBSI episodes and their related complications in the U.S. is up to $2.3 billion, with approximately 250,000 CRBSI episodes per year (Becker's Hospital Review).

According to the 2024 United States Renal Disease System, reporting data from 2022, there were nearly 816,000 End-Stage-Renal-Disease, or ESRD, patients on permanent hemodialysis in the U.S. and nearly 25% of these utilized a CVC for vascular access. Of the total population, approximately 131,000 hemodialysis patients were new patients diagnosed with ESRD during the year and nearly 85% of those were receiving dialysis through a CVC. Patients are typically treated in various care settings including inpatient hospitals and outpatient dialysis clinics. Kidney failure patients can include both those affected by Acute Kidney Injury, or AKI and Chronic Kidney Disease, or CKD, populations that progress into dialysis. Kidney failure patients that present in the hospital have an average length of stay of 13.3 days and additionally high 30-day readmission rates both for same diagnosis and all-cause with the all-cause readmissions being higher.

The two primary causes of CLABSI are the external introduction of pathogens to the catheter site and the internal proliferation of pathogens within the catheter lumens. Intralumen infections are often caused by the formation of biofilm. Biofilm build up is the pathogenesis of both infections and thrombotic complications in central venous catheters. Prevention of CRBSI and inflammatory complications requires both removal of pathogens from the internal surface of the catheter to prevent the systemic dissemination of organisms contained within the biofilm as well as an anticoagulant to retain blood flow during dialysis. Biofilm forms when bacteria adhere to surfaces in aqueous environments and begin to excrete a slimy, glue-like substance that can anchor them to various types of materials, including intravenous catheters. The presence of biofilm has many adverse effects, including the ability to release bacteria into the blood stream. The current standard of catheter care is to instill a heparin lock solution at a concentration of 1000 u/mL into each catheter lumen immediately following treatment, in order to prevent clotting between dialysis treatments. However, a heparin lock solution provides no protection from the risk of infection.

Other than DefenCath, there are no pharmacologic drug products approved in the U.S. for the prevention or reduction of CRBSIs in CVCs. We believe there is a significant need for reduction or prevention of CRBSIs in the hemodialysis patient population as well as for other patient populations utilizing central venous catheters such as total parenteral nutrition and oncology/chemotherapy.

DefenCath, our FDA-approved product, is a non-antibiotic, broad-spectrum antimicrobial and anticoagulant combination that is active against common microbes including antibiotic-resistant strains of certain pathogens whose mechanism of action inhibits the first steps in biofilm formation. We believe that using DefenCath as an antimicrobial catheter-lock solution will significantly reduce the incidence of life-threatening catheter-related blood stream infections, thus reducing the need for systemic antibiotics while prolonging catheter function. We are unaware of any drug products other than DefenCath approved by the FDA with an indication for use as a catheter lock solution.

Patents

We announced on May 1, 2023 that the United States Patent and Trademark Office ("USPTO") allowed our patent application directed to a locking solution composition for treating and reducing infection and flow reduction in central venous catheters. This application was granted on August 29, 2023 as U.S. Patent No. 11,738,120. Our newly granted U.S. Patent reflects the unique and proprietary formulation of our product, DefenCath, for which we received FDA approval on November 15, 2023. This patent supplements the coverage of our existing licensed U.S. Patent No. 7,696,182, and has the potential to provide an additional layer of patent protection for DefenCath through 2042.

We currently believe the patent that is most material to our business is U.S. Patent No. 11,738,120 (expiring April 15, 2042).

License Agreement with ND Partners, LLP

In 2008, we entered into a License and Assignment Agreement (the "ND License Agreement") with ND Partners, LLP ("NDP"). Pursuant to the ND License Agreement, NDP granted us exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the "NDP Technology"). As consideration in part for the rights to the NDP Technology, upon execution of the ND License Agreement, we paid NDP an initial licensing fee of $325,000 and granted NDP a 5% equity interest, consisting of 7,996 shares of our common stock.

Under the ND License Agreement, we are required to make cash and equity payments to NDP upon the achievement of certain milestones. Under the ND License Agreement, the maximum aggregate amount of cash payments due upon achievement of applicable milestones was $2,500,000, with the balance being $2,000,000 as of December 31, 2024. The outstanding sales milestones were met in the third quarter of 2024 and, accordingly, we anticipate payment will be due in accordance with the agreement terms at the end of the twelve month period post attainment.

Beginning in the second quarter of 2024, the license intangible asset is amortized as cost of goods sold over its estimated economic life of approximately 10 years. The amortization start period correlates with the product launch of DefenCath and the first period in which revenue will be recognized. Amortization expense of approximately $52,000 and $156,000 was recorded during the three and twelve month periods ending December 31, 2024, respectively.

The ND License Agreement will expire on a country-by-country basis upon the earlier of (i) the expiration of the last patent claim under the ND License Agreement in a given country, or (ii) the payment of all milestone payments. Upon the expiration of the ND License Agreement in each country, we will have an irrevocable, perpetual, fully paid-up, royalty-free exclusive license to the NDP Technology in such country. The ND License Agreement also may be terminated by NDP if we materially breaches or defaults under the ND License Agreement and that breach is not cured within 60 days following the delivery of written notice to us, or by us on a country-by-country basis upon 60 days prior written notice in the event our Board determines not to proceed with the development of the NDP Technology. If the ND License Agreement is terminated by either party, our rights to the NDP Technology will revert back to NDP.

Competitive Landscape

The drug and medical device industries are highly competitive and subject to rapid and significant technological change. DefenCath's potential competitors could include large as well as specialty pharmaceutical and biotechnology companies and large and specialty medical device companies. Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly more experience in the development and commercialization of drugs and medical devices. Further, the development of new treatment methods could render DefenCath non-competitive or obsolete.

We believe that the key competitive factors that will affect the commercial success of DefenCath are established efficacy and safety, as well as pricing and reimbursement mechanisms across the continuum of care. Given that DefenCath is the only approved antimicrobial catheter lock solution in the U.S., we believe that with adequate reimbursement there is an opportunity for DefenCath to become the new standard of care as a CLS in the U.S. market. We are not aware of any potentially competitive CLS which are approved or under development by other companies in the U.S. As a means to reduce infections, some dialysis providers are using anti-infective infused catheter caps and/or compounded unapproved antibiotic catheter lock solutions.

Customers

We expect sales of DefenCath to generate substantially all of our product revenues for the foreseeable future. Sales to one customer accounted for 86% of our total revenue for the year ended December 31, 2024, and we had two customers that accounted for 87% and 12% of our accounts receivable, respectively, for the year ended December 31, 2024.

Pricing and Reimbursement

Sales of DefenCath and any future product lines will depend, in part, on the extent to which such products will be covered by third-party payors, such as Medicare, Medicaid, and other federal and state government programs, managed care entities, commercial insurers, and other organizations, as well as the level of reimbursement such third-party payors provide for DefenCath and any future product lines. It is essential to obtain third-party payor coverage policies and adequate payment in order to continue to successfully commercialize DefenCath. We expect to sell DefenCath primarily to outpatient dialysis clinics and inpatient hospitals.

Inpatient Reimbursement

For Medicare, inpatient acute-care hospitals are paid under the inpatient prospective payment system (referred to herein as the "IPPS"). The IPPS pays a flat rate based on the average charges across all hospitals for a specific diagnosis, regardless of whether that particular patient costs more or less. Under the IPPS, each case is categorized into a diagnosis-related group, or DRG, which is weighted and multiplied by a standardized amount (updated each year for inflation and other factors), to yield a fixed payment for that DRG and adjusted for hospital-specific factors (e.g., wages, teaching hospitals) to cover care furnished during the inpatient stay. Additional, temporary payment is available for new medical services and technologies called New Technology Add-on Payment, or NTAP, if certain criteria are met. There are three criteria required for new technologies to be eligible to receive NTAP:

1. Product must meet "newness" criteria;
2. Product must meet "substantial clinical improvement" over existing technologies; and
3. Product must meet certain cost thresholds.

CMS created several alternative NTAP approval pathways for certain devices that obtain breakthrough designation and drugs that obtain Qualified Infectious Disease Product, or QIDP, designation from the FDA. Under these alternative pathways, the new technology need only meet the cost criterion because CMS assumes that those products meet the newness and substantial clinical improvement criteria.

CMS has issued the IPPS 2024 proposed rule that includes a NTAP per hospital stay for DefenCath. This NTAP represents reimbursement to inpatient facilities of 75% of the WAC price per 3 mL vial, and an average utilization of 19.5 vials per hospital stay. The final IPPS rule was published in early August 2023 and subsequently amended as of October 1, 2024 to reflect the current WAC of $249.99 per 3ml vial.

NTAP is granted for a period of 2-3 years after the date of FDA approval. Although NTAP is intended to identify and ensure adequate payment for qualifying new technologies, it may have a limited effect depending on the DRG assignment after the NTAP period ends. With established reimbursement in the inpatient setting, we launched DefenCath in hospitals first while outpatient reimbursement became effective July 1, 2024.

Outpatient Reimbursement

As discussed above, in 2024 DefenCath was found to be subject to Medicare ESRD PPS, which provides bundled payment for renal dialysis services and affords a TDAPA, which provides temporary, additional payments for certain new drugs and biologicals. TDAPA reimbursement is calculated based on 100 percent ASP (or 100 percent of wholesale acquisition price or manufacturers' list price, respectively, if such data is unavailable). TDAPA and post-TDAPA add-on payment adjustments for DefenCath apply for five years (with such add-on payments applying to all ESRD PPS payments for years three through five). The HCPCS J-code for DefenCath was published by CMS on April 2, 2024. CMS confirmed a July 1, 2024 implementation date for HCPCS and TDAPA.

CMS also determined that DefenCath qualified for pass-through status under the hospital Out-Patient Prospective Payment System ("OPPS") in June 2024. Pass-through status provides for separate payment under Medicare Part B for the utilization of DefenCath in the outpatient ambulatory setting for a period of at least two years, and up to a maximum of three years. While vascular access for hemodialysis can be initiated in an inpatient setting, ambulatory surgical centers or vascular access centers offer a less-invasive, outpatient-based alternative for patients. We estimate that up to 100,000 HD-CVC placements occur each year, and pass-through status offers providers a separate reimbursement mechanism in this setting of care administration of DefenCath.

Manufacturing/Supply Chain

We do not own or operate any manufacturing facilities related to the production of our products. All our manufacturing processes currently are, and we expect them to continue to be, outsourced to third parties. We rely on third-party manufacturers to produce sufficient quantities of drug product for use both commercially and in clinical trials. We intend to continue this practice in the future.

We currently have one FDA approved source for each of our two key active pharmaceutical ingredients ("APIs") for DefenCath, taurolidine and heparin sodium, respectively. With regards to taurolidine, we have a drug master file ("DMF") filed with the FDA. There is a master commercial supply agreement between a third-party manufacturer and the Company which has been in place since August 2018. In addition, we are working with our existing manufacture to source sufficient quantities of taurolidine API to cover at least 24 months of potential future demand. With respect to heparin sodium API, we have identified an alternate third-party supplier and may qualify such supplier under the DefenCath NDA over the next twelve months.

We received FDA approval of DefenCath with finished dosage production from our European based contract manufacturing organization ("CMO") Rovi Pharma Industrial Services. We believe this CMO has adequate capacity to produce the volumes needed to meet near-term projected demand for the commercial launch of DefenCath. We have also qualified Siegfried Hameln as an alternate finished dosage manufacturing site.

We note that CMOs and our API suppliers are subject to FDA oversight and inspection regarding compliance with Current Good Manufacturing Practices ("cGMP"), and if deemed non-compliant with cGMP by FDA, we could face shortages or risk with respect to producing sufficient quantities of drug product or drug substance.

Indications

We may pursue additional indications for DefenCath use as a CLS in populations with unmet medical needs that may also represent potentially significant market opportunities. While we are continuing to assess these areas, potential future indications may include use as a CLS to reduce CRBSIs in total parenteral nutrition patients using a central venous catheter and in certain oncology patients using a central venous catheter.

In June 2024, we announced that the FDA provided feedback to our request to discuss development plans for additional indications for DefenCath. In response to these comments, we created and submitted three clinical protocols specifically, the post-marketing requirement of a pediatric hemodialysis ("HD") study as an obligation under the Pediatric Research Equity Act ("PREA"), a Phase 3 study protocol to reduce the risk of central-line associated bloodstream infections ("CLABSI") for adult patients receiving total parenteral nutrition ("TPN") through a CVC and Expanded Access Program ("EAP") to FDA that allows for pediatric and adult patients, utilizing a CVC for the treatment or maintenance of many serious illness, to access DefenCath to protect their central line from serious infection. We launched the EAP at the end of 2024 and expect to begin enrollment for the adult TPN and pediatric HD studies in the first half of 2025.

As part of the DefenCath approval letter, the FDA communicated the existence of a required pediatric assessment under the PREA. PREA requires sponsors to conduct pediatric studies for, among other things, NDAs for a new active ingredient, such as taurolidine in DefenCath, unless a waiver or deferral is obtained from the FDA. A deferral acknowledges that a pediatric assessment is required but permits the applicant to submit the pediatric assessment after the submission of an NDA. FDA deferred submission of the pediatric study for DefenCath because the product is ready for approval for use in adults and the pediatric study has not been completed. We are currently obligated to conduct the study as communicated in the NDA approval letter: an open-label, two-arm (DefenCath vs. standard of care) study to assess safety and time to CRBSI in subjects from birth to less than 18 years of age with kidney failure receiving hemodialysis via a central venous catheter. Because this is a required post-marketing study, we would be required to make annual reports to the FDA. Pediatric studies for an approved product conducted under PREA may qualify for pediatric exclusivity, which, if granted, provides an additional six months of exclusivity that attaches to the end of existing marketing exclusivity and patent periods for DefenCath. Depending on the timing of final report submission, DefenCath could potentially receive the additional 0.5 years of exclusivity associated with this pediatric study (a total marketing exclusivity period of 10.5 years). There are factors that could affect whether this exclusivity is received or the duration of exclusivity, and DefenCath may or may not ultimately be eligible for the additional 0.5 years of exclusivity associated with this pediatric study.

We may seek CMS reimbursement for DefenCath in other catheter indications beyond ESRD, such as oncology patients and total parenteral nutrition patients, including through (i) relevant hospital inpatient diagnosis-related groups ("DRGs"), (ii) additional NTAP payments, or (iii) outpatient ambulatory payment classifications, or APCs, and payment under these Medicare benefit categories is not guaranteed for these additional potential indications.

United States Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our products are extensively regulated by governmental authorities in the U.S. and other countries.

In the U.S., the FDA regulates drugs and medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the FDA's implementing regulations. If we fail to comply with the applicable U.S. requirements at any time during the product development process, clinical testing, and during the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution, among other actions. Any agency enforcement action and/or any related impact could have a material adverse effect on us.

Drug Approval Process

The research, development, and approval process in the U.S. and elsewhere is intensive and rigorous and generally takes many years to complete. The typical process required by the FDA before a therapeutic drug may be marketed in the U.S. includes:

- Pre-clinical laboratory and animal tests performed under the FDA's Good Laboratory Practices("GLP"), regulations;
- submission to the FDA of an investigational new drug application ("IND"), which must become effective before human clinical trials may commence;
- human clinical studies to evaluate the drug's safety and effectiveness for its intended uses;
- FDA review of whether the facility in which the drug is manufactured, processed, packaged, or held meets standards designed to assure the product's continued quality and compliance with cGMPs, and FDA review of clinical trial sites to determine whether the clinical trials were conducted in accordance with Good Clinical Practices ("GCPs"); and
- submission of a NDA, to the FDA, and approval of the application by the FDA to allow sales of the drug.

Clinical trial programs in humans generally follow a three-phase process. Typically, Phase 1 studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease. Phase 1 studies are conducted to determine the metabolic and pharmacological action of the product line in humans and the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In Phase 2, studies are generally conducted in larger groups of patients having the target disease or condition in order to validate clinical endpoints, and to obtain preliminary data on the effectiveness of the product line and optimal dosing. This phase also helps determine further the safety profile of the product line. In Phase 3, large-scale clinical trials are generally conducted in patients having the target disease or condition to provide sufficient data for the statistical proof of effectiveness and safety of the product line as required by United States and foreign regulatory agencies. Typically, two Phase 3 trials are required for marketing approval, though one such trial, plus confirmatory evidence, may be acceptable.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or post-approval.

The clinical trial process for a new compound can take ten years or more to complete. The FDA may prevent clinical trials from beginning or may place clinical trials on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. Trials may also be prevented from beginning or may be terminated by institutional review boards, or IRBs, who must review and approve all research involving human subjects and amendments thereto. The IRB must continue to oversee the clinical trial while it is being conducted. This includes the IRB receiving information concerning unanticipated problems involving risk to subjects. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market.

Following the completion of a clinical trial, the data are analyzed by the sponsoring company to determine whether the trial successfully demonstrated safety and effectiveness and whether a product approval application may be submitted. In the United States, if the product is regulated as a new drug, an NDA must be submitted and approved by the FDA before commercial marketing may begin. The NDA must include a substantial amount of data and other information concerning the safety and effectiveness of the compound from laboratory, animal, and human clinical testing, as well as data and information on manufacturing, product quality and stability, and proposed product labeling.

Once accepted for filing, the FDA's review of an application may involve review and recommendations by an independent FDA advisory committee. The FDA must refer applications for drugs that contain active ingredients, including any ester or salt of the active ingredients that have not previously been approved by the FDA to an advisory committee or provide in an action letter a summary for not referring it to an advisory committee. The FDA may also refer drugs to advisory committees when it is determined that an advisory committee's expertise would be beneficial to the regulatory decision-making process, including the evaluation of novel products and the use of new technology. An advisory committee is typically a panel that includes clinicians and other experts, which review, evaluate, and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter, or CRL. If a CRL is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval and describes all the specific deficiencies that the FDA identified in the NDA. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or pre-clinical testing in order for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes; or major, for example, requiring additional clinical trials. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy

the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a Risk Evaluation and Mitigation Strategy, or a REMS, or otherwise limit the scope of any approval.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Such deferred studies become required post-marketing studies upon approval of the product.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including Fast Track designation, priority review and breakthrough designation, that are intended to expedite or simplify the process for the development and FDA review of certain drug products that are intended for the treatment of serious or life-threatening diseases or conditions, and demonstrate the potential to address unmet medical needs or present a significant improvement over existing therapy. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if the product will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy, safety, or public health factors. If Fast Track designation is obtained, drug sponsors may be eligible for more frequent development meetings and correspondence with the FDA. In addition, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. A Fast Track product is also eligible to apply for accelerated approval and priority review.

Exclusivity

For approved drug products, market exclusivity provisions under the FDCA provide periods of exclusivity, which gives the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug.

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application in which the applicant, in part, relies on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics, and intended use, among other things, to a previously approved product. Limited changes must be pre-approved by the FDA via a suitability petition.

Five years of exclusivity are available to New Chemical Entities, or NCEs. A NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA submitted under Section 505 of the FDCA. An active moiety is the molecule or ion, excluding those appended portions of the molecule, that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent derivatives, such as a complex, chelate, or clathrate, of the molecule, responsible for the physiological or pharmacological action of the drug substance.

During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA application submitted by another company that contains the previously approved active moiety, except that an ANDA or 505(b)(2) that contains a certification that the patents listed by the NCE sponsor in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book, are invalid or will not be infringed by the manufacture, use, or sale of the drug product for which approval is sought, may be submitted one year before NCE exclusivity expires. Five-year exclusivity will also not delay the submission or approval of a 505(b)(1) NDA; however, an applicant submitting a 505(b)(1) NDA would be required to conduct or obtain a right of reference to all the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving NDAs or ANDAs for drugs containing the original active agent.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of exclusivity to the term of any existing exclusivity for the product, such as NCE exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the required time frames, whatever statutory or regulatory periods of exclusivity that cover the drug are extended by six months. For patent protection, pediatric exclusivity does not extend the term of the patent or the term a patent extension, but rather the period during which FDA cannot approve an ANDA or 505(b)(2) NDA that certifies to a patent listed in the Orange Book. Moreover, pediatric exclusivity attaches to all formulations, dosage forms, and indications for products with existing marketing exclusivity or patent life that contain the same active moiety as that which was studied.

The Orphan Drug Act also provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting fewer than 200,000 individuals annually in the United States, or affecting more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making the drug available in the United States will be recovered from sales in the United States. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan designation if there is a drug already approved by the FDA that is intended for the same indication and that is considered by the FDA to be the same drug as the already approved drug. This hypothesis must be demonstrated to obtain orphan drug exclusivity. If granted, prior to product approval, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers. In addition, if a product receives FDA approval for the indication for which it has orphan designation, the product is generally entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

For certain infectious disease products, the above discussed exclusivity periods may be further extended if the product is designated as a QIDP and receives GAIN Act exclusivity. A qualified infectious disease product, or QIDP, is an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or qualifying pathogens designated by the FDA that have the potential to pose a serious threat to public health. Subject to the specified statutory limitations, a drug that is designated as a QIDP and is approved for the use for which the QIDP designation was granted will receive a 5-year extension to any exclusivity for which the application qualifies upon approval. For example, if the FDA approves an NDA for a drug designated as a QIDP, the NCE exclusivity period is extended to ten years and the FDA may not accept applications for nine years. Moreover, if a product is designated as a QIDP and an orphan product, the orphan product exclusivity period is extended to twelve years. These extensions are in addition to any extension that an application may be entitled to under the pediatric exclusivity provisions. To receive a QIDP designation, the sponsor must request that the FDA designate the product as such prior to the submission of an NDA. This designation may not be withdrawn except if the FDA finds that the request for designation contained an untrue statement of material fact. QIDPs are also eligible for Fast Track status and priority review.

Post Approval Requirements

Significant legal and regulatory requirements also apply after FDA approval to market under an NDA. These include, among other things, requirements related to adverse event and other reporting, product tracking and tracing, suspect and illegitimate product investigations and notifications, product advertising and promotion and ongoing adherence to cGMPs, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. FDA can also require the completion of studies post-approval, such as required studies under PREA. The FDA also enforces the requirements of the Prescription Drug Marketing Act which, among other things, imposes various requirements in connection with the distribution of product samples to physicians. The FDA enforces these requirements through, among other ways, review of promotional material submissions, review of adverse events, review of annual reports, periodic announced and unannounced facility inspections.

The FDA also strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product's labeling and that differ from those tested and approved by the FDA. Pharmaceutical companies, however, are allowed to promote their drug products only for the approved indications and in accordance with the provisions of the approved label; off-label promotion is prohibited, as is false and misleading promotion. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including, but not limited to, criminal and civil penalties under the FDCA and the civil False Claims Act, or FCA, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment, and refusal of government contracts.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or Biologics License Application ("BLA"), including recall.

After approval of a drug is granted, FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, or imposition of additional post-market surveillance or clinical trials to assess new safety risks. Other potential consequences include, among other things: restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls; fines, warning letters or other enforcement-related letters or clinical holds on investigational or post-approval clinical trials; refusal by FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals; product seizure or detention, or refusal to permit the import or export of products; injunctions or the imposition of civil or criminal penalties; and consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

Moreover, individual states may have laws and regulations that we must comply with, such as laws and regulations concerning licensing, promotion, sampling, distribution, and reporting.

Healthcare Regulation

Federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, also govern our business. If we fail to comply with those laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. Such laws include, but are not

limited to: the federal Anti-Kickback Statute ("AKS"); federal pricing transparency and reporting laws and regulations; federal Physician Payments Sunshine Act and Open Payments requirements to track and report certain payments and other transfers of value; federal and state civil and criminal false claims laws, including the civil False Claims Act. Additionally, we are subject to state and local law equivalents of the above federal laws, which may be broader in scope and apply regardless of whether the payer is a governmental healthcare program. We may also be subject to certain state healthcare laws that may not have a federal parallel, such as pharmaceutical detailing and disclosure laws and requirements.

We are subject to federal government price reporting, such as those applicable to the Medicare Part B program, those under the Medicaid Drug Rebate Program ("MDRP"), the 340 Drug Pricing Program and individual state laws relating to pricing and sales and marketing practices. Manufacturers report Average Sales Price (ASP) data for Part B-covered drugs and biologicals and related items, services, supplies, and products that are paid as drugs or biologicals. We also participate in the MDRP and report ASP, Best Price and other metrics related to our participation in such program. We pay rebates to state Medicaid agencies based on those metrics on Medicaid beneficiary utilization of products. In addition, we are required to sell our covered outpatient drugs at or below the 340B Ceiling Price to 340B Covered Entities. We are also required to discount our products to authorized users of the Federal Supply Schedule, under which additional laws and requirements apply. Each of these programs require submission of pricing data and calculation of discounts and/or rebates pursuant to complex statutory formulas and regulatory guidance, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources. Failure to properly calculate prices, or to offer required discounts or rebates could subject us to substantial penalties including, but not limited to, potential False Claims Act liability. CMS continues to issue guidance and rulemaking governing our participation in the MDRP, and we cannot predict how future guidance or rules would affect our profitability (including the potential for increases in our overall Medicaid rebate liability and the obligation to charge greatly reduced prices to 340B Covered Entities).

In the U.S., the federal and state governments are considering proposals or have enacted legislative and regulatory changes to the healthcare system that could affect our ability to sell our products profitably. Among policy makers and payers in the U.S., there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

There has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing practices. In particular, there have been several recent U.S. Congressional inquiries, hearings and proposed and enacted federal legislation and rules, as well as executive orders and sub-regulatory guidance that may impact pricing for pharmaceutical products. These initiatives include, among others:

- efforts to reevaluate, reduce or limit the prices of drugs and make them more affordable for patients;
- implementation of additional data collection and transparency reporting regarding drug pricing, rebates, fees and other remuneration provided by drug manufacturers;
- revisions to rules associated with ESRD PPS Transitional Drug Add-on Payment Adjustment;
- potential revisions to rules associated with the calculation of average sales price;
- revisions to rules associated with the calculation of average manufacturer price and best price under Medicaid;
- changes to the MDRP, including through a May 2023 CMS-proposed rulemaking for this program, that could significantly increase manufacturer rebate liability;
- implementation of the inflation Reduction Act of 2022 (Inflation Reduction Act), including provisions that generally require manufacturers of Medicare Part B and Part D drugs to pay inflation rebates to the Medicare program if pricing metrics associated with their products increase faster than the rate of inflation;
- potential elimination of the AKS discount safe harbor protection for manufacturer rebate arrangements with Medicare Part D plan sponsors; and
- reevaluation of safe harbors under the AKS.

In addition, at the state level, legislatures have increasingly passed legislation and implemented regulations similar to those under consideration at the federal level, as well as laws designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, restrictions or other limitations on patient assistance, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing.

In addition, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business.

These laws and regulations may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Foreign Regulatory Requirements

We have not made any filings seeking approval for DefenCath outside of the United States. In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products.

Employees and Human Capital Resources

As of February 28, 2025 we employed approximately 64 full-time employees and one part-time employee, who work out of our corporate offices in Berkeley Heights, NJ or work remotely in various locations throughout the United States.. In December 2024, the company engaged Syneos Health Commercial Services, LLC to build and provide to the Company a dedicated inpatient field sales force that will exclusively promote DefenCath to hospitals and health systems. In light of this, the Company terminated a large percentage of its internal field sales team, which was expected to cover both inpatient and outpatient settings.

The Company also engaged WSI PBG, LLC, a subsidiary of Golden State Medical Supply, to promote DefenCath to healthcare providers in facilities operated by the Department of Veterans Affairs and other federal facilities. These individuals started in the field in early January 2025.

We invest in our workforce by offering competitive salaries and benefits. We endeavor to foster a strong sense of ownership by offering stock options under our stock incentive program. We also offer comprehensive and benefits for all eligible employees. We recognize and support the growth and development of our employees and we provide performance feedback and conduct employee goal and development discussions.

None of our employees are subject to a collective bargaining agreement. We emphasize organizational communication and consider our relationship with our employees to be strong.

Corporate Information

We were organized as a Delaware corporation on July 28, 2006 under the name “Picton Holding Company, Inc.” and we changed our corporate name to “CorMedix Inc.” on January 18, 2007. Our principal executive offices are located at 300 Connell Drive, Suite 4200, Berkeley Heights, New Jersey 07922.

Available Information

We maintain our website at www.cormedix.com. This Annual Report on Form 10-K and all of our filings under the Exchange Act, including copies of annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, are available free of charge through our website on the date we file those materials with, or furnish them to, the SEC. Such filings are also available to the public on the internet at the SEC’s website at www.sec.gov. The information contained on, or that can be accessed through, the websites referenced in this Annual Report on Form 10-K is not a part of, nor shall it be deemed to be, incorporated by reference into this filing or any of our other filings with the SEC. Further, the Company’s references to website URLs are intended to be inactive textual references only.

Item 1A. Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital

We have a history of operating losses, may incur additional operating losses in the future and may never achieve sustained profitability.

Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in the early stages of operation. We incurred net losses of approximately $17.9 million and $46.3 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of approximately $339.6 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trial and commercialization activities increase as we commercialize DefenCath and develop our other product lines. As a result, we may experience negative cash flow at times as we fund our operating expenses and capital expenditures. Our ability to generate revenue and maintain profitability will depend on, among other things, the following: successfully continued marketing and selling DefenCath in the U.S.; obtaining and/or maintaining reimbursement for DefenCath in appropriate settings of care; obtaining necessary regulatory approvals for our other products from the FDA and, if sought, international regulatory agencies; establishing additional manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities if we are unable to generate sufficient revenue from the commercialization of DefenCath in the U.S. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We may need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Any additional funds that we obtain may not be on terms favorable to us or our stockholders, may dilute our stockholders, and may require us to relinquish valuable rights.

To date, our commercial operations have not generated sufficient revenues to enable profitability on an annual basis. We estimate that we have sufficient cash to fund (i) operations for at least twelve months from the date of issuance of this Annual Report on Form 10-K and (ii) the ongoing commercial marketing, sale and promotion of DefenCath. These estimates are based upon the base case assumptions for market penetration, average selling price, research and development ("R&D") expense and commercial infrastructure cost.

We may need additional financing to the extent we are unable to generate sufficient revenue from the commercialization of DefenCath in the U.S. We can provide no assurances that any financing or strategic relationships will be available to us on acceptable terms, or at all. We expect to continue to use significant cash to fund our operations as we commercialize DefenCath in the U.S, pursue development of our other product lines and other business development activities, and potentially incur additional legal costs to defend our intellectual property.

To raise needed capital, we may sell additional equity or debt securities, obtain a bank credit facility, or enter into a corporate collaboration or licensing arrangement. The sale of additional debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in fixed obligations and could also result in covenants that would restrict our operations. Raising additional funds through collaboration or licensing arrangements with third parties may require us to relinquish valuable rights to our technologies, future revenue streams, research programs or product lines, or to grant licenses on terms that may not be favorable to us or our stockholders.

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may, as we have in the past, sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be further diluted by subsequent sales. New investors could gain rights superior to existing stockholders.

Risks Related to the Commercialization of DefenCath

We are highly dependent on the continued successful commercialization of our only approved product, DefenCath.

Our ability to generate operating revenue is dependent upon our continued successful commercialization of DefenCath in the U.S. DefenCath was approved by FDA on November 15, 2023, and is indicated to reduce the incidence of CRBSIs in adult patients with kidney failure receiving chronic hemodialysis through a CVC.

This drug is indicated for use in a limited and specific population of patients. We launched DefenCath commercially in April 2024 in the inpatient setting and in July 2024 in the outpatient hemodialysis setting. The safety and effectiveness of DefenCath have not been established for use in populations other than adult patients with kidney failure receiving chronic hemodialysis through a CVC.

We have not commercialized any product lines other than DefenCath. Continued successful commercialization of DefenCath is subject to many risks, including but not limited to:

- ongoing maintenance of regulatory approvals;
- emergence of superior or equivalent products;
- ongoing compliance with a broad range of post-marketing requirements including those related to labeling, promotion and advertising, manufacturing and quality, pharmacovigilance and adverse event reporting, commercial distribution and supply chain requirements, and pediatric post-marketing study requirements; and
- failure to achieve significant market acceptance adoption.

There is no guarantee that our continued commercialization efforts will be successful, or that we will be able to successfully launch and commercialize any other product lines that receive regulatory approval.

The continued successful commercialization of DefenCath will depend on maintaining coverage and reimbursement for use of DefenCath from third-party payors.

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs, such as Medicare, Medicaid and/or private health insurers. Further, significant uncertainty exists as to the reimbursement status of newly approved health care products. We currently sell DefenCath directly to hospitals and outpatient dialysis center operators, but also may expand its usage into oncology and total parenteral nutrition patients requiring catheters if those indications can be secured from the FDA. For any new indication of use, all new potential customers are healthcare providers who depend upon reimbursement by government and commercial insurance payors for dialysis and other treatments. Depending on the treatment setting of any new indication for use, we believe that DefenCath would be eligible for coverage under various reimbursement programs, such as the IPPS, including certain temporary payment adjustments (e.g., NTAP); however, payment under these payment systems could later be modified or decreased by future regulations. Further, CMS, which administers Medicare, and works with states to administer Medicaid, has adopted and will continue to adopt and/or amend rules governing reimbursement for specific treatments. We anticipate that insurers may increasingly demand that manufacturers demonstrate the cost effectiveness of their products as part of the reimbursement review and approval process. Healthcare reform proposals and medical cost containment proposals designed to target rising healthcare costs could be introduced in the U.S. Any measures affecting the reimbursement programs of governmental and private insurance payors, including any uncertainty in the medical community regarding their nature and effect on reimbursement programs, could have an adverse effect on purchasing decisions regarding DefenCath, as well as limit the price we may charge for DefenCath. The failure to obtain or maintain reimbursement coverage for DefenCath or any other products could materially harm our operations.

In anticipation that payers may increasingly demand that we demonstrate the cost effectiveness of DefenCath as part of the reimbursement review and approval process, we have submitted posters and abstracts to support our health economic analysis and continue to commission and develop health economic evaluations to support this review. We are pursuing opportunities to work with healthcare systems to demonstrate the clinical and economic effectiveness of DefenCath; however, our studies might not be sufficient to support coverage or reimbursement at levels that allow providers to use DefenCath.

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

We derive a large portion of our revenues from a few major customers. Sales to one customer accounted for 86% of our total revenue for the year ended December 31, 2024, and we had two customers that accounted for 87% and 12% of our accounts receivable, respectively, for the year ended December 31, 2024. These customers have no purchase commitments and may cancel, change or delay purchases with little or no notice or penalty. As a result of

these customer concentrations, our revenue could fluctuate materially and could be materially and disproportionately impacted by purchasing decisions of these customers or any other significant customer. These customers may decide to purchase less DefenCath from us than management anticipates, may alter purchasing patterns at any time with limited notice, or may decide not to continue to purchase DefenCath at all, any of which could cause our revenue to decline materially and materially harm our financial condition and results of operations. If we are unable to diversify and grow our customer base, we will continue to be susceptible to risks associated with customer concentration.

Risks Related to the Development and Commercialization of our Other Products

Successful development and commercialization of new product lines is uncertain.

Our development and commercialization of our product, and future product lines, is subject to the risks of failure and delay inherent in the development of new pharmaceutical products, including but not limited to the following:

- inability to produce positive data in pre-clinical and clinical trials;
- delays in product development, pre-clinical and clinical testing, or manufacturing;
- unplanned expenditures in product development, clinical testing, or manufacturing;
- challenges with securing the supply chain for raw materials;
- uncertainties relating to, or changes in FDA view of, the appropriate product approval pathway;
- failure to obtain treatment of a drug or application under expedited development and review programs or to obtain marketing exclusivities;
- failure to receive or maintain regulatory approvals;
- emergence of superior or equivalent products;
- inability to manufacture our product lines on a commercial scale on our own, or in collaboration with third parties;
- failure to comply with a broad range of post-marketing requirements including those related to labeling, promotion and advertising, manufacturing and quality, pharmacovigilance and adverse event reporting, commercial distribution and supply chain requirements, and drug sample distribution requirements; and
- failure to achieve market acceptance.

Because of these risks, our development efforts may not result in any future commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained or any approved products are not commercialized successfully, our business, financial condition, and results of operations could be materially harmed.

Final approval by regulatory authorities of our product lines for commercial use may be delayed, limited or denied, any of which could adversely affect our ability to generate operating revenues.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, export, marketing, promotion and distribution, and other possible activities relating to our product lines are subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions that may negatively impact the approval of one or more of our product lines or otherwise negatively impact our business. Compliance with such regulations may consume substantial financial and management resources and expose us and our collaborators to the potential for other adverse circumstances which could delay or prevent us from generating revenue from the commercialization of these drugs and cause us to incur significant additional costs.

We are not permitted to market a product line in the United States until the particular product line is approved for marketing by the FDA. Specific pre-clinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug ("IND") application, and clinical trials may commence only after the IND application becomes effective. To market a new drug

in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and pre-clinical data, as well as extensive information regarding chemistry, manufacturing and controls, to demonstrate the safety and effectiveness of the product line, and the FDA will also assess whether the manufacturing processes and facilities are suitable to support the application. Approval of an NDA may be delayed due to delays in FDA's review of the manufacturing facility, which may require an onsite inspection.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. Review time can be impacted by the quality of the information included in the application, FDA's internal resources such as the availability of reviewers, or requests from the FDA for additional information. Regulatory approval of an NDA is not guaranteed. The number and types of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the product line, the disease or condition that the product line is designed to target and the regulations applicable to any particular product line. Despite the time and expense exerted in pre-clinical and clinical studies, failure can occur at any stage, and we could encounter problems that delay our product line development or that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The FDA can delay, limit or deny approval of a product line for many reasons, and product line development programs may be delayed or may not be successful for many reasons including but not limited to, the following:

- The FDA or IRBs may not authorize us to commence, amend, or continue clinical studies;
- we may not be able to enroll a sufficient number of qualified patients for clinical trials in a timely manner or at all, patients may drop out of our clinical trials or be lost to follow-up at a higher rate than we anticipate, patients may not follow the clinical trial procedures, or the number of patients required for clinical trials may be larger than we anticipate;
- the FDA may not accept an NDA or other submission due to, among other reasons, the content or formatting of the submission;
- a product line may not be deemed adequately safe or effective for an intended use;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient;
- the FDA may require that we conduct additional pre-clinical or clinical studies, change our manufacturing process, or gather additional manufacturing information above what we currently have planned for;
- the FDA's interpretation and our interpretation of data from pre-clinical studies and clinical trials or chemistry, manufacturing and controls data may differ significantly;
- the FDA may not agree with our intended indications, the design of our clinical or pre-clinical studies, or there may be a flaw in the design that does not become apparent until the studies are well advanced;
- we may not be able to establish agreements with contractors or collaborators or they or we may fail to comply with applicable regulatory requirements, including those identified in other risk factors;
- the FDA may not accept aspects of our proposed labeling, or impose specific limitations in the labeling and require post-marking commitments or Phase 4 clinical trials before the labeling can be expanded;
- the FDA may determine that the manufacturing processes and facilities for our product line do not have sufficient good manufacturing practice ("GMP") controls in place to support approval; or
- the FDA may change its approval policies or adopt new regulations.

Our pre-clinical and clinical data, other information and procedures relating to a product line may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. Failure to conduct required post-approval studies, or confirm a clinical benefit, will allow the FDA to withdraw the drug from the market on an expedited basis. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our product lines. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop.

Additionally, other factors may serve to delay, limit or prevent the final approval by regulatory authorities of our product lines for commercial use, including, but not limited to:

- we or our licensees will need to conduct significant clinical testing and development work to demonstrate the quality, safety, and efficacy of these product lines before applications for marketing can be filed with the FDA, or with the regulatory authorities of other countries;
- development and testing of product formulation, including identification of suitable excipients, or chemical additives intended to facilitate delivery of our product lines;
- it may take us many years to complete the testing of our product lines, and failure can occur at any stage of this process; and
- negative or inconclusive results or adverse medical events during a clinical trial could cause us to delay or terminate our development efforts.

The successful development of any product lines is uncertain and, accordingly, we may never commercialize any of these product lines or generate significant revenue.

Risks Related to Healthcare Regulatory and Legal Compliance Matters

Our approved product, DefenCath, is, and our other product lines (if approved) will be, subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply in the United States. These include, among other things, requirements related to pharmacovigilance and adverse event and other reporting, supply chain security requirements, suspect and illegitimate product investigations and notifications, limitations on product advertising and promotion and on the distribution of product samples, required post-marketing studies, and ongoing adherence to cGMPs, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Establishing and maintaining systems and procedures for compliance with these requirements, and for training and monitoring personnel relative to their compliance, is expensive, time consuming, and an ongoing effort. Depending on the circumstances, failure to meet post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA, foreign and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA or a foreign regulatory body to modify or withdraw product approval. Failure to complete a PREA post-marketing study can result in a PREA non-compliance letter, which is publicly posted on FDA's website, and could result in the product being considered misbranded and subject to additional enforcement.

Current healthcare laws and regulations in the U.S. and future legislative or regulatory reforms to the U.S. healthcare system may affect our ability to commercialize DefenCath and future marketed products profitably.

Federal and state governments in the U.S. are considering legislative and regulatory proposals to change the U.S. healthcare system in ways that could affect our ability to commercialize DefenCath and future marketed products profitably. Similarly, among payors and other third-parties, there is significant interest in promoting such changes through legislation and regulation (in additional to through restrictions introduced via contracting and other methods). The life sciences industry and specifically the market for the sale, insurance coverage and distribution of pharmaceuticals has been a particular focus of these efforts and would likely be significantly affected by any major legislative or regulatory initiatives. In addition, there have been, and may in the future be, initiatives at both the federal and state level that could significantly modify the terms and scope of government-provided health insurance coverage, ranging from changes to some or all of the provisions of existing law, to establishing a single-payer, national health insurance system, to more limited "buy-in" options to existing public health insurance programs, any of which could have a significant impact on the healthcare industry. It is possible that additional legislative, executive and judicial activities in the future could have a material adverse impact on our business, financial condition and results of operations.

Healthcare policy changes, including reimbursement policies for drugs and medical devices, may have an adverse effect on our business, financial condition and results of operations.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payors to manage, contain or reduce the costs of health care through various means, such as capping prices, limiting price increases, reducing reimbursement, and requiring rebates. Market acceptance and sales of DefenCath or any other product lines that we develop, will depend on reimbursement policies and may be affected by health care reform measures in the U.S. and abroad. Government authorities and other third-party payors, such as private health insurers, decide which drugs they will pay for and establish reimbursement levels. While DefenCath has been approved for reimbursement in certain settings, we cannot be sure that reimbursement will be available for DefenCath by other payers. That uncertainty applies for any other product lines that we develop. Also, we cannot be sure that the amount of reimbursement that is available will not reduce the demand for, or the price of, our products. If reimbursement is not available by certain payors or is available only at limited levels, we may not be able to continue to successfully commercialize DefenCath or any other product lines that we develop.

In the U.S. there has been, and we expect there will continue to be, a number of legislative and regulatory changes to the health care system that could affect our ability to profit from our approved products. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any such government-adopted reform measures may adversely affect the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

In recent years, the U.S. Congress has sought to repeal and has significantly amended the Affordable Care Act. We expect that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Certain of these changes could impose limitations on the prices we will be able to charge for any products that are approved or the amounts of reimbursement available for these products from governmental agencies or other third-party payors or may increase the tax requirements for life sciences companies such as ours. Any such changes could have an adverse effect on our business, financial condition and results of operations.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent congressional inquiries and proposed and enacted bills by Congress and the states designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the U.S. government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. The U.S. government enacted the Inflation Reduction Act of 2022 (Inflation Reduction Act or IRA). The IRA brought sweeping changes to Medicare coverage and reimbursement for prescription drugs that could negatively impact us and other pharmaceutical manufacturers. Of note, beginning January 1, 2025, the eliminates the Medicare Part D coverage gap, and reduces a beneficiary's out-of-pocket maximum to $2,000. The existing coverage gap discount program for pharmaceutical manufacturers will be replaced by a new manufacturer discount program effective in 2025. Under the new program, manufacturers will provide a 10 percent discount off the negotiated price for applicable drugs (branded drugs and biologics manufactured by companies that have Part D discount agreements) after the deductible is satisfied through the catastrophic phase of the benefit. In the catastrophic phase, manufacturers will provide a 20 percent discount off negotiated price.

Any reduction in reimbursement rates under Medicare, Medicaid, or private insurers could negatively affect the pricing of our products. If we are not able to charge a sufficient amount for our products, then our margins and our profitability will be adversely affected.

Risks relating to data privacy could create additional liabilities for us.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information. Failure to comply with applicable privacy and data security laws and regulations could result in enforcement actions against us, including possible fines, imprisonment of company

officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide. There are numerous U.S. federal and state laws and regulations related to the privacy, data protection and security of personal information. At the federal level, regulations promulgated pursuant to HIPAA establish privacy and security standards for "covered entities" (group health plans and most healthcare providers) that limit the use and disclosure of individually identifiable health information those entities and their service providers receive or create ("protected health information"). Although we generally are not subject to the HIPAA privacy or security regulations, we do business with various entities (including clinical trial investigators) that are subject those regulations, and we have to expend resources to understand their obligations, adjust contractual terms in light of those obligations, or otherwise modify our business practices. Any amendments to HIPAA or other legislation amending or broadening the scope of HIPAA might require us to make substantial expenditures and would likely create additional liability risks.

The Federal Trade Commission ("FTC") has used its authority under Section 5 of the FTC Act, which prohibits unfair and deceptive practices affecting consumers, to bring numerous cases against companies for failing to protect the privacy or security of personal information in a manner that is reasonable and fully consistent with stated privacy policies, notices, or other representations. The FTC has considered codifying its requirements in regulations, but has not done so; as a result, the optimal means to mitigate the risk of such an action are uncertain.

In addition, many U.S. states in which we operate have laws that protect the privacy and security of personal information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, which complicates compliance efforts. For example, the California Confidentiality of Medical Information Act (the "CMIA") imposes stringent data privacy and security requirements and obligations with respect to the personal health information of California residents. The CMIA authorizes administrative fines and civil penalties of up to $25,000 for willful violations and up to $250,000 if the violation is for purposes of financial gain, as well as criminal fines. Other states, including California, Colorado, Connecticut, Delaware, Indiana, Iowa, Montana, New Hampshire, New Jersey, Oregon, Tennessee, Texas, Utah, and Virginia, have recently adopted broadly applicable privacy laws, though these laws typically exempt personal health information or entities that handle personal health information pursuant to laws like HIPAA. Both Nevada and Washington State have enacted laws specifically to protect the privacy of health information. Violations of the Washington State law can result in civil penalties of up to $7,500 per violation, up to $25,000 in treble damages at the sole discretion of the court, and injunctive relief. Consumers also may bring their own actions to recover (i) actual damages, (ii) treble damages; and (iii) attorney's fees. Violations of the Nevada law can result in up to $10,000 civil penalties per violation and injunctive relief.

New legislation may be enacted in other states. The effects on our business of this growing body of privacy and data protection laws are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

If we or our third-party service providers are unable to properly protect the privacy and security of personal information, or other confidential data we process in our business, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, we could face civil and criminal penalties. Enforcement activity by regulatory authorities in relation to privacy and cybersecurity matters can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. The threat of class action lawsuits based on data security breaches or alleged unfair practices further increases the risk to our business. We cannot be sure how these privacy laws and regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Clinical trials required for our product lines, including, but not limited to, new uses or formulations of DefenCath and the required DefenCath PREA study, may be expensive and time-consuming, and their outcome is uncertain.

In order to obtain FDA approval to market a new drug or device product, we must demonstrate proof of safety and effectiveness in humans. To meet FDA requirements, we are obligated to conduct "adequate and well-controlled" clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. The length of time may

vary substantially according to the type, complexity, novelty, and intended use of the product line, and often can be several years or more per trial. Delays associated with the development plans for our product lines may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

- inability to manufacture sufficient quantities of qualified materials under the FDA's cGMP requirements for use in clinical trials;
- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of patients;
- modification of clinical trial protocols;
- changes in regulatory requirements for clinical trials;
- lack of effectiveness during clinical trials;
- emergence of unforeseen safety issues;
- delays, suspension, or termination of clinical trials due to the IRB responsible for overseeing the study at a particular study site; and
- government or regulatory delays or "clinical holds" requiring suspension or termination of the trials.

Further, the results from early pre-clinical and clinical trials are not necessarily predictive of results to be obtained in later clinical trials. Accordingly, even if we obtain positive results from early pre-clinical or clinical trials, we may not achieve the same success in later clinical trials. Moreover, comparisons of results across different studies should be viewed with caution as such comparisons are limited by a number of factors, including differences in study designs and populations. Such comparisons also will not provide a sufficient basis for any comparative claims following product approval. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

Our clinical trials may be conducted in patients with serious or life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product is expected to be used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. We cannot ensure that safety issues will not arise with respect to our products in clinical development.

Clinical trials may not demonstrate statistically significant safety and effectiveness to obtain the requisite regulatory approvals for product lines. The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of our product lines. Such a failure could cause us to abandon a product line and could delay development of other product lines. Any delay in, or termination of, our clinical trials would delay the filing of any NDA or any Premarket Approval Application, or PMA, or De Novo application, with the FDA and, ultimately, our ability to commercialize our product lines and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operations.

Changes in funding for the FDA and other government agencies or future government shutdowns or disruptions could cause delays in the submission and regulatory review of marketing applications, including supplements, which could negatively impact our business or prospects.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept submission, applications, and the payment of user fees, and statutory, regulatory, and policy changes. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. The impact of the new administration, changes in federal policy priorities as well as global events, including terrorism, natural disasters and pandemics, or other health emergencies, may also cause disruptions in the normal functioning of the FDA or other government agencies.

Risks Related to Our Business and Industry

Healthcare institutions, physicians and patients may not accept and use our products.

Even though we have received FDA approval for DefenCath, healthcare institutions, physicians and patients may not accept and use our products. Acceptance and use of our products will depend upon a number of factors including the following:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product;
- prevalence of the disease to be treated or prevented;
- prevalence and severity of any side effects;
- cost-effectiveness of our product relative to current standard of care;
- availability of coverage and reimbursement from government and other third-party payers;
- timing of market introduction of our drugs and competitive drugs;
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any;
- potential or perceived advantages or disadvantages over alternative treatments;
- potential post-marketing commitments imposed by regulatory authorities, such as patient registries;
- price of our future products, both in absolute terms and relative to alternative treatments; and
- the effect of current and future healthcare laws and regulations on our product lines.

Because we expect sales of DefenCath to generate substantially all of our product revenues for the foreseeable future, the failure of DefenCath to find market acceptance would harm our business and would require us to seek additional financing.

Competition and technological change may make DefenCath, as well as our other product lines or indications, less attractive or obsolete.

We compete with established pharmaceutical and medical device companies that are pursuing other forms of prevention or treatment for the same or similar indications we are pursuing, and that have greater financial and other resources. Other companies may succeed in developing products earlier than we do, may develop products that are more effective than our product lines. Research and development by others may render our technology or product lines obsolete or noncompetitive, or result in processes, treatments or cures superior to any therapy we develop. We face competition from companies that develop competing technology internally, or acquire competing technology through acquisitions of other companies, or from universities and other research institutions. As these competitors develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of DefenCath or our other product lines if any of such other product lines receive marketing approval.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in compensation costs, our business may materially suffer.

We are highly dependent on the principal members of our management and scientific staff, specifically, Joseph Todisco, our Chief Executive Officer, Dr. Matthew David, our Executive Vice President and Chief Financial Officer, Beth Zelnick Kaufman, our Executive Vice President, Chief Legal and Compliance Officer and Corporate Secretary, Elizabeth Hurlburt, our Executive Vice President and Chief Clinical Strategy & Operations Officer and Erin Mistry, our Executive Vice President and Chief Commercial Officer. Our future success will depend in part on our ability to identify, hire, and retain current and additional personnel. We experience intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of our business. Because of this competition, our compensation costs may increase significantly. In addition, we have only limited ability to prevent former employees from competing with us.

We may not successfully manage our growth.

Our success will depend upon the expansion of our operations to continue to commercialize DefenCath and the effective management of any growth, which could place a significant strain on our management and our administrative, operational and financial resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. Additionally, if market demand exceeds our third-party manufacturer's ability to produce DefenCath, we may not be able to fulfill our customers orders in a timely manner or at all, which may have an adverse impact on our results of operations and reputation. If we are unable to manage our growth effectively, our business may be materially harmed.

If we are unable to effectively recruit, train, retain and equip our sales force, our ability to continue successfully commercialize DefenCath will be harmed.

None of the newly hired members of our sales force has promoted DefenCath before, and we are required to, and will continue to be required to, expend significant time and effort to train the sales force to be credible, persuasive, and compliant with applicable laws in marketing DefenCath for its approved indication. We must train the sales force to ensure that a consistent and appropriate message about DefenCath is being delivered to our customers. If we are unable to successfully train the sales force and provide them with appropriate materials, including medical and sales literature to help them educate and inform customers about the benefits and risks of DefenCath our efforts to continue to successfully commercialize DefenCath may be challenged.

We face the risk of product liability claims and the amount of insurance coverage we hold now or in the future may not be adequate to cover all liabilities we might incur.

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs. If the use of one or more of our or our collaborators' drugs or devices harms people, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products.

We currently carry product liability insurance. We cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage we hold may not be adequate to cover all liabilities we might incur. Our insurance covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions and exclusions. Our coverage also includes the sale of commercial products.

If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we may be exposed to significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our or our collaborators' products and do not have sufficient insurance coverage, our liability could exceed our total assets and our ability to pay the liability. A successful product liability claim or series of claims brought against us would decrease our cash and could cause the value of our capital stock to decrease.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third-party contractors may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local, as well as foreign, laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we and the third-party could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local, as well as foreign, laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

If we and our licensors do not obtain protection for and successfully defend our respective intellectual property rights, competitors may be able to take advantage of our research and development efforts to develop competing products.

Our commercial success will depend in part on obtaining further patent protection for our products, product lines and other technologies and successfully defending any patents that we currently have or will obtain against third-party challenges. The patents which we currently believe are most material to our business are as follows:

We may seek further patent protection for our compounds and methods of treating diseases. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following:

- patents that may be issued or licensed may be challenged, invalidated, or circumvented, or otherwise may not provide any competitive advantage;
- our competitors, many of which have substantially greater resources than we have and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets;
- there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

In addition, the USPTO and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated. Additionally, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that, should any patents issue, we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that should patents issue, they will be of commercial value to us, or that private parties, including competitors, will not successfully challenge our patents or circumvent our patent position in the U.S. or abroad.

The above-mentioned patents are exclusively licensed to or owned by us. To support our patent strategy, we have engaged in a review of patentability and certain freedom to operate issues, including performing certain searches. However, patentability and certain freedom to operate issues are inherently complex, and we cannot provide assurances that a relevant patent office and/or relevant court will agree with our conclusions regarding patentability issues or with our conclusions regarding freedom to operate issues, which can involve subtle issues of claim interpretation and/or claim liability. Furthermore, we may not be aware of all patents, published applications or published literature that may affect our business either by blocking our ability to commercialize our product lines, preventing the patentability of our product lines to us or our licensors, or covering the same or similar technologies that may invalidate our patents, limit the scope of our future patent claims or adversely affect our ability to market our product lines. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administration panel to affect the validity or enforceability of a claim. If a third-party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product lines. Such loss of patent protection could have a material adverse impact on our business. Additionally, since patent applications in the United States are maintained in secrecy until published or issued and as publication of discoveries in the scientific or patent literature often lag behind the actual discoveries, we cannot be certain that we were the first to make the inventions covered by the pending patent applications or issued patents referred to above or that we were the first to file patent applications for such inventions.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we take measures to protect this information by entering into confidentiality and inventions agreements with our employees, and some but not all of our scientific advisors, consultants, and collaborators, we cannot provide any assurances that these agreements will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure or dispute ownership if they are breached, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may also be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of our intellectual property may be greatly reduced. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

Intellectual property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights.

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may initiate or become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or we may become subject to proceedings initiated by our competitors or other third parties or the PTO or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. In addition, litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. If we are required to defend patent infringement actions brought by third parties, or if we sue to protect our own patent rights, we may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is not adverse to us. In addition, any legal action that seeks damages or an injunction to stop us from carrying on our commercial activities relating to the affected technologies could subject us to monetary liability and require us or any third-party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms or at all. Furthermore, to the extent that we or our consultants or research collaborators use intellectual property owned by others in work performed for us, disputes may also arise as to the rights in such intellectual property or in resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. See *Note 7, Commitments and Contingencies*, of this Annual Report on Form 10-K for additional detail on the Company's legal proceedings.

Risks Related to Dependence on Third Parties

We depend on third-party suppliers and contract manufacturers for the supply and manufacture of DefenCath and our product lines, as well as our APIs, which subjects us to potential cost increases and manufacturing delays that are not within our control.

We do not manufacture DefenCath or any of its raw materials or components ourselves, and we rely on third parties for our drug supplies both for clinical trials and for commercial quantities. All of our manufacturing processes currently are, and we expect them to continue to be, outsourced to third parties, some of which are single-source suppliers. We have made the strategic decision not to manufacture APIs for DefenCath or our other product lines, as these can be more economically supplied by third parties with particular expertise in this area. We have engaged contract facilities that are registered with the FDA, have a track record of large-scale API manufacture, and have already invested in capital and equipment.

We currently have one FDA approved source for each of our two key APIs for DefenCath, taurolidine and heparin sodium, respectively. With regards to taurolidine, we have a DMF filed with the FDA. There is a master commercial supply agreement between a third-party manufacturer and the Company in place from August 2018. In addition, we are working with our existing manufacture to source sufficient quantities of taurolidine API to cover at least 24 months of potential future demand. With respect to heparin sodium API, we have identified an alternate third-party supplier and may qualify such supplier under the DefenCath NDA over the next twelve months.

We received FDA approval of DefenCath with finished dosage production from our European based CMO Rovi Pharma Industrial Services. We believe this CMO has adequate capacity to produce the volumes needed to meet near-term projected demand for the commercial launch of DefenCath. We have also received FDA approval for finished dosage manufacturing of DefenCath from Siegfried Hameln.

We have no direct control over the manufacturing of DefenCath or our product lines. If the contract manufacturers are unable to produce sufficient quantities of DefenCath or our product lines, as a result of a lack of available materials, supply chain delays or otherwise, then we would need to identify and contract with additional or replacement third-party manufacturers. Additionally, if the manufacturers are not able to quickly scale production to algin with rapid changes in demand, our results of operations may be negatively impacted. If we are unable to identify suitable additional or replacement third-party manufacturers, or are only able to do so on unfavorable terms, our ability to commercialize DefenCath and our future profitability would be adversely affected.

In addition, we have no direct control over manufacturing costs of DefenCath or our product lines. If the cost of manufacturing increases, or if the cost of the materials used increases, these costs will be passed on to us, making the cost of clinical trials and commercializing DefenCath and our product lines more expensive. Increases in manufacturing costs could adversely affect our future profitability if we are unable to pass all of the increased costs along to our customers.

Our continuing reliance on third parties for manufacturing entails a number of additional risks, including reliance on third parties for legal and regulatory compliance and quality assurance, the possible breach of the manufacturing or supply agreement by such third parties, and the possible termination or nonrenewal of the agreement by such third parties at a time that is costly or inconvenient for the Company. Further, we, along with our contract manufacturers, are required to comply with FDA requirements for cGMPs, related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers may fail to comply with the applicable FDA regulatory requirements, which could result in delays to our product development programs, result in adverse regulatory actions against them or us, and prevent us from ultimately receiving product marketing approval. They also generally must pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our product lines and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other applicable government regulations and corresponding foreign standards. Not complying with FDA requirements could result in a product recall or prevent commercialization of our product lines and delay our business development activities. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter. Similarly, we, along with our contract manufacturers, are required to comply with all applicable healthcare laws and regulations, such as, without limitation, the federal AKS, the civil False Claims Act, and civil monetary penalty laws, as well as similar state laws. Violation of any such laws by a contract manufacturer could materially impact our operations.

We rely on third parties to conduct our clinical trials and pre-clinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our product lines may not advance in a timely manner or at all.

In the course of our pre-clinical and clinical trials, we may rely on third parties, including laboratories, investigators, and manufacturers, to perform critical services for us, many of which are required to be conducted consistent with regulations on Good Laboratory Practice ("GLP"). Study sites are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we may rely on these third parties to conduct our pre-clinical and clinical trials, we are responsible for ensuring that each of our trials is conducted in accordance with its investigational plan and protocol and that the integrity of the studies and resulting data is protected. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as Good Clinical Practices ("GCPs"), for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in such trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. These independent third parties may also have

relationships with other commercial entities, some of which may compete with us. In addition, if such third parties fail to perform their obligations in compliance with our protocols or the applicable regulatory requirements, our trials may not meet regulatory requirements or may need to be repeated, we may not receive marketing approvals, or we or such third parties may face regulatory enforcement. As a result of our dependence on third parties, we may face delays, failures or cost increases outside of our direct control. These risks also apply to the development activities of collaborators, and we do not control their research and development, clinical trial or regulatory activities.

Risks Related to our Common Stock

Our executive officers and directors may exercise stock options and sell shares of their stock, and these events could adversely affect our stock price.

Sales of our common stock and exercise of stock options by our executive officers and directors, or the perception that such events may occur, could adversely affect the market price of our common stock. Our executive officers and directors may sell stock in the future, either as part, or outside, of trading plans under Rule 10b5-1 under the Exchange Act.

Our common stock price has fluctuated considerably and is likely to remain volatile, in part due to the limited market for our common stock and you could lose all or a part of your investment.

From December 31, 2023, through December 31, 2024, the high and low sales prices for our common stock were $13.85 and $2.89, respectively.

The market price of our common stock has fluctuated considerably and may continue to fluctuate significantly in response to a number of factors, some of which are beyond our control.

In addition, the stock markets in general, and the stock of pharmaceutical and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In addition, changes in economic conditions in the U.S., the European Union or globally, particularly in the context of current global events, could impact upon our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or our results of operations. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

For these reasons and others, an investment in our securities is risky and you should invest only if you can withstand wide fluctuations in and a significant or complete loss of the value of your investment.

A significant number of additional shares of our common stock may be issued at a later date, and their sale could depress the market price of our common stock.

As of December 31, 2024, we had outstanding the following securities that are convertible into or exercisable for shares of our common stock:

- options to purchase an aggregate of 257,138 shares of our common stock issued to our officers, directors and non-employee consultants under our 2013 Stock Plan, with a weighted average exercise price of $8.39 per share;
- options to purchase an aggregate of 6,025,255 shares of our common stock issued to our officers, directors and non-employee consultants under our 2019 Stock Plan and Amended and Restated 2019 Stock Plan, with a weighted average exercise price of $4.29 per share;
- 291,494 shares of restricted stock units issuable into 291,494 shares of common stock;
- 2,000 shares of Series C-3 Preferred Stock, which are convertible into 4,000 shares of common stock;
- 89,623 shares of Series E Preferred Stock, which are convertible into 391,953 shares of common stock;

- 45,000 shares of Series G Preferred Stock, which are convertible into 2,502,064 shares of common stock; and
- 48,909 shares of common stock issuable for payment of deferred board compensation.

Additionally, there are 4,756,909 shares of common stock available for grants under the Amended and Restated 2019 Omnibus Stock Plan (adopted on October 13, 2022 and amended on November 21, 2024).

The possibility of the issuance of these shares, as well as the actual sale of such shares, could substantially reduce the market price for our common stock and impede our ability to obtain future financing.

Our internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause the trading price of our common stock to fall dramatically.

A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be satisfied. Internal control over financial reporting and disclosure controls and procedures are designed to give a reasonable assurance that they are effective to achieve their objectives. We cannot provide absolute assurance that all of our possible future control issues will be detected. These inherent limitations include the possibility that judgments in our decision making can be faulty, and that isolated breakdowns can occur because of simple human error or mistake. The design of our system of controls is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed absolutely in achieving our stated goals under all potential future or unforeseeable conditions. Because of the inherent limitations in a cost-effective control system, misstatements due to error could occur and not be detected. This and any future failures could cause investors to lose confidence in our reported financial information, which could have a negative impact on our financial condition and stock price.

In future periods, if the process required by Section 404 of the Sarbanes-Oxley Act reveals any material weaknesses or significant deficiencies, the correction of any such material weaknesses or significant deficiencies could require remedial measures which could be costly and time-consuming. In addition, in such a case, we may be unable to produce accurate financial statements on a timely basis. Any associated accounting restatement could create a significant strain on our internal resources and cause delays in our release of quarterly or annual financial results and the filing of related reports, increase our costs and cause management distraction. Any of the foregoing could cause investors to lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

We are a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to such companies could make our common stock less attractive to investors.

We are a "smaller reporting company", as defined in the Exchange Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements, including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), only being required to provide two years of audited financial statements in annual reports and reduced disclosure obligations regarding executive compensation in periodic reports and proxy statements.

We cannot predict if investors will 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.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Management and Strategy

The Company has processes in place for assessing, identifying, preventing, and managing material risks from cybersecurity threats, including related to the use of third-party service providers. In addition, the Company leverages the security and monitoring tools of third-party service providers. These processes are integrated into the Company's overall risk management program and systems, as overseen by the Board, primarily through the Audit Committee.

We maintain physical, technical and administrative safeguards to prevent and identify cybersecurity risks, and have implemented practices and procedures to address cybersecurity risks. To this end, among other things, we:

- provide annual mandatory training for our employees regarding cybersecurity threats as a means to equip them with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices;
- conduct regular simulation modules for all employees to enhance awareness and responsiveness to possible threats;
- conduct cybersecurity management and incident training for employees involved in our systems and processes that handle sensitive data; and
- carry cyber liability insurance that is intended to provide protection against the potential losses arising from a cybersecurity incident.

We are currently working with outside counsel to further develop a formal cybersecurity incident response plan as a part of our review of and improvements to the Company's cybersecurity policies.

While we are regularly exposed to malicious technology-related events and threats, none of these, either individually or in the aggregate of related occurrences, have materially affected the Company in the period covered by this Annual Report on Form 10-K. In determining materiality, cybersecurity incidents are reviewed not only for potential financial impacts, which could include potential legal and regulatory penalties, stolen assets or funds, system damage, forensic and remediation costs, lost revenue or litigation costs, but also the breadth and sensitivity of data exposure, data exfiltration, impacts on the ability to operate our business or provide our services and loss of investor confidence.

Governance

The Board executes its oversight responsibility for risk management both directly and through delegating oversight of certain risks to its committees. The Board has authorized the Audit Committee to oversee risks related to cybersecurity threats. Our Audit Committee has primary oversight responsibility for cybersecurity and information security risk management and controls. As part of its oversight function, the Audit Committee oversees the Company's risk assessment and risk management policies, including related to cybersecurity and the overall data protection program.

Our senior management is responsible for assessing and managing the Company's various exposures to risk, including those related to cybersecurity, on a day-to-day basis, including the identification of risks through an enterprise risk management framework and the creation of appropriate risk management programs and policies to address such risks. In particular, the Company's Senior Manager, IT, has 24 years of experience in enterprise IT and has primary responsibility for managing our cybersecurity program and efforts. Our finance and IT teams are responsible for the testing and audit of our information-technology related internal controls.

See *Item 1A, Risk Factors*, for additional information on the Company's cybersecurity risk profile, in particular the risk factor under the headings entitled "*Risks relating to data privacy could create additional liabilities for us*".

Item 2. Properties

In March 2020, we entered into a seven-year operating lease agreement for an office space at 300 Connell Drive, Berkeley Heights, New Jersey 07922. The lease agreement, with a monthly average cost of approximately $17,000, commenced on September 16, 2020.

Our subsidiary leases its offices in Fulda, Germany pursuant to a three-month lease agreement which commenced in June 2017, renewable every three months for a base monthly payment of €400. The lease was terminated in June 2024.

We believe that our existing facilities are adequate to meet our current needs.

Item 3. Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. For information regarding our legal proceedings, see Note 7, *Commitments and Contingencies*, included in the Financial Statements in this Annual Report on Form 10-K, which is incorporated into this item by reference.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market for Common Equity

Our common stock is listed on the Nasdaq Global Market under the symbol "CRMD."

Based upon information furnished by our transfer agent, at March 23, 2025, we had approximately 62 active holders of record of our common stock.

Dividend Policy

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Subject to applicable law and the Company's charter and bylaws and the terms of any preferred stock, the payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board of Directors.

Equity Compensation Plan Information

A table with information about our common stock that may be issued upon the exercise of options, warrants and rights under all our existing equity compensation plans is found in Item 12 of the report under the heading "Equity Compensation Plan Information."

Item 6. [RESERVED]

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

You should read the following discussion and analysis together with our audited consolidated financial statements and the accompanying notes contained elsewhere in this report. This discussion contains forward-looking statements, within the meaning of Section 27A of Securities Act, Section 21E of the Exchange Act, and the Private Securities Litigation Reform Act of 1995, including statements regarding *our expected financial condition, business and financing plans. These statements involve risks and uncertainties. Our actual results could differ materially from the results described in or implied by these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report on Form 10-K, particularly under the heading "Risk Factors."*

Overview

The Company is a biopharmaceutical company focused on developing and commercializing therapeutic products for life-threatening diseases and conditions.

Our primary focus is commercializing our lead product, DefenCath® (taurolidine and heparin), in the U.S. The name DefenCath is the U.S. proprietary name approved by the U.S. Food and Drug Administration ("FDA"). CorMedix launched the product commercially in April 2024 in the inpatient setting and July 2024 in the outpatient hemodialysis setting.

DefenCath is an FDA approved antimicrobial CLS (a formulation of taurolidine 13.5 mg/mL, and heparin 1000 USP Units/mL) indicated to reduce the incidence of CRBSI in adult patients with kidney failure receiving chronic hemodialysis through a CVC. It is indicated for use in a limited and specific population of patients. CRBSIs, a clinically confirmed subset of the epidemiological surveillance term, central line associated bloodstream infection ("CLABSI"), can lead to treatment delays and increased costs to the healthcare system when they occur due to extended and often repeat hospitalizations, need for IV antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the CVC, related treatment costs, as well as increased mortality. We believe DefenCath can address a significant unmet medical need.

Following the submission of a duplicate NTAP application to CMS, CMS issued the IPPS 2024 proposed rule that includes a NTAP per hospital stay for DefenCath. This NTAP represents reimbursement to inpatient facilities of 75% of the wholesaler acquisition cost ("WAC") price per 3 mL vial, and an average utilization of 19.5 vials per hospital stay. The final IPPS rule amended as of October 1, 2024 to reflect the current WAC of $249.99 per 3ml vial resulting in a potential maximum NTAP of $3,656.10.

On November 15, 2023, we announced that the FDA approved the NDA for DefenCath to reduce the incidence of CRBSI in adult patients with kidney failure receiving chronic hemodialysis through a CVC. DefenCath is the first and only FDA-approved antimicrobial CLS in the U.S. and was shown to reduce the risk of CRBSI by up to 71% in a Phase 3 clinical study. As a result of the November 2023 FDA approval, CorMedix launched the product commercially in April 2024 in the inpatient setting and July 2024 in the outpatient hemodialysis setting.

DefenCath is listed in the Orange Book as having NCE exclusivity (5 years) expiring on November 15, 2028, and the GAIN exclusivity extension of the NCE exclusivity (an additional 5 years) expiring on November 15, 2033. The GAIN exclusivity extension of 5 years is the result of the January 2015 designation of DefenCath as a QIDP.

On January 25, 2024, CMS determined that DefenCath should be classified as a renal dialysis service that is subject to the Medicare ESRD PPS. The ESRD PPS provides bundled payment for renal dialysis services, but also affords a transitional drug add-on payment adjustment, or TDAPA, which provides temporary, additional payments for certain new drugs and biologicals. We submitted an application for TDAPA on January 26, 2024, and received confirmation that our application was approved on April 18, 2024 for a July 1, 2024 implementation. We also submitted a HCPCS application for a J-code to CMS on December 8, 2023, for DefenCath, which is relevant to billing and the TDAPA application. The HCPCS J-code for DefenCath was published by CMS on April 2, 2024. TDAPA reimbursement is calculated based on 100 percent ASP (or 100 percent of wholesale acquisition price or manufacturers' list price, respectively, if such data is unavailable). TDAPA and post-TDAPA add-on payment adjustments for DefenCath apply for five years (with such add-on payments applying to all ESRD PPS payments for years three through five). CMS confirmed a July 1, 2024 implementation date for HCPCS and TDAPA.

We announced on June 6, 2024 that the CMS has determined that DefenCath qualified for pass-through status under the hospital Out-Patient Prospective Payment System ("OPPS"). Pass-through status provides for separate payment under Medicare Part B for the utilization of DefenCath in the outpatient ambulatory setting for a period of at least two years, and up to a maximum of three years. While vascular access for hemodialysis can be initiated in an inpatient setting, ambulatory surgical centers or vascular access centers offer a less-invasive, outpatient-based alternative for patients. We estimate that up to 100,000 HD-CVC placements occur each year, and pass-through status offers providers a separate reimbursement mechanism in this setting of care administration of DefenCath.

Subsequent to the launch of DefenCath in April 2024, we announced U.S.-based multi-year commercial supply agreements consisting of a large and several mid-sized dialysis organizations. Each provider has customized an implementation plan to provide access to patients based on a variety of clinical and other factors. We believe the currently contracted customer base represents roughly 60% of the outpatient dialysis centers in the U.S.

Financial Operations Overview

Revenue

Our ability to continue to generate revenue and become profitable depends on our ability to continue to successfully commercialize DefenCath and achieve gross profits from DefenCath sales that are greater than our ongoing operating costs. If we fail to continue to successfully commercialize DefenCath, or any other product lines we advance in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, could be adversely affected. Prior to the commercial launch of DefenCath, we have funded our operations primarily through equity financings.

Cost of Revenues

Cost of revenues include direct and indirect costs related to the manufacturing and distribution of DefenCath, including product cost, packaging services, freight, amortization of the license intangible asset and an allocation of overhead costs that are primarily fixed such as salaries, benefits and insurance.

Research and Development Expense

Research and development, or R&D, expense consists of: (i) internal costs associated with our development activities; (ii) payments we make to third-party contract research organizations, contract manufacturers, investigative sites, and consultants; (iii) technology and intellectual property license costs; (iv) manufacturing development costs; (v) personnel related expenses, including salaries, stock — based compensation expense, benefits, travel and related costs for the personnel involved in drug development; (vi) activities relating to regulatory filings and pre-clinical studies and clinical trials; and (vii) manufacturing-related costs, including previously expensed pre-NDA approval inventory amounting to approximately $6,400,000, through November 15, 2023. All R&D is expensed as incurred.

The process of conducting pre-clinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. The probability of success for each product line and clinical trial may be affected by a variety of factors, including, among others, the quality of the product line's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of future clinical stages of our product lines or when, or to what extent, we will generate revenues from the commercialization and sale of any of our future product lines.

Development timelines, probability of success and development costs vary widely. We are currently focused on the commercialization of DefenCath in the U.S.

Selling and Marketing Expense

Selling and marketing, or S&M, expense includes the cost of salaries and related costs for personnel in sales and marketing, brand building, advocacy, market research and consulting costs. Selling and marketing expenses are expensed as incurred.

General and Administrative Expense

General and administrative, or G&A, expenses consist principally of salaries and related costs for personnel in executive, finance and administrative functions including payroll taxes and health insurance, stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, insurance and professional fees for legal, patent review, consulting, and accounting services. General and administrative expenses are expensed as incurred.

Foreign Currency Exchange Transaction Gain (Loss)

Foreign currency exchange transaction gain (loss) is the result of re-measuring transactions denominated in a currency other than our functional currency and is reported in the consolidated statement of operations as a separate line item within other income (expense). The intercompany loans outstanding between our New Jersey-based company and our subsidiaries will not be repaid and the nature of the funding advanced was of a long-term investment nature. As such, unrealized foreign exchange movements related to long-term intercompany loans are recorded in other comprehensive income (loss).

Interest Income

Interest income consists of interest earned on our cash and cash equivalents and short-term investments.

Interest Expense

Interest expense consists of interest incurred on financing of expenditures.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following is a tabular presentation of our consolidated operating results for the years ended December 31, 2024 and 2023 *(in thousands)*:

	2024	2023	% of Change Increase (Decrease)
Revenue	$ 43,472	$ —	—
Cost of revenue	(3,190)	—	—
Gross profit	40,282	—	—
Operating Expenses:			
Research and development	(3,942)	(13,155)	(70)%
Selling and marketing	(28,737)	(18,115)	59%
General and administrative	(29,959)	(17,688)	69%
Total operating expenses	(62,638)	(48,958)	28%
Loss from operations	(22,356)	(48,958)	(54)%
Interest income	2,579	2,682	(4)%
Foreign exchange transaction loss	(31)	(29)	6%
Interest expense	(37)	(34)	6%
Other income	520	—	—
Total other income	3,031	2,619	16%
Loss before income taxes	(19,325)	(46,339)	(58)%
Tax benefit	1,395	—	—
Net loss	(17,930)	(46,339)	(61)%
Other comprehensive (loss) income	(3)	11	(130)%
Comprehensive loss	$ (17,933)	$ (46,328)	(61)%

Revenue. Revenue for the year ended December 31, 2024 was $43.5 million as compared to $0 for the same period in 2023. Revenue consists of sales of DefenCath, which was approved by the FDA in November 2023 and launched in the U.S in April 2024 (inpatient setting) and July 2024 (outpatient setting) and reflects the shipment of DefenCath to direct customers and specialty distributors, net of estimates for applicable variable consideration, which consists primarily of distribution service fees, prompt pay and other discounts, product returns, chargebacks, rebates and volume incentive rebates.

Cost of Revenue. Cost of revenue for the year ended December 31, 2024 was $3.2 million as compared to $0 for the same period in 2023. Cost of revenues include direct and indirect costs related to the manufacturing and distribution of DefenCath, including product cost, packaging services, freight, amortization of the license intangible asset and an allocation of overhead costs that are primarily fixed such as salaries, benefits and insurance. Direct costs of product sales during the year ended December 31, 2024 were minimal as DefenCath sold to date represented validation lot units previously expensed as R&D. This only marginally benefited the total gross margin in 2024 and the majority of validation batch product has been sold as of December 31, 2024. Indirect costs of approximately $3.0 million for the year ended December 31, 2024, represent the proportion of supply chain and quality personnel, benefits and insurance expenses representing excess capacity in the production of sellable product. As unit sales increase, a greater proportion of these costs will be capitalized as a component of inventory and expensed at the point-of-sale.

Research and Development Expense. R&D expense for the year ended December 31, 2024 was $3.9 million, a decrease of $9.2 million, or 70%, from $13.2 million for the same period in 2023. The decrease was driven by the approval of DefenCath. As a result of the transition to commercial operations, costs related to medical affairs and certain other personnel that supported R&D efforts prior to the FDA approval of DefenCath of approximately $6.9 million began supporting non research and development operations and have been recognized in cost of revenue or general and administrative expense during the year ended December 31, 2024 Also, in 2023, prior to FDA approval, there were $1.5 million of costs recognized in R&D related to the manufacturing of DefenCath validation batches. These types of costs are now capitalized in inventory as DefenCath is a commercialized product.

Selling and Marketing Expense. S&M expense was $28.7 million for the year ended December 31, 2024, an increase of $10.6 million, or 59%, from $18.1 million for the same period in 2023. The increase was due primarily to increased marketing efforts and new personnel hired in late 2023 or throughout 2024, inclusive of our sales force and support for the commercial launch of DefenCath during 2024. Subsequent to December 31, 2024, we severed our internal sales force, future costs associated with the Syneos sales force are expected to be similar to those recognized internally in 2024.

General and Administrative Expense. G&A expense for the year ended December 31, 2024 was $30.0 million, an increase of $12.3 million, or 69%, from $17.7 million for the same period in 2023. The increase was driven by the approval of DefenCath. As a result of the transition to commercial operations, certain medical affairs, other personnel and consulting expenses of approximately $6.0 million previously classified in R&D are included in G&A expense during the year ended December 31, 2024. Additional G&A personnel were also hired throughout 2024 in anticipation of and to support commercial operations, representing an increases of $2.8 million as well as increases in legal and compliance of $1.7 million and consulting fees of $0.9 million.

Interest Income. Interest income for the year ended December 31, 2024 was $2.6 million, a decrease of $0.1 million, or 4%, from $2.7 million for the same period in 2023, due to lower short-term investments during this period as compared to the same period last year.

Foreign Exchange Transaction Income (Loss). Foreign exchange transaction income (losses) for the years ended December 31, 2024 and 2023 were due to the re-measuring of transactions denominated in a currency other than our functional currency. Balances and changes were immaterial for all periods presented.

Other Income. Other income relates to a settlement with a previously utilized vendor, occurring during the year ended December 31, 2024.

Interest Expense. Interest expense pertains to certain liabilities we chose to finance. Balances and changes were immaterial for all periods presented.

Tax Benefit. Tax benefit for the year ended December 31, 2024 was $1.4 million, due to the sale of our unused NJ State net operating losses for fiscal year 2023, which were sold in fiscal year 2024, through the NJEDA Program. There was no tax benefit from the sale of unused net operating losses for fiscal year 2023.

Other Comprehensive (Loss) Income. Unrealized foreign exchange movements related to long-term intercompany loans, the translation of the foreign affiliate financial statements to U.S. dollars and unrealized movements related to short-term investment are recorded in other comprehensive (loss) income. Other comprehensive income (loss) is considered immaterial for all periods presented.

Quarterly Results of Operations (Unaudited):

The following table is the summary of the Company's unaudited quarterly condensed consolidated results of operations for the year ended December 31, 2024 (amounts in thousands, except for per share amounts):

	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
Revenue	$ 31,210	$ 11,456	$ 806	$ —
Gross profit (loss)	$ 30,034	$ 10,770	$ 296	$ (819)
Income (loss) from operations	$ 12,936	$ (3,287)	$ (15,301)	$ (16,705)
Net income (loss) per common shares – basic*	$ 0.22	$ (0.05)	$ (0.25)	$ (0.25)
Weighted average common shares outstanding – basic*	61,509	58,825	57,621	57,503

* Diluted earnings per share are not presented in this table

Liquidity and Capital Resources

Sources of Liquidity

As a result of our R&D, S&M and G&A expenditures and the lack of substantial product sales revenue, our ongoing operations have not been profitable on an annual basis since our inception. We achieved profitability in the fourth quarter of 2024, driven by product sales of DefenCath. During the year ended December 31, 2024, we received net proceeds of $18.9 million from the issuance of 3,049,878 shares of common stock under our at-the-market-issuance sales agreement, or ATM program, as compared to $12.9 million net proceeds in 2023 from the issuance of 2,977,637 shares of common stock. Also, in 2023, we received net proceeds of $42.9 million from the issuance of 9,000,093 shares of common stock and pre-funded warrants to purchase 2,500,625 shares of common stock in connection with a public offering. We may continue to be reliant on external sources of cash until we are able to generate sufficient operating cash flow to fund operations.

In March 2024, we received $1.4 million, net of expenses, from the sale of our unused New Jersey net operating losses ("NOL"), that were eligible for sale under the State of New Jersey's Economic Development Authority's New Jersey Technology Business Tax Certificate Transfer program ("NJEDA Program"). The NJEDA Program allowed us to sell our available fiscal 2023 NJ state NOL tax benefits in the amount of approximately $1.5 million.

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2024 was $50.6 million as compared to $38.4 million in 2023, an increase in net cash use of $12.2 million. The increase in cash use is primarily driven by an increase in trade receivables of $51.8 million and inventories of $3.4 million offset by a net increase in the change of accrued expenses and accounts payable of $15.4 million, primarily attributable to the gross-to-net-deductions accruals and decreased net loss of $28.4 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the year ended December 31, 2024, was $21.2 million as compared to $17.1 million of net cash used in investing activities for the same period in 2023. The net cash provided during the year ended December 31, 2024, was mainly driven by maturing short-term investments used to help fund operations, and lower purchases of short-term investments in 2024.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024, was $26.3 million as compared to $55.9 million for the same period in 2023, a decrease of $29.6 million. The decrease was mainly attributable to the net proceeds of $42.9 million from a public offering completed during the year ended December 31, 2023, offset by increases in proceeds from the exercise of stock options of $7.4 million, and increased ATM net proceeds of $6.0 million during the year ended December 31, 2024.

Funding Requirements and Liquidity

Our total cash, cash equivalents and short-term investments as of December 31, 2024, was $51.7 million, excluding restricted cash of $0.1 million, compared with $76.0 million for the year ended December 31, 2023, excluding restricted cash of $0.2 million. As of December 31, 2024, $30.2 million of the Company's common stock remains available for potential sale under the ATM program. Additionally, we have $100.0 million of remaining capacity available under our 2024 Shelf Registration Statement for the issuance of Company securities.

We expect to continue to fund operations from cash collections from accounts receivable, plus cash, cash equivalents and short-term investments and through capital raising sources, which may be dilutive to existing stockholders. In May 2024, we implemented an ATM program, which may be utilized to support our ongoing funding requirements. We may seek to sell additional equity or debt securities through one or more discrete transactions, or enter into a strategic alliance arrangement, but can provide no assurances that any such financing or strategic alliance

arrangement will be available on acceptable terms, or at all. Moreover, the incurrence of indebtedness would result in increased fixed obligations and could contain covenants that would restrict our operations. Raising additional funds through strategic alliance arrangements with third parties may require significant time to complete and could force us to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders.

Our actual cash requirements may vary materially from those now planned due to a number of factors, including any material change in commercial operations pertaining to DefenCath or the focus and direction of our research and development programs, any acquisition or pursuit of development of new product candidates, competitive and technical advances, the costs of commercializing any of our product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights. Because our business has not generated consistent and sustained positive operating cash flow, we may need to raise additional capital in order to continue to fund our research and development activities, as well as to fund operations generally and we can provide no assurances that financing or strategic relationships will be available on acceptable terms, or at all, if additional funds are needed. If we are unable to raise additional funds when needed, we may be forced to slow or discontinue our commercial operations pertaining to DefenCath. We may also be required to delay, scale back or eliminate some or all of our anticipated research and development programs. Each of these alternatives would likely have a material adverse effect on our business.

We currently estimate that as of December 31, 2024, we have sufficient cash, cash equivalents and short-term investments to fund operations for at least twelve months from the issuance of these financial statements.

Contractual Obligations

We entered into a seven-year operating lease agreement in March 2020 for an office space at 300 Connell Drive, Berkeley Heights, New Jersey 07922. The lease agreement, with a monthly average cost of approximately $17,000, commenced on September 16, 2020.

In December 2024, we entered into a three-year agreement with Syneos Health Commercial Services, LLC ("Syneos") where Syneos will provide a dedicated inpatient field sales force of sales that will exclusively promote DefenCath to hospitals and health systems. We are obligated to an up-front implementation and a fixed monthly fee. Upon the twelve-month anniversary of the deployment date, expected to be in the second quarter of 2025, the agreement is cancelable provided 60 days written notice. As of December 31, 2024, the minimum amount committed under this agreement totals $9.6 million.

In 2008, the Company entered into a License and Assignment Agreement (the ND License Agreement) with ND Partners, LLP (NDP). Pursuant to the ND License Agreement, NDP granted the Company exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the NDP Technology). During the year ended December 31, 2024, net sales milestones in the amount of $2 million were achieved and are accrued in our consolidated balance sheet. The Company anticipates payment will be due in 2025 in accordance with the agreement terms at the end of the twelve-month period post attainment.

Critical Accounting Estimates

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, which require our management to make estimates that affect the reported amounts of assets, liabilities and disclosures of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis. We consider an accounting estimate to be critical if: (1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (2) changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used

in the current period, would have a material impact on our financial condition or results of operations. Management has discussed the development and selection of these critical accounting estimates with the Audit Committee of our Board of Directors. In addition, there are other items within our financial statements that require estimation, but are not deemed critical as defined above. Changes in estimates used in these and other items could have a material impact on our financial statements.

- Litigation contingencies are assessed and judgments are made to determine if an unfavorable outcome is considered probable or reasonably possible, and when considered reasonably possible but not probable, the contingency is disclosed along with an estimate of the possible loss or range of loss. If a liability is possible or probable, but no reasonable estimation of loss can be made, we will disclose the nature of the contingency and state that such an estimate cannot be made. Such estimates and judgements are based on information obtained through the discovery process, court filings and follow on filings by the plaintiffs as well as the stage of litigation. There have been no changes in management's estimates in 2024.

- We account for product revenue from the sale of our product, DefenCath, in accordance with ASC 606, Revenue from Contracts with Customers ("ASC 606") which entails our estimates and judgments primarily in determining the transaction price and more specifically as it relates to variable consideration associated with the contracts. Our customers are located in the United States and consist primarily of outpatient service providers and to a lesser extent specialty wholesale distributors. Variable consideration pertaining to an allowance for product returns of short-dated or expired product requires estimation as our customers may have differing utilization, storage and distribution methods and we do not yet have significant historical trends. The Company's product accrual takes into consideration estimates of product held by its customers, the distribution channel, the shelf life of the product held by customers, as well as when the product is eligible for return based on our returns good policy. At December 31, 2024, the Company had $0.7 million in accrued returns allowance. We have established the estimate for returns based on specific customer circumstances, industry best practices and management experiences. Once return windows open and we experience actual returns we will further refine our estimate methods.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

N/A.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is included in Part IV, Item 15, and is incorporated by reference.

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

None.

Item 9A. Controls and Procedures

As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Exchange Act Rules 13a-15(e) and 15d-15(e)) (the "Exchange Act"). Based on the foregoing evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during our year ended December 31, 2024, or in other factors that could significantly affect these controls, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements in accordance with U.S. generally accepted accounting principles.

Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In connection with the preparation of our annual consolidated financial statements, management, including, our Principal Executive and Financial Officer, has undertaken an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the criterial established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2024.

Item 9B. Other Information

Rule 10b5-1 Plans

During the three months ended December 31, 2024, no director or officer of the Company (as defined in Rule 16a-1(f) under the Exchange Act) informed us of the adoption or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of SEC Regulation S-K.

2025 Annual Meeting of Shareholders

We currently plan to hold our 2025 Annual Meeting of Shareholders (the "2025 Annual Meeting") on June 24, 2025. The time and location of the 2025 Annual Meeting, and the matters to be considered, will be as set forth in our definitive proxy statement for the 2025 Annual Meeting to be filed with the SEC.

Because the scheduled date of the 2025 Annual Meeting is more than 30 days from the anniversary of the Company's 2024 Annual Meeting of Stockholders, prior disclosed deadlines regarding the submission of stockholder proposals pursuant to Rule 14a-8 ("Rule 14a-8") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), for the 2025 Annual Meeting are no longer applicable. The Company is hereby providing notice of certain revised deadlines for the submission of stockholder proposals in connection with the 2025 Annual Meeting. In order for a stockholder proposal, submitted pursuant to Rule 14a-8, to be considered timely for inclusion in the Company's proxy statement and form of proxy for the 2025 Annual Meeting, such proposal must be received by the Company by April 8, 2025, which the Company determined to be a reasonable time before the Company plans to

begin printing and mailing its proxy materials. Therefore, in order for a stockholder to submit a proposal for inclusion in the Company's proxy materials for the 2025 Annual Meeting, the stockholder must comply with the requirements set forth in Rule 14a-8, including with respect to the subject matter of the proposal, and must deliver the proposal and all required documentation to the Company no later than April 8, 2025. The public announcement of an adjournment or postponement of the date of the 2025 Annual Meeting will not commence a new time period (or extend any time period) for submitting a proposal pursuant to Rule 14a-8.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this Item will be included in our Proxy Statement, which will be filed within 120 days after the close of the 2024 fiscal year, or an amendment to this Annual Report, and is hereby incorporated by reference.

Code of Ethics

We have adopted a written Code of Conduct and Ethics that applies to our directors, executive officers and all employees. We intend to disclose any amendments to, or waivers from, our code of ethics and business conduct that are required to be publicly disclosed pursuant to rules of the SEC by filing such amendment or waiver with the SEC. This code of ethics and business conduct can be found in the "Investors — Corporate Governance" section of our website, *www.cormedix.com*.

Insider Trading Policy

We have adopted insider trading and 10b5-1 trading plan policies and procedures applicable to our directors, officers, employees, and other covered persons, and have implemented processes for the company, that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations, and the Nasdaq Stock Market LLC listing standards. Our insider trading policy and our 10b5-1 trading plan policy are filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this Item will be included in our Proxy Statement, which will be filed within 120 days after the close of the 2024 fiscal year, or an amendment to this Annual Report, and is hereby incorporated by reference.

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

The information required by this Item will be included in our Proxy Statement, which will be filed within 120 days after the close of the 2024 fiscal year, or an amendment to this Annual Report, and is hereby incorporated by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this Item will be included in our Proxy Statement, which will be filed within 120 days after the close of the 2024 fiscal year, or an amendment to this Annual Report, and is hereby incorporated by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item will be included in our Proxy Statement, which will be filed within 120 days after the close of the 2024 fiscal year, or an amendment to this Annual Report, and is hereby incorporated by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

1. *Financial Statements*. The following consolidated financial statements of CorMedix Inc. are filed as part of this Annual Report on Form 10-K:

2. Financial Statement Schedules. The Financial Statement Schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the financial statements or notes thereto.

3. *Exhibit Index*. The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed or Furnished Herewith
1.1	At-the-Market Issuance Sales Agreement, dated August 12, 2021, by and among CorMedix Inc., Truist Securities, Inc. and JMP Securities LLC	8-K	08/12/2021	1.1	
3.1	Form of Amended and Restated Certificate of Incorporation	S-1/A	3/01/2010	3.3	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated February 24, 2010	S-1/A	3/19/2010	3.5	
3.3	Second Amended and Restated Bylaws as amended October 8, 2020	8-K	10/14/2020	3.1	
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated December 3, 2012	10-K	3/27/2013	3.3	
3.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated August 9, 2017	8-K	8/10/2017	3.1	
3.6	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated March 25, 2019	8-K	3/25/2019	3.1	
3.7	Amended and Restated Certificate of Designation of Series C-3 Non-Voting Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on September 15, 2014	8-K	9/16/2014	3.16	
3.8	Second Amended and Restated Certificate of Designation of Series E Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on September 5, 2019	8-K	9/11/2019	3.2	
3.9	Certificate of Designation of Series G Convertible Preferred Stock of CorMedix Inc., filed with the Delaware Secretary of State on September 5, 2019	8-K	9/11/2019	3.1	
4.1	Specimen of Common Stock Certificate	S-1/A	3/19/2010	4.1	
4.2	Form of Warrant issued on January 8, 2014.	8-K	1/09/2014	4.23	
4.3	Form of Series B Warrant to Purchase Common Stock of CorMedix Inc. issued on May 3, 2017	8-K	5/03/2017	4.2	
4.4	Form of Underwriter's Warrant to Purchase Common Stock of CorMedix Inc., issued May 3, 2017	8-K	5/03/2017	4.3	
4.5	Description of Capital Stock of CorMedix Inc.	10-K	03/16/2020	4.5	
4.6	Form of Pre-Funded Warrant issued June 28, 2023	8-K	06/30/2023	4.1	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed or Furnished Herewith
10.1*	License and Assignment Agreement, dated as of January 30, 2008, between CorMedix Inc. and ND Partners LLC	S-1/A	12/31/2009	10.5	
10.2+	Form of Indemnification Agreement between CorMedix Inc. and each of its directors and executive officers	10-Q	5/15/2023	10.1	
10.3**+	Executive Employment Agreement, dated and effective May 11, 2020, between CorMedix Inc. and Matthew David	10-K	3/30/2021	10.10	
10.4+	Letter Agreement, dated and effective October 26, 2021, between CorMedix Inc. and Matthew David, M.D.	8-K	10/29/2021	10.1	
10.5	Form of Securities Purchase Agreement, dated November 17, 2017, between CorMedix Inc. and the investors signatory thereto	8-K	11/13/2017	10.1	
10.6	Backstop Agreement, dated November 9, 2017, between CorMedix Inc. and the investor named therein	8-K	11/13/2017	10.2	
10.7	Form of Registration Rights Agreement, dated November 9, 2017, by and between CorMedix Inc. and the investor named therein	8-K	11/13/2017	10.3	
10.8	Amendment No. 1, dated as of December 11, 2017, to Registration Rights Agreement, dated November 9, 2017, by and between CorMedix Inc. and the investor named therein	8-K	12/11/2017	10.1	
10.9**+	Executive Employment Agreement, dated and effective March 10, 2021, between CorMedix Inc. and Elizabeth Hurlburt	8-K	3/12/2021	10.1	
10.10	Securities Purchase Agreement, dated December 31, 2018, between CorMedix Inc. and the investor named therein	8-K	1/03/2019	10.1	
10.11	Securities Exchange Agreement, dated August 14, 2019, by and among CorMedix Inc. and the Existing Security holders listed on the Schedule of Holders thereto	8-K	8/15/2019	10.1	
10.12	Amended and Restated Registration Rights Agreement, dated as of September 6, 2019, by and among CorMedix Inc. and Manchester Securities Corp., and Elliot International, L.P. and Elliot Associates, L.P.	8-K	9/11/2019	10.1	
10.13	Amended and Restated 2019 Omnibus Stock Incentive Plan	S-8	10/26/2022	99.1	
10.14+	2021 Executive Bonus Plan	8-K	12/23/2021	10.1	
10.15+	Executive Employment Agreement, dated March 16, 2022, between CorMedix Inc. and Joseph Todisco.	8-K	03/21/2022	10.2	
10.16+	Executive Employment Agreement, dated December 12, 2023, between CorMedix Inc. and Beth Zelnick Kaufman.				X
10.17	Amendment No. 1 to the Amended and Restated CorMedix Inc. 2019 Omnibus Stock Incentive Plan	8-K	11/21/2024	10.1	
19.1	Insider Trading Policies and Procedures				X
21.1	List of Subsidiaries	10-K	3/27/2013	21.1	
23.1	Consent of Independent Registered Public Accounting Firm				X
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1***	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2***	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
97.1	Board Policy on Recouping Incentive Compensation	10-K	3/12/2024	97.1	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed or Furnished Herewith
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				X

* Confidential treatment has been granted for portions of this document. The omitted portions of this document have been filed separately with the SEC.

** Portions of the exhibit have been omitted in reliance on Item 601(b)(10)(iv) of Regulation S-K.

*** These certifications are furnished.

\+ Indicates management contract or compensation plan.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CORMEDIX INC.

March 25, 2025 By: /s/ Joseph Todisco
Joseph Todisco
Chief Executive Officer
(Principal Executive Officer)

March 25, 2025 By: /s/ Matthew David
Matthew David
Chief Financial Officer
(Principal Financial and Accounting 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 and on the dates indicated:

Signature	Title	Date
/s/ Joseph Todisco Joseph Todisco	Chief Executive Officer and Director (Principal Executive Officer)	March 25, 2025
/s/ Matthew David Matthew David	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2025
/s/ Myron Kaplan Myron Kaplan	Director and Chairman of the Board	March 25, 2025
/s/ Janet Dillione Janet Dillione	Director	March 25, 2025
/s/ Gregory Duncan Gregory Duncan	Director	March 25, 2025
/s/ Alan Dunton Alan Dunton	Director	March 25, 2025
/s/ Steven Lefkowitz Steven Lefkowitz	Director	March 25, 2025
/s/ Robert Stewart Robert Stewart	Director	March 25, 2025

CORMEDIX INC. AND SUBSIDIARIES

FINANCIAL STATEMENTS

Financial Statements Index

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
CorMedix Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CorMedix Inc. (the "Company") and Subsidiaries as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audits, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our 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 audits 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Variable Consideration: Product Returns

Description of the Matter

As discussed in Note 3 of the consolidated financial statements, the Company includes estimates of variable consideration in its transaction price at the time control of the product transfers to the customer. The variable consideration includes an estimate for future product returns. The Company permits returns for product that is within six months prior to or past the labeled expiration date. The Company's product return accrual takes into consideration estimates of product held by its customers, the distribution channel, the shelf life of the product held by customers, as well as when the product is eligible for return based on the contractual terms. At December 31, 2024, the Company had $0.7 million in accrued returns allowance.

Auditing the allowance for sales returns was complex due to the significant estimation required in determining product held by customers and in the distribution channel, as well as product that may not be sold to, or consumed by, the end user prior to the dates eligible for return under the contractual terms. The allowance for sales returns is sensitive to the level of product and turnover at the customer and in the distribution channel, which could exceed future end user demand and be subject to return.

How We Addressed the Matter in Our Audit

We obtained an understanding and evaluated the design of the Company's controls over the estimation for sales returns. In order to test the estimated sales return reserve, we performed audit procedures that included, among others, reviewing sell-through information of the Company's major customers. We analyzed the estimated remaining inventory with selected customers and their distribution channel as compared to product sold to that customer and forecasted sales to, or usage by, the end users giving consideration to the remaining shelf life of the product. Further, for direct sales to outpatient dialysis centers, we reviewed the Company's sales made to certain customers individual dialysis center locations by month during both the reporting period and through the financial statement issuance date to evidence follow on orders and utilization by those individual dialysis centers. We also performed direct management inquiries with Company sales and supply chain department personnel, and reviewed key customer contract terms and their alignment with such reserve assumptions.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2014.

Morristown, New Jersey
March 25, 2025

CORMEDIX INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2024 and 2023

	December 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 40,650,770	$ 43,642,684
Restricted cash	—	77,453
Short-term investments	11,036,857	32,388,130
Trade receivables, net	51,653,583	—
Inventories	7,599,535	2,106,345
Prepaid research and development expenses	152,823	353,574
Other prepaid expenses and current assets	3,481,868	882,214
Total current assets	114,575,436	79,450,400
Property and equipment, net	1,828,016	1,866,224
License intangible asset, net	1,844,156	—
Restricted cash, long term	105,368	103,055
Operating lease right-of-use assets	492,697	640,278
TOTAL ASSETS	$ 118,845,673	$ 82,059,957
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,720,177	$ 4,279,679
Accrued expenses	31,951,533	6,970,217
Operating lease liabilities, short-term	167,922	150,619
Total current liabilities	33,839,632	11,400,515
Operating lease liabilities, net of current portion	349,091	517,013
TOTAL LIABILITIES	34,188,723	11,917,528
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY		
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 136,623 and 181,622 shares issued and outstanding at December 31, 2024 and 2023, respectively	137	182
Common stock - $0.001 par value: 160,000,000 shares authorized at December 31, 2024 and 2023; 64,411,295 and 54,938,258 shares issued and outstanding at December 31, 2024 and 2023, respectively	64,411	54,938
Accumulated other comprehensive gain	90,646	94,108
Additional paid-in capital	424,131,789	391,693,214
Accumulated deficit	(339,630,033)	(321,700,013)
TOTAL STOCKHOLDERS' EQUITY	84,656,950	70,142,429
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 118,845,673	$ 82,059,957

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

CORMEDIX INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
Years Ended December 31, 2024 and 2023

	December 31,	
	2024	**2023**
Revenue:		
Net sales	$ 43,472,170	$ —
Cost of sales	(3,190,534)	—
Gross profit	40,281,636	—
Operating Expenses:		
Research and development	(3,942,270)	(13,155,125)
Selling and marketing	(28,736,605)	(18,115,313)
General and administrative	(29,959,150)	(17,687,350)
Total operating expenses	(62,638,025)	(48,957,788)
Loss From Operations	(22,356,389)	(48,957,788)
Other Income (Expense):		
Interest income	2,578,792	2,681,851
Foreign exchange transaction loss	(30,788)	(28,994)
Other income	520,000	—
Interest expense	(36,405)	(34,296)
Total other income	3,031,599	2,618,561
Net Loss Before Income Taxes	(19,324,790)	(46,339,227)
Tax benefit	1,394,770	—
Net Loss	(17,930,020)	(46,339,227)
Other Comprehensive Income (Loss):		
Unrealized (loss) gain from investments	(4,830)	9,683
Foreign currency translation gain	1,368	1,682
Total other comprehensive gain (loss)	(3,462)	11,365
Comprehensive Loss	$ (17,933,482)	$ (46,327,862)
Net Loss Per Common Share – Basic and Diluted	$ (0.30)	$ (0.91)
Weighted Average Common Shares Outstanding – Basic and Diluted	58,871,582	50,902,931

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

CORMEDIX INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
Years Ended December 31, 2024 and 2023

	Common Stock		Preferred Stock – Series C-3, Series E, Series F and Series G		Accumulated Other Comprehen-sive Gain (Loss)	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	42,815,196	$ 42,815	181,622	$ 182	$ 82,743	$ 330,294,782	$ (275,360,786)	$ 55,059,736
Stock issued in connection with ATM sale of common stock, net	2,977,637	2,978	—	—	—	12,946,132	—	12,949,110
Stock and pre-funded warrants issued in connection with public offering, net	9,000,093	9,000	—	—	—	42,869,399	—	42,878,399
Stock issued in connection with options exercised	79,041	79	—	—	—	287,659	—	287,738
Issuance of vested restricted stock, net of shares withheld for employee withholding taxes	66,291	66	—	—	—	(198,509)	—	(198,443)
Stock-based compensation	—	—	—	—	—	5,493,751	—	5,493,751
Other comprehensive gain	—	—	—	—	11,365	—	—	11,365
Net loss	—	—	—	—	—	—	(46,339,227)	(46,339,227)
Balance at December 31, 2023	54,938,258	$ 54,938	181,622	$ 182	$ 94,108	$ 391,693,214	$ (321,700,013)	$ 70,142,429
Stock issued in connection with ATM sale of common stock, net	3,049,878	3,050	—	—	—	18,878,537	—	18,881,587
Stock issued in connection with the exercise of pre-funded warrants	2,500,625	2,501	—	—	—	—	—	2,501
Stock issued in connection with options exercised	1,357,802	1,358	—	—	—	7,722,771	—	7,724,129
Conversion of Series G preferred stock to common stock	2,502,005	2,502	(44,999)	(45)		(2,457)	—	—
Issuance of vested restricted stock, net of shares withheld for employee withholding taxes	84,559	84	—	—	—	(289,706)	—	(289,622)
Cancelation of shares held in escrow	(21,832)	(22)	—	—	—	22	—	—
Stock-based compensation	—	—	—	—	—	6,129,408	—	6,129,408
Other comprehensive loss	—	—	—	—	(3,462)	—	—	(3,462)
Net loss	—	—	—	—	—	—	(17,930,020)	(17,930,020)
Balance at December 31, 2024	64,411,295	$ 64,411	136,623	$ 137	$ 90,646	$ 424,131,789	$ (339,630,033)	$ 84,656,950

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

CORMEDIX INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2024 and 2023

	December 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (17,930,020)	$ (46,339,227)
Adjustments to reconcile net loss to net cash used in operating activities:		
Provision for current expected credit losses	137,000	—
Stock-based compensation	6,129,408	5,493,751
Change in right-of-use assets	147,581	134,807
Depreciation	153,937	70,755
Amortization of intangible	155,844	—
Changes in operating assets and liabilities:		
Increase in trade receivables	(51,790,583)	—
Increase in inventory	(5,493,190)	(2,106,345)
Increase in prepaid expenses and other current assets	(2,399,221)	(600,983)
(Decrease) Increase in accounts payable	(2,559,491)	2,077,479
Increase in accrued expenses	22,984,701	2,995,084
Decrease in operating lease liabilities	(150,619)	(134,801)
Net cash used in operating activities	(50,614,653)	(38,409,480)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term investments	(26,769,749)	(77,084,385)
Maturity of short-term investments	48,116,192	60,350,000
Purchase of equipment	(115,730)	(327,300)
Net cash provided by (used in) investing activities	21,230,713	(17,061,685)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock from at-the-market program, net	18,881,587	12,949,110
Proceeds from public offering of common stock and pre-funded warrants, net	—	42,878,399
Payment of employee withholding taxes on vested restricted stock units	(289,622)	(198,443)
Proceeds from exercise of pre-funded warrants	2,501	—
Proceeds from exercise of stock options	7,724,129	287,738
Net cash provided by financing activities	26,318,595	55,916,804
Foreign exchange effects on cash	(1,709)	2,808
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(3,067,054)	448,447
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH – BEGINNING OF YEAR	43,823,192	43,374,745
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH – END OF YEAR	$ 40,756,138	$ 43,823,192
Cash paid for interest	$ 36,405	$ 34,296
Supplemental Disclosure of Non-Cash and Investing Activities:		
Liability related to license agreement	$ 2,000,000	—
Unrealized (loss) gain from investments	$ (4,830)	$ 9,683

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

Note 1 — Organization and Description of Business:

Organization and Business:

CorMedix Inc. (collectively, with our wholly owned subsidiaries, referred to herein as "we," "us," "our" or the "Company") is a biopharmaceutical company focused on developing and commercializing therapeutic products for life-threatening diseases and conditions.

Our primary focus is commercializing our lead product, DefenCath® (taurolidine and heparin), in the U.S. The name DefenCath is the U.S. proprietary name approved by the U.S. Food and Drug Administration ("FDA"). CorMedix launched the product commercially in April 2024 in the inpatient setting and July 2024 in the outpatient hemodialysis setting.

DefenCath is an FDA approved antimicrobial catheter lock solution ("CLS") (a formulation of taurolidine 13.5 mg/mL, and heparin 1000 USP Units/mL) indicated to reduce the incidence of catheter-related bloodstream infections ("CRBSI") in adult patients with kidney failure receiving chronic hemodialysis through a central venous catheter ("CVC"). It is indicated for use in a limited and specific population of patients. CRBSIs can lead to treatment delays and increased costs to the healthcare system when they occur due to hospitalizations, need for IV antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the CVC, related treatment costs, as well as increased mortality. We believe DefenCath can address a significant unmet medical need.

On November 15, 2023, we announced that the FDA approved the new drug application ("NDA") for DefenCath to reduce the incidence of CRBSI in adult patients with kidney failure receiving chronic hemodialysis through a CVC. DefenCath is the first and only FDA-approved antimicrobial CLS in the U.S. and was shown to reduce the risk of CRBSI by up to 71% in a Phase 3 clinical study. As a result of the November 2023 FDA approval, CorMedix launched the product commercially in April 2024 in the inpatient setting and July 2024 in the outpatient hemodialysis setting.

Note 2 — Liquidity and Uncertainties:

The consolidated financial statements have been prepared in conformity with generally accepted accounting principles which contemplate continuation of the Company as a going concern. To date, the Company's commercial operations have not generated sufficient revenues to enable profitability. The Company's current commercial and development expenses for DefenCath and its other operating requirements are expected to be funded for at least twelve months from the issuance of these financial statements by the Company's existing cash, cash equivalents and short-term investments at December 31, 2024 as well as the additional expected liquidity from commercial operations.

The Company's operations are subject to a number of other factors that can affect its operating results and cash flow projections over the next twelve months from the issuance of these financial statements. Such factors include, but are not limited to: the ability to market DefenCath and generate necessary revenue in the time periods required; ability to manufacture successfully; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, Company products; and the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products. As such, the Company may be required to raise additional capital through various potential sources, such as equity and/or debt financing, strategic relationships, potential strategic transactions and/or out-licensing. Management can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. As of December 31, 2024, approximately $30,216,000 of the Company's common stock remains available for sale under the 2024 ATM program, with $100,000,000 of remaining capacity under the 2024 Shelf Registration Statement for the issuance of Company securities (see Note 8).

Note 3 — Summary of Significant Accounting Policies:

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities and disclosure of contingent assets and liabilities in the Company's consolidated balance sheets and the reported amounts of revenue and expenses reported for each of the periods presented are affected by estimates and assumptions. The more significant areas in which estimates and the exercise of judgment relate include; variable consideration for product returns, realization of receivables, valuation of inventory, share-based payment grant date valuation, deferred tax asset valuation changes and contingent liability recognition and disclosures. Estimates are based on historical experience and other assumptions that are considered appropriate in the circumstances. They are continuously reviewed but may vary from the actual values.

Reclassifications

Certain reclassifications were made to the prior year's amounts to conform to the 2024 presentation.

Basis of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Trade Accounts Receivable and Allowances

The Company recognizes an allowance that reflects a current estimate of credit losses expected to be incurred over the life of a financial asset, including trade receivables. The allowance for credit losses reflects the best estimate of expected credit losses of the accounts receivable portfolio determined on the basis of current information, forecasts of future economic conditions, industry knowledge and to some extent our historical experience. The Company determines its allowance methodology by pooling receivable balances at the customer level. The Company considers various factors, including individual credit risk associated with each customer, the current and future condition of the general economy and industry knowledge. These credit risk factors are monitored on a quarterly basis and updated as necessary. To the extent any individual debtor is identified whose credit quality has deteriorated, the Company establishes allowances based on the individual risk characteristics of such customer. The Company makes concerted efforts to collect all outstanding balances due, however account balances are charged off against the allowance when management believes it is probable the receivable will not be recovered. The Company does not have any off-balance sheet credit exposure related to its customers. Allowances recorded for credit losses as of December 31, 2024 were approximately $0.1 million, there were no write-offs or recoveries during the year ended December, 31, 2024.

Concentrations

The major customers of the Company are defined as those constituting greater than 10% of its total revenue. For the year ended December 31, 2024, the Company had sales to one customer that accounted for 86% of its total revenue of $43,472,000. For the year ended December 31, 2024, the Company had two customers that accounted for 87% and 12% of the accounts receivable, respectively.

The Company currently has one FDA approved source for each of our two key active pharmaceutical ingredients ("APIs") for DefenCath, taurolidine and heparin sodium, respectively. With regards to taurolidine, the Company has a drug master file ("DMF") filed with the FDA. There is a master commercial supply agreement between a third-party manufacturer which has been in place since August 2018. In addition, the Company is working with its existing manufacture to source sufficient quantities of taurolidine API to cover at least 24 months of potential future demand. With respect to heparin sodium API, the Company has identified an alternate third-party supplier and may qualify such supplier under the DefenCath NDA over the next twelve months.

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

The Company received FDA approval of DefenCath with finished dosage production from its European based contract manufacturing organization ("CMO") Rovi Pharma Industrial Services. The Company believes this CMO has adequate capacity to produce the volumes needed to meet near-term projected demand for the commercial launch of DefenCath. The Company also qualified Siegfried Hameln as an alternate finished dosage manufacturing site.

Financial Instruments

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, short-term investments and accounts receivable. The Company maintains its cash and cash equivalents in bank deposit and other interest-bearing accounts, the balances of which, , may exceed federally insured limits.

The following table is the reconciliation of the accounting standard that modifies certain aspects of the recognition, measurement, presentation and disclosure of financial instruments as shown on the Company's consolidated statement of cash flows:

	December 31,	
	2024	2023
Cash and cash equivalents	$ 40,650,770	$ 43,642,684
Restricted cash, short-term and long-term	105,368	180,508
Total cash, cash equivalents and restricted cash	$ 40,756,138	$ 43,823,192

The appropriate classification of marketable securities is determined at the time of purchase and reevaluated as of each balance sheet date. Investments in marketable debt, classified as available-for-sale, are reported at fair value. Fair value is determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported in other comprehensive income. Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in other income (expense). The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. There were no deemed permanent impairments at December 31, 2024 or December 31, 2023.

The Company's marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with original maturities of more than 90 days. As of December 31, 2024 and 2023, all of the Company's investments had contractual maturities which were less than one year. The following table summarizes the amortized cost, unrealized gains and losses and the fair value at December 31, 2024 and 2023:

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Fair Value
December 31, 2024:				
Money Market Funds and Cash Equivalents	$ 23,121,752	$ —	$ —	$ 23,121,752
U.S. Government Agency Securities	11,032,606	—	4,251	11,036,857
Total December 31, 2024	$ 34,154,358	$ —	$ 4,251	$ 34,158,609
December 31, 2023:				
Money Market Funds and Cash Equivalents	$ 32,541,862	$ —	$ —	$ 32,541,862
U.S. Government Agency Securities	29,701,677	—	10,506	29,712,183
Commercial Paper	2,676,740	(1,425)	—	2,675,315
Subtotal	32,378,417	(1,425)	10,506	32,387,498
Total December 31, 2023	$ 64,920,279	$ (1,425)	$ 10,506	$ 64,929,360

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

Fair Value Measurements

In accordance with Accounting Standards Codification ("ASC") 825, *Financial Instruments,* disclosures of fair value information about financial instruments is required, whether or not recognized in the consolidated balance sheet, for which it is practicable to estimate that value. The Company's financial instruments recorded in the consolidated balance sheets include cash and cash equivalents, accounts receivable, investment securities and accounts payable. The carrying value of certain financial instruments, primarily cash and cash equivalents, accounts receivable and accounts payable approximate their estimated fair values based upon the short-term nature of their maturity dates.

The Company categorizes its financial instruments into a three-level fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets (Level 1) and the lowest priority to unobservable inputs (Level 3). If the inputs used to measure fair value fall within different levels of the hierarchy, the category level is based on the lowest priority level input that is significant to the fair value measurement of the instrument. Financial assets recorded at fair value on the Company's consolidated balance sheets are categorized as follows:

Level 1 inputs — Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 inputs — Significant other observable inputs (e.g., quoted prices for similar items in active markets, quoted prices for identical or similar items in markets that are not active, inputs other than quoted prices that are observable such as interest rate and yield curves, and market-corroborated inputs).

Level 3 inputs — Unobservable inputs for the asset or liability, which are supported by little or no market activity and are valued based on management's estimates of assumptions that market participants would use in pricing the asset or liability.

The following table provides the carrying value and fair value of the Company's financial assets measured at fair value as of December 31, 2024 and 2023:

	Carrying Value	Level 1	Level 2	Level 3
December 31, 2024:				
Money Market Funds and Cash Equivalents. .	$ 23,121,752	$ 23,151,752	$ —	$ —
U.S. Government Agency Securities.	11,036,857	11,036,857	—	—
Total December 31, 2024	$ 34,158,609	$ 34,158,609	$ —	$ —
December 31, 2023:				
Money Market Funds and Cash Equivalents. .	$ 32,541,862	$ 32,541,862	$ —	$ —
U.S. Government Agency Securities.	29,712,183	29,712,183	—	—
Commercial Paper.	2,675,315	—	2,675,315	—
Subtotal	32,387,498	29,712,183	2,675,315	—
Total December 31, 2023	$ 64,929,360	$ 62,254,045	$ 2,675,315	$ —

Foreign Currency Translation and Transactions

The consolidated financial statements are presented in U.S. Dollars (USD), the reporting currency of the Company. For the financial statements of the Company's foreign subsidiaries, whose functional currency is the EURO, foreign currency asset and liability amounts, if any, are translated into USD at end-of-period exchange rates. Foreign currency income and expenses are translated at average exchange rates in effect during the year. Translation gains and losses are included in other comprehensive income (loss). The Company had a foreign currency translation gain of $1,368 and $1,682 for the years ended December 31, 2024 and 2023, respectively.

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

Foreign currency exchange transaction gain (loss) is the result of re-measuring transactions denominated in a currency other than the functional currency of the entity recording the transaction.

Restricted Cash

The Company was required by the District Courts of Mannheim to provide security deposit to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The Company furthermore had to provide a deposit for the first and second instances, respectively, in connection with the unfair competition proceedings in Cologne. As of December 31, 2023, the Company had restricted cash in connection with the patent and utility model infringement proceedings against TauroPharm in the amount of approximately $77,000, which was refunded to the Company during the year ended December 31, 2024.

As of December 31, 2024 and 2023, the Company had $105,000 and $103,000, respectively in long-term restricted cash for a lease security deposit.

Prepaid Research and Development and Other Prepaid Expenses

Prepaid expenses consist of payments made in advance to vendors relating to service contracts for clinical trial development, manufacturing, pre-clinical development and insurance policies. These advanced payments are amortized to expense either as services are performed or over the relevant service period using the straight-line method.

Inventories

The Company engages third parties to manufacture and package inventory held for sale and warehouse such goods until packaged for final distribution and sale. Costs related to the manufacturing of DefenCath incurred prior to FDA approval to support the preparation for commercial launch of its product were expensed as research and development expenses (R&D) as incurred. Upon FDA approval, costs related to the manufacturing of inventory are stated at the lower of cost or net realizable value with cost determined on a first-in, first-out basis.

Inventory is valued utilizing the standard cost method, which approximates costs determined on the first-in first-out basis. The Company regularly reviews inventory quantities on hand and writes down to its net realizable value any inventory that it believes to be impaired. Management considers forecast demand in relation to the inventory on hand, competitiveness of product offering and sales volume assumptions, market conditions and product life cycle and expiration dating when determining net realizable value adjustments. Once inventory is written down and a new cost basis is established, it is not written back up if demand increases. The Company has not experienced any write-downs for any items listed above during 2023 or 2024.

Inventories consist of raw materials (including labeling and packaging), work-in-process, and finished goods, if any, for the DefenCath product. Inventories consist of the following:

	December 31,	
	2024	2023
Raw materials	$ 1,111,409	$ 1,525,420
Work in progress	3,528,401	580,925
Finished goods	2,959,725	—
Total	$ 7,599,535	$ 2,106,345

The pre-commercial inventory previously expensed as R&D prior to FDA approval, consists of certain raw materials and inventory at various stages of completion with a value approximating $5,318,000 as of December 31, 2024.

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

Property and Equipment

Property and equipment consist primarily of furnishings, fixtures, leasehold improvements, office equipment and computer equipment, all of which are recorded at cost. Depreciation is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. Property and equipment, as of December 31, 2024 and 2023 were approximately $1,828,000 and $1,866,000, respectively, net of accumulated depreciation of approximately $674,000 and $521,000, respectively. Depreciation and amortization of property and equipment is included in cost of goods sold and general and administrative expenses.

Description	Estimated Useful Life	Income Statement Classification
Office equipment and furniture	5 years	G&A
Leasehold improvements	7 years or remaining term of the lease	G&A
Computer equipment	3 years	G&A
Computer software	3 years	G&A
Packaging equipment	5 years	COGS

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, current portion of operating lease liabilities and operating lease liabilities, net of current portion, on the consolidated balance sheet (see Note 9).

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

The Company has elected, as an accounting policy, not to apply the recognition requirements in ASC 842, *Accounting for Leases*, to short-term leases. Short-term leases are leases that have a term of 12 months or less and do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise. The Company recognizes the lease payments for short-term leases on a straight-line basis over the lease term.

The Company has also elected, as a practical expedient, by underlying class of asset, not to separate lease components from non-lease components and, instead, account for them as a single component.

Revenue Recognition

The Company recognizes revenue from the sale of its product, DefenCath, in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). The provisions of ASC 606 require the following steps to determine revenue recognition: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company recognizes revenue when it believes that it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer. The Company's product revenue is recognized at a point in time when the performance obligation is satisfied by transferring control of the promised goods or services to a customer. In accordance with the Company's contracts with customers, control

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

of the product is transferred upon the conveyance of title, which occurs when the product is received by a customer. The Company's customers are located in the United States and consist primarily of outpatient service providers and wholesale distributors.

Variable Consideration

The Company includes an estimate of variable consideration in its transaction price at the time of sale when control of the product transfers to the customer. Variable consideration includes:

- Distribution service fees;
- Prompt pay and other discounts;
- Product returns;
- Chargebacks;
- Rebates;
- Volume incentive rebates;

The Company assesses whether or not an estimate of variable consideration is constrained based on the probability that a significant reversal in the amount of cumulative revenue may occur in the future when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received may vary from our estimates. If actual results in the future vary from estimates, the Company adjusts these estimates, which would affect product sales and earnings in the period such variances become known.

The specific considerations that the Company uses in estimating these amounts related to variable considerations are as follows:

Distribution services fees — The Company pays distribution service fees primarily to its wholesale distributors. The Company reserves these fees based on actual net sales and the contractual fee rates negotiated with the customers in the distribution channel. The Company records these fees as contra accounts receivable on the balance sheet.

Prompt pay and other discounts — The Company provides customers with prompt pay discounts. The specific prompt pay terms vary by customer and are contractually fixed. Prompt pay discounts are expected to be taken by the Company's customers, so an estimate of the discount is recorded at the time of sale based on the invoice price. Prompt pay discount estimates are recorded as contra accounts receivable on the balance sheet.

Product returns — Customers have the right to return product that is within six months or less of the labeled expiration date or that is past the expiration date by no more than six months. The Company determines its estimate for product returns based on: (i) data provided to the Company by its distributors (including weekly reporting of distributors' sales and inventory held by distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to both inpatient and outpatient facilities), and (ii) the estimated remaining shelf life of DefenCath held by the wholesale distributors and outpatient service providers. Since the returns primarily consist of expired and short dated products that will not be resold, the Company does not record a return asset for the right to recover the goods returned by the customer at the time of the initial sale (when recognition of revenue is deferred due to the anticipated return). Estimated product returns are recorded as accrued expenses on the balance sheet.

Chargebacks — Certain covered entities, group purchasing organizations ("GPO") and government entities will be able to purchase the product at a price discounted below wholesaler acquisition cost ("WAC"). The difference between the GPO, government or covered entity purchase price and the wholesale distributor purchase price of WAC will be charged back to the Company. The Company estimates the amount in chargebacks based on the expected

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

number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Estimated chargebacks are recorded as contra accounts receivable on the balance sheet.

Rebates — The Company is or may become subject to negotiated discount obligations to different GPO, direct purchasers, other commercial organizations or government programs. The rebate amounts for these programs are determined by statutory requirements or contractual arrangements. Rebates are owed after the product has been dispensed to an end user and the Company has been invoiced. Rebates are typically invoiced in arrears. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter based on expected product utilization, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel at the end of each reporting period. Rebate estimates are recorded as accrued expenses on the balance sheet.

Volume Incentive Rebates — The Company is subject to negotiated volume incentive rebates with certain direct and indirect customers (primarily outpatient service providers). Rebates are owed based on predetermined volume levels and payable per the terms in the customer contracts. The Company estimates and records volume incentive rebates based on anticipated purchase volume with specific customers based on communications with the customer. Volume incentive rebates are recorded as accrued expenses on the balance sheet.

Provisions for the revenue reserves described above totaled $24,128,000 for the year ended December 31, 2024. As of December 31, 2024, total accrued reserves and allowances to accounts receivable on the balance sheet associated with variable consideration were $23,161,000.

A roll forward of the major categories of variable consideration deductions for the years ended December 31, 2024 and 2023 is as follows:

	Volume Incentive Rebates	Prompt Pay and Other Discounts	Accrued Returns Allowance
Balance at December 31, 2023	$ —	$ —	$ —
Provisions related to sales recorded in the period	21,582,371	1,202,526	746,310
Credits/payments issued during the period	(664,380)	(267,240)	—
Balance at December 31, 2024	$ 20,917,991	$ 935,286	$ 746,310

License Agreement

The Company's rights under the License and Assignment Agreement with ND Partners, LLP are capitalized and stated at cost. The Company amortizes the intangible asset utilizing the straight-line method over the estimated economic life of the intangible asset based on the Company's assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the launch date of DefenCath, the strength of the intellectual property protection of DefenCath and associated technology and various other competitive, developmental and regulatory considerations, and contractual terms. See Note 7 — Commitments and Contingencies for further discussion.

Loss Per Common Share

Basic loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the Company.

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

The Company's outstanding shares of Series E preferred stock entitle the holders to receive dividends on a basis equivalent to the dividends paid to holders of common stock. As a result, the Series E preferred stock meet the definition of participating securities requiring the application of the two-class method. Under the two-class method, earnings available to common shareholders, including both distributed and undistributed earnings, are allocated to each class of common stock and participating securities according to dividends declared and participating rights in undistributed earnings, which may cause diluted earnings per share to be more dilutive than the calculation using the treasury stock method. No loss has been allocated to these participating securities since they do not have contractual obligations that require participation in the Company's losses.

Since the Company has only incurred losses, potentially dilutive securities are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive, and therefore basic and diluted loss per share are the same for all periods presented. The shares outstanding at the end of the respective periods presented below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Number of Shares of Common Stock Issuable At December 31,	
	2024	2023
Series C non-voting preferred stock	4,000	4,000
Series E voting preferred stock	391,953	391,953
Series G voting preferred stock	2,502,064	5,004,069
Shares issuable for payment of deferred board compensation	48,909	48,909
Shares underlying outstanding stock options	6,282,393	6,211,508
Restricted stock units	291,494	153,735
Total potentially dilutive shares	9,520,813	11,814,174

Stock-Based Compensation

Stock-based compensation cost is measured at grant date, based on the estimated fair value of the award using the Black-Scholes option pricing model for options with service or performance-based conditions. Stock-based compensation is recognized as expense over the requisite service period on a straight-line basis or when the achievement of the performance condition is probable.

Research and Development

Research and development costs are charged to expense as incurred. Research and development include fees associated with operational consultants, contract clinical research organizations, contract manufacturing organizations, clinical site fees, contract laboratory research organizations, contract central testing laboratories, licensing activities, and allocated executive, human resources and facilities expenses. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial and the invoices received from its external service providers. As actual costs become known, the Company adjusts its accruals in the period when actual costs become known. Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development expense.

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

Other Income

Other income relates to a settlement with a previously utilized vendor, occurring during the year ended December 31, 2024.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the 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 rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some or all of the deferred tax assets will not be realized.

Recent Authoritative Pronouncements, not yet adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe the adoption of recently issued standards have or may have a material impact on its consolidated financial statements or disclosures.

ASU No. 2023-09

In December 2023, the FASB issued Accounting Standards Update (ASU) No. 2023-09, *Income Taxes — Improvements to Income Tax Disclosures* (Topic 740). The standard requires disaggregation of the effective rate reconciliation into standard categories, enhances disclosure of income taxes paid, and modifies other income tax-related disclosures. The standard will be effective for CorMedix beginning in annual reporting period ending December 31, 2025, with early adoption permitted. CorMedix is currently assessing the impact of adopting this guidance on its consolidated financial statements.

ASU 2024-03

In November 2024, the FASB issued ASU 2024-03, *ASC 220- Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures*, which requires entities, in the notes to financial statements, with specified information about certain costs and expenses. The guidance is effective for CorMedix's annual reporting period ending December 31, 2027, with interim periods beginning with CorMedix's interim period ended March 31, 2027. Early adoption is permitted. CorMedix is assessing the impact of adopting this guidance on its consolidated financial statements.

Recently Adopted Authoritative Pronouncements:

ASU No. 2023-07

In November 2023, the FASB issued ASU No. 2023-07 *Segment Reporting — Improving Reportable Segment Disclosures* (Topic 280). The standard requires disclosures to include significant segment expenses that are regularly provided to the chief operating decision maker (CODM), a description of other segment items by reportable segment, and any additional measures of a segment's profit or loss used by the CODM when deciding how to allocate resources. The ASU also requires all annual disclosures currently required by Topic 280 to be included in interim periods. CorMedix adopted this guidance as of December 31, 2024. See Note 10 for the disclosure related to the adoption of ASU No. 2023-07.

Note 4 — Other Prepaid Expenses and Current Assets:

Other Prepaid Expenses and Current Assets

Other prepaid expenses and current assets consist of the following:

	December 31, 2024	December 31, 2023
Prepaid API	$ 1,039,494	$ —
Commercial	666,288	171,393
FDA filing fee	449,558	—
Medical affairs	412,118	—
Subscriptions	409,774	466,114
Insurance	342,172	126,616
Clinical	70,564	—
Other	91,900	118,091
Total	$ 3,481,868	$ 882,214

Note 5 — Accrued Expenses:

Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2024	2023
Accrued gross-to-net-deductions	$ 21,860,335	$ —
Accrued payroll and payroll taxes	6,530,469	2,718,770
License agreement payable	2,000,000	—
Professional and consulting fees	865,413	2,270,022
Manufacturing related	572,959	1,835,101
Other	122,357	146,324
Total	$ 31,951,533	$ 6,970,217

Note 6 — Income Taxes:

The Company's U.S. and foreign loss before income taxes are set forth below:

	December 31,	
	2024	2023
United States	$ (19,065,449)	$ (45,946,020)
Foreign	(259,341)	(393,207)
Total	$ (19,324,790)	$ (46,339,227)

There were no current or deferred income tax provision for the years ended December 31, 2024 and 2023 because the Company has incurred operating losses since inception.

Note 6 — Income Taxes: (cont.)

The Company's deferred tax assets consist of the following:

	December 31,	
	2024	2023
Net operating loss carryforwards – Federal	$ 55,778,000	$ 53,614,000
Net operating loss carryforwards – State	2,820,000	4,603,000
Net operating loss carryforwards – Foreign	10,000	6,000
Capitalized licensing fees	86,000	165,000
Stock-based compensation	2,976,000	6,151,000
Accrued compensation	1,601,000	720,000
Section 174 capitalization	5,159,000	5,522,000
Other	738,000	(4,000)
Totals	69,168,000	70,777,000
Less valuation allowance	(69,168,000)	(70,777,000)
Deferred tax assets	$ —	$ —

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The net change in the total valuation allowance for the year ended December 31, 2024 was $1,609,000.

The Company had the following potentially utilizable net operating loss tax carryforwards:

	December 31,	
	2024	2023
Federal	$ 265,610,000	$ 255,306,000
State	$ 41,090,000	$ 64,738,000
Foreign	$ 38,000	$ 25,000

Approximately $113,600,000 of net operating losses generated will expire in 2026 through 2037 for Federal purposes whereas the operating losses for state purposes will expire between 2043 and 2044. The Tax Cuts and Jobs Act of 2017 (the "Act") limits the net operating loss deduction to 80% of taxable income for losses arising in tax years beginning after December 31, 2017. However, the net operating losses now have an indefinite carryforward as opposed to the former 20-year carryforward. The foreign net operating loss tax carryforwards do not expire. Our federal and state operating loss carryforwards include windfall tax deductions from stock option exercises.

The Company's foreign earnings, if any, are derived from its German and Spanish subsidiaries. The Company does not expect any foreign earnings to be repatriated in the U.S. in the near future. The winding down of its operations in the EU is ongoing and there was no income during the year ended December 31, 2024.

The Company's effective tax rate varied from the statutory rate as follows:

	December 31,	
	2024	2023
Statutory federal tax rate	21.0%	21.0%
State income tax rate (net of federal)	(11.3)%	8.7%
Change in foreign NOL	(0.3)%	(0.2)%
Stock compensation prior year true-up	(6.8)%	—
Stock compensation	(7.6)%	—
Sale of NJ NOL	7.2%	0.0%
Deferred only adjustment	(0.1)%	0.0%
Other permanent differences	(2.7)%	(1.4)%
Effect of valuation allowance	7.8%	(28.1)%
Effective tax rate	7.2%	0.0%

Note 6 — Income Taxes: (cont.)

In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income of the appropriate character during the periods in which those temporary differences become deductible and the loss carryforwards are available to reduce taxable income. In making its assessment, the Company considered all sources of taxable income including carryback potential, future reversals of existing deferred tax liabilities, prudent and feasible tax planning strategies, and lastly, objectively verifiable projections of future taxable income exclusive of reversing temporary differences and carryforwards. At December 31, 2024 and 2023, the Company maintained a full valuation allowance against its net deferred tax assets. The Company will continue to assess all available evidence during future periods to evaluate the realization of its deferred tax assets.

The following table presents the changes in the deferred tax asset valuation allowance for the periods indicated:

Year Ended	Balance at Beginning of Year	Increase (Decrease) Charged (Credited) to Income Taxes (Benefit)	Increase (Decrease) Charged (Credited) to OCI	Balance at End of Year
December 31, 2024	$ 70,777,000	$ (1,574,000)	$ (35,000)	$ 69,168,000
December 31, 2023	$ 57,761,000	$ 13,050,000	$ (34,000)	$ 70,777,000

Accounting for uncertainty in income taxes requires uncertain tax positions to be classified as non-current income tax liabilities unless they are expected to be paid within one year. The Company has concluded that there are no uncertain tax positions requiring recognition in its consolidated financial statements as of December 31, 2024 and 2023. The Company recognizes interest and penalties related to uncertain tax positions if any as a component of income tax expense.

The Company files U.S. federal and state returns. The Company's foreign subsidiary also files a local tax return in their local jurisdiction. From a U.S. federal, state and local perspective the years that remain open to examination are consistent with each jurisdiction's statute of limitations.

During the year ended December 31, 2024, the Company received approximately $1,395,000, net of expenses, from the sale of its unused New Jersey net operating losses (NOL), that was eligible for sale under the State of New Jersey's Economic Development Authority's New Jersey Technology Business Tax Certificate Transfer program (NJEDA Program). The NJEDA Program allowed the Company to sell its available NOL tax benefits for the state fiscal year 2023 in the amount of approximately $1,500,000. During the year ended December 31, 2023 the Company did not sell any of its unused NOL.

Note 7 — Commitments and Contingencies:

Contingency Matters

In re CorMedix Inc. Securities Litigation, *Case No. 2:21-cv-14020 (D.N.J.)*

On October 13, 2021, the United States District Court for the District of New Jersey consolidated into In re CorMedix Inc. Securities Litigation, Case No. 2:21-cv 14020-JXN-CLW, two putative class action lawsuits filed on or about July 22, 2021 and September 13, 2021, respectively, and appointed lead counsel and lead plaintiff, a purported stockholder of the Company. The lead plaintiff filed a consolidated amended class action complaint on December 14, 2021, alleging violations of Sections 10(b) and 20(a) of the Exchange Act, along with Rule 10b-5 promulgated thereunder, and Sections 11 and 15 of the Securities Act of 1933. On October 10, 2022, the lead plaintiff filed a second amended consolidated complaint that superseded the original complaints in In re CorMedix Securities Litigation. On March 21, 2024, the court denied Defendant's motion to dismiss without prejudice and granted lead plaintiff leave to amend the complaint. On April 22, 2024, lead plaintiff filed a third amended consolidated complaint that superseded the second amended consolidated complaint. In the third amended complaint, the lead plaintiff seeks to represent a class

Note 7 — Commitments and Contingencies: (cont.)

of shareholders who purchased or otherwise acquired CorMedix securities between October 16, 2019 and August 8, 2022, inclusive. The third amended complaint names as defendants the Company and six (6) current and former officers of CorMedix, namely Khoso Baluch, Robert Cook, Matthew David, Phoebe Mounts, John L. Armstrong, and Joseph Todisco (the "Officer Defendants" and collectively with CorMedix, the "CorMedix Defendants"). The third amended complaint alleges that the CorMedix Defendants violated Section 10(b) of the Exchange Act (and Rule 10b-5) and that the Officer Defendants violated Section 20(a). In general, the purported bases for these claims are allegedly false and misleading statements and omissions related to the NDA submissions to the FDA for DefenCath, subsequent complete response letters, as well as communications from the FDA related and directed to the Company's contract manufacturing organization and heparin supplier. The Company intends to vigorously contest such claims. The Company filed its motion to dismiss the third amended complaint on June 6, 2024, and received from Plaintiffs their opposition to the Company's motion to dismiss on July 22, 2024. The Company filed its response on August 21, 2024.

In re CorMedix Inc. Derivative Litigation, *Case No. 2:21-cv-18493-JXN-LDW (D.N.J.)*

On or about October 13, 2021, a purported shareholder, derivatively and on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the District of New Jersey, in a case entitled Voter v. Baluch, et al., Case No. 2:21-cv-18493-JXN-LDW (the "Derivative Litigation"). The complaint names as defendants Khoso Baluch, Janet Dillione, Alan W. Dunton, Myron Kaplan, Steven Lefkowitz, Paulo F. Costa, Greg Duncan, Matthew David, Phoebe Mounts and Joseph Todisco along with the Company as Nominal Defendant. The complaint alleges breaches of fiduciary duties, abuse of control, and waste of corporate assets against the defendants and a claim for contribution for purported violations of Sections 10(b) and 21D of the Exchange Act against certain defendants. The individual defendants intend to vigorously contest such claims. On January 21, 2022, pursuant to a stipulation between the parties, the Court entered an order staying the case while the motion to dismiss the class action lawsuit described in the foregoing paragraph is pending. The stay may be terminated before the motion to dismiss is resolved according to certain circumstances described in the stipulation available on the Court's public docket.

On or about January 13, 2023, another purported shareholder, derivatively and on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the District of New Jersey, in a case entitled *DeSalvo v. Costa, et al.*, Case No. 2:23-cv-00150-JXN-CLW. Defendants Paulo F. Costa, Janet D. Dillione, Greg Duncan, Alan Dunton, Myron Kaplan, Steven Lefkowitz, Joseph Todisco, Khoso Baluch, Robert Cook, Matthew David, Phoebe Mounts, and John L. Armstrong along with the Company as Nominal Defendant. The complaint alleges breaches of fiduciary duty and unjust enrichment against the individual defendants.

On or about January 25, 2023, another purported shareholder, derivatively and on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the District of New Jersey, in a case entitled *Scullion v. Baluch, et al.*, Case No. 2:23-cv-00406-ES-ESK. Defendants Khoso Baluch, Janet Dillione, Alan W. Dunton, Myron Kaplan, Steven Lefkowitz, Paulo F. Costa, Gregory Duncan, Matthew David, and Phoebe Mounts, along with the Company as Nominal Defendant. The complaint alleges breaches of fiduciary duties.

On or about April 18, 2023, the Court entered an order consolidating the above-mentioned shareholder derivative complaints for all purposes, including pretrial proceedings, trial and appeal. The consolidated derivative action is entitled, *In re CorMedix Inc. Derivative Litigation*, C.A. No. 2:21-cv-18493-JXN-LDW. The individual defendants intend to vigorously contest the claims set forth in the consolidated derivative action. The provisions of the Order to Stay entered in the *Voter* Action on January 21, 2022, apply to the consolidated derivative action. On April 20, 2023, the consolidated derivative action was administratively terminated and removed from the Court's docket until the motion to dismiss the class action is resolved and the Private Securities Litigation Reform Act, or PSLRA, stay is lifted. On April 22, 2024, the lead plaintiff in the class action filed a third amended complaint. The class action remains stayed under the PSLRA.

Note 7 — Commitments and Contingencies: (cont.)

Demand Letter

On or about June 23, 2022, the Company's Board received a letter demanding it investigate and pursue causes of action, purportedly on behalf of the Company, against certain current and former directors, officers, and/or other employees of the Company (the "Letter"), which the Board believes are duplicative of the claims already asserted in the Derivative Litigation. As set forth in the Board's response to the Letter, the Board will consider the Letter at an appropriate time, as circumstances warrant, as it continues to monitor the progress of the Derivative Litigation.

Commitments

License and Assignment Agreement

In 2008, the Company entered into a License and Assignment Agreement (the ND License Agreement) with ND Partners, LLP (NDP). Pursuant to the ND License Agreement, NDP granted the Company exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the NDP Technology). As consideration in part for the rights to the NDP Technology, upon execution of the ND License Agreement, the Company paid NDP an initial licensing fee of $325,000 and granted NDP a 5% equity interest in the Company, consisting of 7,996 shares of the Company's common stock.

Under the ND License Agreement, the Company is required to make cash and equity payments to NDP upon the achievement of certain milestones. In 2014, a certain milestone was achieved resulting in the release of 7,277 shares held in escrow. As of December 31, 2022, the shares remaining in escrow were cancelled in accordance with the terms of the escrow agreement. Under the ND License Agreement, the maximum aggregate amount of cash payments due upon achievement of applicable milestones was $2,500,000, with the balance being $2,000,000 as of December 31, 2024 and 2023. The initial licensing fee of $325,000, the fair value of the 5% equity interest (7,996 shares of the Company's common stock) and an additional $500,000, as a result of the achievement of one milestone, were recognized on the Company's statement of operations in R&D in prior periods, as the related milestones were achieved by the Company prior to the FDA approval. During the year ended December 31, 2024, the Company determined it was probable that the net sales milestones would be achieved in future periods and, as a result, the Company recorded a license intangible asset of $2,000,000 and a license agreement liability of $2,000,000, which is included within accrued expenses in the Company's consolidated balance sheet as of December 31, 2024. These sales milestones were met during the year ended December 31, 2024. The Company anticipates payment will be due in accordance with the agreement terms at the end of the twelve month period post attainment.

Beginning in the second quarter of 2024, the license intangible asset is amortized as cost of goods sold over its estimated economic life of approximately 10 years. The amortization start period correlates with the product launch of DefenCath and the first period in which revenue will be recognized. Amortization expense of approximately $156,000 was recorded during the year ended December 31, 2024.

The ND License Agreement will expire on a country-by-country basis upon the earlier of (i) the expiration of the last patent claim under the ND License Agreement in a given country, or (ii) the payment of all milestone payments. Upon the expiration of the ND License Agreement in each country, we will have an irrevocable, perpetual, fully paid-up, royalty-free exclusive license to the NDP Technology in such country. The ND License Agreement also may be terminated by NDP if the Company materially breaches or defaults under the ND License Agreement and that breach is not cured within 60 days following the delivery of written notice to the Company, or by the Company on a country-by-country basis upon 60 days prior written notice in the event the Company's Board determines not to proceed with the development of the NDP Technology. If the ND License Agreement is terminated by either party, the Company's rights to the NDP Technology will revert back to NDP.

Note 7 — Commitments and Contingencies: (cont.)

Other

In December 2024, the Company entered into a project agreement with Syneos Health Commercial Services, LLC ("Syneos") where Syneos will provide a field force of sales representatives to provide certain sales operations services, compliance services and training services with respect to DefenCath to us in exchange for an up-front implementation fee and a fixed monthly fee. The term of the agreement is 3 years and is cancelable provided 60 days written notice, upon the twelve-month anniversary of the deployment date, which has yet to be determined as of the filing of this Form 10-K. As of December 31, 2024, the minimum amount committed totals $9.6 million.

The Company entered into a seven-year operating lease agreement in March 2020 for an office space at 300 Connell Drive, Berkeley Heights, New Jersey 07922. The lease agreement, with a monthly average cost of approximately $17,000, commenced on September 16, 2020.

Note 8 — Stockholders' Equity:

Common Stock:

On June 28, 2023, the Company entered into an underwriting agreement (the "Underwriting Agreement") with RBC Capital Markets, LLC and Truist Securities, Inc., as representatives of the several underwriters named therein, relating to the issuance and sale of an aggregate of 7,500,000 shares of the Company's common stock, and in lieu of common stock to certain investors, pre-funded warrants to purchase 2,500,625 shares of common stock to the underwriters. Pursuant to the Underwriting Agreement, the Company also granted the underwriters a 30-day option to purchase up to 1,500,093 additional shares of common stock. The offering pursuant to the 2021 Shelf Registration Statement closed on July 3, 2023. Upon closing, the Company issued and sold an aggregate of 7,500,000 shares of its common stock at a public offering price of $4.00 per share and, in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 2,500,625 shares of its commons stock at a price of $3.999 per pre-funded warrants. The Company realized net proceeds of approximately $37,300,000 from the sale of its common stock and the pre-funded warrants. On July 26, 2023, the underwriters' representatives fully exercised the option to purchase additional shares of the Company's common stock, and on July 28, 2023, the Company issued and sold an aggregate of 1,500,093 shares of its common stock at the public offering price of $4.00 per share, less underwriting discounts and commissions, and the Company realized net proceeds of approximately $5,600,000. In October 2024, the pre-funded warrants were exercised resulting in the issuance of 2,500,625 shares of common stock by the Company. Due to the pricing of the pre-funded warrants, net proceeds related to this transaction are de minimis.

On May 9, 2024, the Company filed a shelf registration statement (the "2024 Shelf Registration Statement") for the issuance of up to $150,000,000 of Company securities. Also on May 9, 2024, the Company entered into an At-The-Market Issuance Sales Agreement with Leerink Partners LLC, as sales agent, pursuant to which the Company may sell, from time to time, an aggregate of up to $50,000,000 of its common stock through the sales agents under the 2024 Shelf Registration Statement, subject to limitations imposed by the Company and subject to the sales agent's acceptance (the "2024 ATM program"). The sales agent is entitled to a commission of up to 3% of the gross proceeds from the sale of common stock sold under the 2024 ATM program. As of December 31, 2024, the Company sold an aggregate of 3,049,878 shares of its common stock under the 2024 ATM program and realized an aggregate net proceeds of approximately $18,900,000. Approximately $30,216,000 of the Company's common stock remains available for sale under its 2024 ATM program, with $100,000,000 of capacity remaining under its 2024 Shelf Registration Statement for the issuance of Company securities.

During the year ended December 31, 2023, the Company sold an aggregate 2,977,637 shares of its common stock under the Company's previous at-the-market program, realizing net proceeds of approximately $12,900,000.

During the year ended December 31, 2024 and 2023, the Company issued an aggregate of 1,357,802 and 79,041 shares of its common stock upon exercise of stock options, resulting in net proceeds to the Company of approximately $7,724,000 and $288,000, respectively.

Note 8 — Stockholders' Equity: (cont.)

In December 2024, 44,999 shares of Series G preferred stock were converted to 2,502,005 shares of common stock.

Restricted Stock Units

During the year ended December 31, 2024 and 2023, the Company granted 283,333 and 50,000 restricted stock units (RSUs), respectively, to its executive officers under its Amended and Restated 2019 Omnibus Stock Incentive Plan with a weighted average grant date fair value of $3.47 and $3.30 per share, respectively. The fair market value of the RSUs was estimated to be the closing price of the Company's common stock on the date of grant. The RSUs issued during the year ended December 31, 2024 vest 25% on the grant date and 25% each on the first, second and third anniversaries of the grant date, subject to continued service as an employee or consultant through the applicable vesting date. During the year ended December 31, 2024, the Company issued 42,844 shares upon the vesting of 25% of these RSUs on the grant date and 27,989 shares were withheld in lieu of withholding taxes. The RSUs issued during the year ended December 31, 2023 vest over four years in four equal installments on the first four anniversaries of the applicable grant date, subject to continued service as an employee or consultant through the applicable vesting date. In December 2024, 12,500 of these RSUs vested which resulted in the issuance of 6,456 shares of common stock and 6,044 shares were withheld in lieu of withholding taxes.

During the year ended December 31, 2024 and 2023, 62,241 and 103,734 RSUs vested, respectively, pursuant to a grant made to the Company's chief executive officer in May 2022, of which 35,259 and 66,291 shares of common stock were issued by the Company, respectively, and 26,982 and 37,443 shares, respectively, were withheld in lieu of withholding taxes.

The Company recorded $690,000 and $262,000 compensation expense for the year ended December 31, 2024 and 2023, respectively. As of December 31, 2024, unrecognized compensation expense for RSUs amounted to $671,000 and the expected weighted average period for the expense to be recognized is 1.5 years. As of December 31, 2024, the Company had 291,494 outstanding RSUs.

Preferred Stock

The Company is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without stockholder approval. The Company's board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. Of the 2,000,000 shares of preferred stock authorized, the Company's board of directors has designated (all with par value of $0.001 per share) the following:

	As of December 31, 2024			As of December 31, 2023		
	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference
Series C-3	2,000	$ 10.00	20,000	2,000	$ 10.00	$ 20,000
Series E	89,623	$ 49.20	4,409,452	89,623	$ 49.20	$ 4,409,452
Series G	45,000	$ 187.36	8,431,200	89,999	$ 187.36	$ 16,862,213
Total	136,623		12,860,652	181,622		$ 21,291,665

The following rights, privileges, terms and conditions apply to the outstanding preferred stock at December 31, 2024:

Series C-3 Non-Voting Preferred Stock

Rank. The Series C-3 non-voting preferred stock will rank senior to our common stock; senior to any class or series of capital stock created after the issuance of the Series C-3 non-voting preferred stock; and junior to the Series E voting convertible preferred stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Note 8 — Stockholders' Equity: (cont.)

Conversion. Each share of Series C-3 preferred stock is convertible into 2 shares of our common stock (subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, or reclassifications affecting our common stock) at a per share price of $5.00 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series C-3 preferred stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of Series C-3 preferred stock will receive a payment equal to $10.00 per share of Series C-3 preferred stock before any proceeds are distributed to the holders of our common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series C-3 preferred stock and holders of Series C-3 preferred stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

Voting Rights. Shares of Series C-3 preferred stock will generally have no voting rights, except as required by law and except that the consent of holders of two thirds of the outstanding Series C-3 preferred Stock will be required to amend the terms of the Series C-3 preferred stock or the certificate of designation for the Series C-3 preferred stock.

Dividends. Holders of Series C-3 preferred stock are entitled to receive, and we are required to pay, dividends on shares of the Series C-3 preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series C-3 preferred stock. Shares of Series C-3 preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing. There is no established public trading market for the Series C-3 preferred stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series C-3 preferred stock on any national securities exchange or trading system.

Fundamental Transactions. If, at any time that shares of Series C-3 preferred stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series C-3 preferred stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

Series E Voting Convertible Preferred Stock

Rank. The Series E voting preferred stock will rank senior to our common stock; senior to any class or series of capital stock created after the issuance of the Series E voting convertible preferred stock; senior to the Series C-3 non-voting convertible preferred stock; and on parity with the Series G voting convertible preferred stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion. Each share of Series E preferred stock is convertible into 4.3733 shares of our common stock (subject to adjustment as provided in the certificates of designation for the Series E preferred stock) at a per share price of $3.75 at any time at the option of the holder, except that a holder will be prohibited from converting shares

Note 8 — Stockholders' Equity: (cont.)

of Series E preferred stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 4.99% of the total number of shares of our common stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of Series E preferred stock will receive a payment equal to $49.20 per share of Series E preferred stock on parity with the payment of the liquidation preference due the Series G preferred stock, but before any proceeds are distributed to the holders of common stock, and the Series C-3 non-voting convertible preferred stock. After the payment of this preferential amount, holders of Series E preferred stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock that participates with the common stock in such distributions.

Voting Rights. Shares of Series E preferred stock are entitled to vote on an as-converted basis, based upon an assumed conversion price of $7.93.

Dividends. Holders of Series E preferred stock are entitled to receive, and we are required to pay, dividends on shares of the Series E preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series E preferred stock. Shares of Series E preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing. There is no established public trading market for the Series E preferred stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series E preferred stock on any national securities exchange or trading system.

Fundamental Transactions. If, at any time that shares of Series E preferred stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series E preferred stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

Debt Restriction. As long as any of the Series E preferred stock is outstanding, we cannot create, incur, guarantee, assume or suffer to exist any indebtedness, other than (i) trade payables incurred in the ordinary course of business consistent with past practice, and (ii) up to $10 million aggregate principal amount of indebtedness with a maturity less than twelve months outstanding at any time, which amount may include up to $5 million of letters of credit outstanding at any time.

Other Covenants. In addition to the debt restrictions above, as long as any of the Series E preferred stock is outstanding, we cannot, among others things: create, incur, assume or suffer to exist any encumbrances on any of our assets or property; redeem, repurchase or pay any cash dividend or distribution on any of our capital stock (other than as permitted, which includes the dividends on the Series E preferred stock and Series G preferred stock); redeem, repurchase or prepay any indebtedness (other than as permitted); or engage in any material line of business substantially different from our current lines of business.

Purchase Rights. In the event we issue any options, convertible securities or rights to purchase stock or other securities pro rata to the holders of common stock, then a holder of Series E preferred stock will be entitled to acquire, upon the same terms a pro rata amount of such stock or securities as if the Series E preferred stock had been converted to common stock.

Note 8 — Stockholders' Equity: (cont.)

Series G Voting Convertible Preferred Stock

Rank. The Series G voting convertible preferred stock will rank senior to our common stock; senior to any class or series of capital stock created after the issuance of the Series G voting convertible preferred stock; junior to the Series C-3 non-voting convertible preferred stock, pending the consent of the holders of such series to the subordination thereof; and on parity with the Series E voting convertible preferred stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion. Each share of Series G preferred stock is convertible into approximately 55.5978 shares of our common stock (subject to adjustment as provided in the certificate of designation for the Series G preferred stock) at a per share price of $3.37 at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series G preferred stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 4.99% of the total number of shares of our common stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of Series E preferred stock will receive a payment equal to $187.36452 per share of Series G preferred stock on parity with the payment of the liquidation preference due the Series E preferred stock, but before any proceeds are distributed to the holders of Series C-3 preferred stock (pending the consent of the holders of such series to the subordination thereof) and any proceeds are distributed to the holders of common stock. After the payment of this preferential amount, holders of Series G preferred stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock that participates with the common stock in such distributions.

Voting Rights. Shares of Series G preferred stock are entitled to vote on an as-converted basis, based upon an assumed conversion price of $7.93.

Dividends. Holders of Series G Preferred stock are entitled to receive, and we are required to pay, dividends on shares of the Series G preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series G preferred stock. Shares of Series G preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing. There is no established public trading market for the Series G preferred stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series G preferred stock on any national securities exchange or trading system.

Fundamental Transactions. If, at any time that shares of Series G preferred stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series G preferred stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of a share of common stock.

Debt Restriction. As long as any of the Series G preferred stock is outstanding, we cannot create, incur, guarantee, assume or suffer to exist any indebtedness, other than (i) trade payables incurred in the ordinary course of business consistent with past practice, and (ii) up to $10 million aggregate principal amount of indebtedness with a maturity less than twelve months outstanding at any time, which amount may include up to $5 million of letters of credit outstanding at any time.

Note 8 — Stockholders' Equity: (cont.)

Other Covenants. In addition to the debt restrictions above, as long as any of the Series G preferred stock is outstanding, we cannot, among others things: create, incur, assume or suffer to exist any encumbrances on any of our assets or property; redeem, repurchase or pay any cash dividend or distribution on any of our capital stock (other than as permitted, which includes the dividends on the Series E preferred stock and the Series G preferred stock); redeem, repurchase or prepay any indebtedness (other than as permitted); or engage in any material line of business substantially different from our current lines of business.

Purchase Rights. In the event we issue any options, convertible securities or rights to purchase stock or other securities pro rata to the holders of common stock, then a holder of Series G preferred stock will be entitled to acquire, upon the same terms a pro rata amount of such stock or securities as if the Series G preferred stock had been converted to common stock.

Stock Options:

On October 13, 2022, the Company's shareholders approved the CorMedix Inc. Amended and Restated 2019 Omnibus Stock Incentive Plan (the "2022 Plan"), pursuant to which the Company may issue as additional 4,800,000 shares of its common stock, respectively, plus any shares that remain available for grant under its existing plan as of the effective date, as long-term equity incentives to the Company's employees, consultants, and directors. On November 21, 2024, the Company's shareholders approved Amendment No. 1 to the 2022 Plan, which increased the number of shares authorized for issuance by an additional 3,360,000 shares. The long-term incentives may be in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, dividend equivalent rights, or other rights or benefits (collectively, "stock rights") to employees, consultants, and directors of the Company or a related entity (collectively, "participants"). The Company believes that the effective use of long- term equity incentives is essential to attract, motivate, and retain employees, consultants and directors, to further align participants' interests with those of the Company's stockholders, and to provide participants incentive compensation opportunities that are competitive with those offered by other companies in the same industry and locations as the Company.

The 2022 Plan amends and restates the 2019 Stock Incentive Plan. The 2013 Stock Incentive Plan and the Amended and Restated 2006 Stock Incentive Plan are referred to collectively as the "Prior Plans." No further awards will be granted under the Prior Plans. Awards outstanding under the Prior Plans will remain outstanding in accordance with their terms and the Prior Plans.

During the years ended December 31, 2024 and 2023, the Company granted ten-year qualified and non-qualified stock options to its officers, directors, employees and consultants covering an aggregate of 2,196,167 and 2,536,200 shares of the Company's common stock under the 2019 Plan, respectively. The weighted average exercise price of these options is $3.80 and $4.18 per share, respectively.

During the years ended December 31, 2024 and 2023, the Company issued 1,357,802 and 79,041 shares of common stock, respectively, as a result of the exercise of stock options. The Company realized net proceeds of $7,724,000 and $288,000, respectively, from the exercise of stock options with a weighted average exercise price of $5.69 and $3.64 per share, respectively.

During the years ended December 31, 2024 and 2023, total compensation expense for stock options issued to employees, directors, officers and consultants was $5,439,000 and $5,232,000, respectively. As of December 31, 2024, there was $6,363,000 total unrecognized compensation expense related to unvested stock options granted which expense is expected to be recognized over an expected remaining weighted average period of 1.4 years. All share-based awards are recognized on a straight-line method, assuming all awards granted will vest. Forfeitures of share-based awards are recognized in the period in which they occur.

Note 8 — Stockholders' Equity: (cont.)

The fair value at grants dates of the grants issued subject to service and performance-based vesting conditions were determined using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,	
	2024	2023
Risk-free interest rate	3.60% – 4.65%	3.45% – 4.81%
Expected volatility	93.2% – 100.5%	92.2% – 105.7%
Average Expected term (years)	6 years	5 years
Expected dividend yield	0.0%	0.0%
Weighted-average grant date fair value of options granted during the period	$ 3.04	$ 3.24

The Company estimated the expected term of the stock options granted based on anticipated exercises in future periods. The expected term of the stock options granted to consultants, if any, is based upon the full term of the respective option agreements. The expected stock price volatility for the Company's stock options is calculated based on the historical volatility of the Company's common stock. The expected dividend yield of 0.0% reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards.

The following table summarizes the Company's stock options activity and related information for the year ended December 31, 2024:

	Shares Underlying Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2023	6,211,508	$ 5.44	6.4	$ 700,241
Granted	2,196,167	$ 3.80	—	$ —
Exercised	(1,357,802)	$ 5.69	—	$ 3,750,304
Expired/Canceled	(418,932)	$ 12.27	—	$ —
Forfeited	(348,548)	$ 3.68	—	$ —
Outstanding at December 31, 2024	6,282,393	$ 4.46	7.8	$ 23,567,676
Vested at December 31, 2024	3,377,378	$ 4.91	7.1	$ 11,415,702
Expected to vest in the future	2,905,015	$ 3.93	8.6	$ 12,151,975

The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying options and the quoted closing price of the common stock of the Company at the end of the reporting period for those options that have an exercise price below the quoted closing price.

Stock-based Deferred Compensation Plan for Non-Employee Directors

In 2014, the Company established an unfunded stock-based deferred compensation plan, providing non-employee directors the opportunity to defer up to one hundred percent of fees and compensation, including restricted stock units. The amount of fees and compensation deferred by a non-employee director is converted into stock units, the number of which is determined based on the closing price of the Company's common stock on the date such compensation would have otherwise been payable. At all times, the plan participants are one hundred percent vested in their respective deferred compensation accounts. On the tenth business day of January in the year following a director's termination of service, the director will receive a number of common shares equal to the number of stock units accumulated in the director's deferred compensation account. The Company accounts for this plan as stock-based compensation under ASC 718. During the years ended December 31, 2024 and 2023 no compensation was deferred under this plan.

Note 9 — Leases:

The Company entered into a seven-year operating lease agreement in March 2020 for an office space at 300 Connell Drive, Berkeley Heights, New Jersey 07922. The lease agreement, with a monthly average cost of approximately $17,000 commenced on September 16, 2020.

The Company entered into an operating lease for office space in Germany that began in July 2017. The rental agreement has a three-month term which automatically renews and includes a monthly cost of 400 Euros. The operating lease was terminated in June 2024.

Operating lease expense in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2024 and 2023 was approximately $204,000 and $207,000, respectively, which includes costs associated with leases for which ROU assets have been recognized as well as short-term leases.

At December 31, 2024, the Company has a total operating lease liability of $517,000, of which approximately $168,000 and $349,000 were classified as operating lease liabilities, short-term and operating lease liabilities, net of current portion, respectively, on the consolidated balance sheet. At December 31, 2023, the Company's total operating lease liability was $668,000, of which $151,000 was classified as operating lease liabilities, short-term and $517,000 was classified as operating lease liabilities, net of current portion, on the consolidated balance sheet. Operating ROU assets as of December 31, 2024 and 2023 are $493,000 and $640,000, respectively.

For the years ended December 31, 2024 and 2023, cash paid for amounts included in the measurement of lease liabilities in operating cash flows from operating leases was $205,000 and $201,000, respectively.

As of December 31, 2024 and 2023, the weighted average remaining lease term were 2.8 years and 3.8 years, respectively, and the weighted average discount rate of 9% at December 31, 2024 and 2023.

As of December 31, 2024, maturities of lease liabilities were as follows:

2025	208,000
2026	211,000
2027	169,000
Total future minimum lease payments	588,000
Less imputed interest	(71,000)
Total	$ 517,000

Note 10 — Segment Reporting

As noted above, the Company's primary focus is the commercialization of our lead product, DefenCath indicated to reduce the incidence of catheter-related bloodstream infections in adult patients with kidney failure receiving chronic hemodialysis through a CVC.

The Company has determined that it currently operates in a single segment — Drug Product, located in a single geographic location — the United States. The accounting policies of the segment are the same as those described in the summary of significant accounting policies. Since the Company operates in a single segment, the measure of segment total assets and loss from operations is the same as that reported on the accompanying balance sheets as total assets, and the accompanying statement of operations as loss from operations, respectively.

Note 10 — Segment Reporting (cont.)

The Company's Chief Executive Officer is the Chief Operating Decision Maker ("CODM"). The CODM manages the Company's business activities as a single operating and reportable segment. The CODM uses consolidated profit and loss to evaluate and measure performance against progress in its commercialization efforts and clinical trials. The following table sets forth significant segment expenses.

	December 31,	
	2024	2023
Research and development:		
Employee expense	$ 2,454,650	$ 7,210,785
Other research and development	1,487,620	5,944,341
Total research and development	3,942,270	13,155,125
Selling and marketing		
Employee expense	$ 13,493,663	$ 2,552,846
Other selling and marketing	15,242,942	15,562,467
Total selling and marketing expense	28,736,605	18,115,313
General and administrative		
Employee expense	$ 18,321,459	$ 10,961,034
Other general and administrative	11,637,691	6,726,316
Total general and administrative expense	29,959,150	17,687,350
Total operating expenses	$ 62,638,025	$ 48,957,788

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