

**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, 2025**

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-34673

**CORMEDIX INC.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**20-5894890**

(I.R.S. Employer  
Identification No.)

**389 Interpace Pkwy, Suite 450**

**Parsippany, NJ**

(Address of Principal Executive Offices)

**07054**

(Zip Code)

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

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

<b>Title of each class</b>	<b>Trading Symbol</b>	<b>Name of each exchange on which registered</b>
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

Non-accelerated filer

Emerging growth company

Accelerated filer

Smaller reporting company

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 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 \$909.7 million.

The number of outstanding shares of the registrant's common stock was 79,050,395 as of March 2, 2026.

**DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the registrant's definitive Proxy Statement to be issued in conjunction with the registrant's 2026 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2025, 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.**  
**2025 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,” “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](http://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 has been commercializing DefenCath® (taurolidine and heparin), in the U.S., which we launched in 2024 in the hemodialysis setting. The name DefenCath is the U.S. proprietary name approved by the U.S. Food and Drug Administration (“FDA”).

On August 29, 2025, the Company acquired Melinta Therapeutics, LLC, a Delaware limited liability company (“Melinta”), which expanded the Company’s team, commercial platform and increased the commercial portfolio with six marketed, hospital- and clinic-focused infectious disease products, comprised of REZZAYO® (rezafungin for injection), MINOCIN® (minocycline) for Injection (“MINOCIN IV”), VABOMERE® (meropenem and vaborbactam), KIMYRSA® (oritavancin), ORBACTIV® (oritavancin), and BAXDELA® (delafloxacin), as well as an additional well-established cardiovascular product, TOPROL-XL® (metoprolol succinate) (together, the “Melinta Portfolio,” and, together with DefenCath, “our Products”). The Melinta Portfolio supports a multi-channel strategy of delivering anti-infectives for serious gram-positive, gram-negative and fungal infections within hospitals and the hospital ecosystem, including emergency departments, outpatient clinics and home infusion care, and provides synergy opportunities to drive growth for DefenCath.

#### Business Strategy

Our corporate strategy is focused on increasing stockholder value by maximizing the value of our current portfolio, with promotional efforts focused on DefenCath, REZZAYO, MINOCIN IV and VABOMERE. In addition, we seek to create additional value through the pursuit of expanded indications for both DefenCath, for the reduction of central line associated bloodstream infection (“CLABSI”) in adult patients receiving total parental nutrition (“TPN”), and REZZAYO in the prophylaxis of invasive fungal infections in adult patients that are immune compromised. We also engage in the pursuit of business development opportunities that could be highly synergistic with our existing or future sales infrastructure deployment.

#### Promoted Commercial Products

##### *DefenCath*

On November 15, 2023, we announced that the FDA approved the new drug application (“NDA”) for DefenCath, an 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”). We launched DefenCath commercially in April 2024 in the inpatient setting and July 2024 in the outpatient hemodialysis setting, and it is the largest contributor to our net sales.

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 customer has customized an implementation plan to provide access to their 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*

CVCs 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 and a subset of them, referred to as CRBSIs, 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 CLABSI 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 80,000 CRBSI episodes and up to 28,000 deaths per year (Pronovost et al., *The New England Journal of Medicine*, 2006).

According to the 2025 United States Renal Disease System, reporting data from 2023, there were approximately 485,000 End-Stage-Renal-Disease (“ESRD”) patients on permanent hemodialysis in the U.S. and over 25% of these utilized a CVC for vascular access. Of the total population, approximately 108,000 hemodialysis patients were new patients diagnosed with ESRD during the year and 80% 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 and chronic kidney disease populations that progress into dialysis. Kidney failure patients who are admitted to the hospital have an average length of stay of approximately two weeks and additionally high 30-day readmission rates both for the 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. Intraluminal infections are caused by pathogens entering and proliferating within the sterile internal surfaces of the CVC and are often associated with late stages of biofilm dispersion. Biofilm build up can be 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 that may be hindered by clot formation. 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 bloodstream. 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, to prevent clotting between dialysis treatments. However, a heparin lock solution has no antimicrobial activity and thus provides no protection from the risk of infection.

Other than DefenCath, there are no pharmacologic drug products FDA-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 recipients.

DefenCath is a non-antibiotic, broad-spectrum antimicrobial and anticoagulant combination that is active against common microbes including antibiotic-resistant strains and also has a secondary mechanism of action that inhibits adherence of microorganisms to biological surfaces which is the first steps in biofilm formation. We believe that using DefenCath as an antimicrobial catheter-lock solution significantly reduces the incidence of life-threatening catheter-related blood stream infections, thus reducing the need for hospital admission and 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.

CRBSIs, a clinically confirmed subset of the epidemiological surveillance term, 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. 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, and as such, we believe it addresses a significant medical need. Additionally, in December 2025, we reported data from an interim analysis of a retrospective, real-world evidence (“RWE”) study that indicates a 70% reduction in annualized number of hospitalizations secondary to CRBSI, when dialysis-patient catheters are locked with DefenCath, demonstrating a significant value proposition to patients as well as to providers and payers.

### *Pricing and Reimbursement*

Sales of DefenCath depend, in large part, on the extent to which it 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. It is essential to obtain third-party payor coverage policies and adequate payment to continue to successfully commercialize DefenCath. We expect to continue 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 (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 (“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 (“NTAP”) if certain criteria are met.

The Centers for Medicare & Medicaid Services (“CMS”) issued the IPPS 2024 proposed rule that included an NTAP per-hospital stay for DefenCath. This NTAP represents reimbursement to inpatient facilities of up to 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 then 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. The NTAP for DefenCath will expire on November 14, 2026 (three years post-approval).

### *Outpatient Reimbursement*

The Medicare ESRD IPPS provides bundled payment for renal dialysis services and affords a Transitional Drug Add-on Payment Adjustment (“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 from July 1, 2024, (with such add-on payments applying to all ESRD IPPS payments for years three through five). The HCPCS J-code for DefenCath was published by CMS on April 2, 2024. DefenCath TDAPA began on July 1, 2024 and will transition into the post-TDAPA Add-On Payment phase on July 1, 2026. As a result of the methodology utilized by CMS, the level of reimbursement provided to institutions treating dialysis patients will significantly decline, and as a result, we anticipate there will be a corresponding reduction to the net pricing for DefenCath for the third and fourth quarters of 2026. The 2027 post-TDAPA add-on adjustment will be effective on January 1, 2027. If CMS utilizes the same methodology to calculate the 2027 post-TDAPA Add-On Adjustment, which will be effective on January 1, 2027, we estimate the value of the Add-On Adjustment will be three to five-times higher than that granted for the third and fourth quarters of 2026, which we expect would result in higher DefenCath sales prices in 2027 relative to the second half 2026. After January 1, 2027, the post-TDAPA Add-On Payment will be reassessed again and be made effective on January 1, 2028 and January 1, 2029, covering the three-year period through June 30, 2029. There can be no assurance that the level of reimbursement determined by CMS will improve. Further changes in these reimbursement rates could lead to significant fluctuations in our operating income and could have a negative impact on our revenues, earnings and cash flows.

CMS 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.

### *Additional Indications*

As a brand expansion opportunity, in the second quarter of 2025, we initiated a Phase 3, randomized, double-blind, adaptive, two-arm, clinical study assessing the safety and efficacy of DefenCath in reducing CLABSIs in adult patients receiving TPN via CVC. The study protocol stipulates a total of up to 200 subjects for a total of 12 months treatment, with the primary endpoint being efficacy of DefenCath as a CLS, when compared to heparin, in delaying time to CLABSI. We currently expect to complete the study in the first half of 2027.

Currently, there is no pharmaceutical standard of care for prevention of bloodstream infections for TPN patients utilizing a CVC and those patients are highly susceptible to CLABSI. CLABSIs occur in up to 26% of TPN patients with a CVC, and TPN is associated with a 4-fold increase in odds ratio for acquiring CLABSIs. In addition, CLABSIs are associated with an excess hospital length of stay of 2 to 3 weeks, and patients who develop a CLABSI are 35% to 40% more likely to be readmitted. We believe that the total addressable market for TPN is between \$500 million and \$750 million in the inpatient and home infusion settings — equating to more than 4.5 million potential infusions.

Also in 2025, we initiated our post-marketing requirement for a pediatric hemodialysis (“HD”) study. We are currently obligated by the FDA to conduct the HD study as communicated in our 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. Pediatric studies for an approved product conducted under the Pediatric Research Equity Act (the “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 an 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.

In 2024, we launched the Expanded Access Program (“EAP”) for DefenCath, which is designed to provide access to a broader population of adult and pediatric patients using CVCs for various serious medical conditions to protect their central line from serious infection. A key aspect of this EAP is its focus on individuals who, due to their unique clinical circumstances, are either ineligible for participation in ongoing clinical trials or do not meet the criteria outlined in the current approved FDA label for DefenCath.

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, and we are regularly assessing these areas. In addition, we may seek CMS reimbursement for DefenCath in other catheter indications beyond ESRD, including but not limited to through (i) relevant hospital inpatient DRGs, (ii) additional NTAP payments, or (iii) outpatient ambulatory payment classifications (“APCs”). Payment under these Medicare benefit categories is not guaranteed for these potential additional indications.

### **REZZAYO**

We acquired distribution and marketing rights to REZZAYO in the U.S. in connection with the acquisition of Melinta in August 2025. REZZAYO is a next generation, once-weekly, IV-formulation echinocandin, which was approved in the U.S. in March 2023 in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. While our licensor Napp Pharmaceutical Group Limited, a member of Mundipharma independent associated companies (“Mundipharma”), currently holds the product NDA and intellectual property rights, upon the earlier of thirty-days following the receipt of the marketing approval for the prophylaxis indication or on June 30, 2028, Mundipharma shall assign and transfer to CorMedix all rights, title and interest in and to the U.S. NDA and sNDAs for REZZAYO. See *Contractual Obligations*, included in Managements’ Discussion and Analysis included within this Annual Report, for additional details on the arrangement with Mundipharma.

### *Market Opportunity*

REZZAYO offers a convenient alternative to the standard of care, daily echinocandin dosing regimen, with its once-weekly dosing schedule, highly simplifying management of candidemia and invasive candidiasis. In practice, REZZAYO’s once-weekly intravenous dosing and efficacy compared to daily echinocandins make it attractive not

only in inpatient settings but also in outpatient patient antimicrobial therapy (“OPAT”) where clinical stability permits transition from hospital care. Available alternatives to REZZAYO include marketed echinocandins — caspofungin, micafungin, and anidulafungin — which share a similar mechanism of action and are used in first-line therapy for candidemia and invasive candidiasis, typically require once-daily intravenous dosing. Azole antifungals (e.g., posaconazole, voriconazole, isavuconazole, fluconazole) are also used for candidemia and invasive candidiasis and may be limited by clinically significant drug-to-drug interactions, tolerability considerations in complex regimens and increasing resistance in some candida species.

Candidemia and invasive candidiasis conditions are typically encountered in acute care hospitals, intensive care units (“ICUs”), and tertiary care centers where patients are critically ill, often immunocompromised, and at high risk for life-threatening fungal infections. The decision to use REZZAYO typically is made by infectious disease specialists, hospitalists, and critical care physicians managing these severe candida infections, especially in situations where daily echinocandin therapy is burdensome or where simplifying antifungal treatment is desirable. Pharmacy and therapeutics committees are also responsible for formulary decisions in hospitals and health systems evaluating antifungal treatment options that may reduce administration frequency and resource utilization without compromising clinical outcomes.

There are an estimated 25,000 cases of candidemia and 50,000 invasive candidiasis each year in the U.S., and REZZAYO is currently indicated for the treatment of such infections. We believe that the total addressable market for the treatment indication is approximately \$250 million to \$350 million.

#### *Additional Indications*

REZZAYO is currently being evaluated for the prophylaxis of invasive fungal infections in adult patients undergoing allogeneic blood and marrow transplantation (“BMT”) (“ReSPECT clinical trial”). The ReSPECT clinical trial is a Phase III, multicenter, randomized, double-blind study evaluating the efficacy and safety of once-weekly REZZAYO versus a standard antimicrobial regimen (“SAR”) for the prevention of invasive fungal diseases (“IFDs”) in adults undergoing allogeneic BMT. Participants in the experimental arm receive a 400 mg loading dose of rezafungin in week one, followed by 200 mg weekly for 13 weeks, along with oral placebos matching the SAR components. The primary endpoint is fungal-free survival at day 90, with secondary objectives including incidence of IFD, discontinuation due to toxicity, and mortality adjusted for comorbidities. This Phase III study, which is being conducted by our licensor Mundipharma, completed enrollment in September 2025, and we expect to announce top-line data in the second quarter of 2026.

In BMT settings, antifungal prophylaxis remains a critical but operationally complex component of care. Current standard options, particularly azole antifungals, are effective but introduce significant drug — drug interaction risk, often affecting conditioning chemotherapy, targeted oncology agents, and post-transplant immunosuppressants. These interactions can necessitate dose reductions, regimen modifications, and intensive therapeutic drug monitoring, increasing clinical burden and the risk of suboptimal cancer treatment delivery. Additional challenges include variable oral absorption, overlapping hepatic and cardiac toxicities, and the need for daily administration, all of which complicate care during the most vulnerable phases of transplant.

REZZAYO represents a differentiated approach to antifungal prophylaxis that directly addresses these limitations. As a once-weekly intravenous echinocandin with minimal drug — drug interaction potential, REZZAYO offers a more predictable and safer option for use alongside complex oncology and transplant regimens. Its extended half-life enables convenient dosing while preserving antifungal efficacy without requiring routine dose adjustments of concomitant therapies. By reducing interaction-driven compromises, simplifying administration, and supporting consistent prophylaxis during high-risk treatment windows, REZZAYO has the potential to meaningfully improve clinical workflow and risk management in transplant care, positioning it as a compelling alternative within the evolving antifungal prophylaxis landscape.

We believe that a prophylaxis indication of REZZAYO could be a key potential growth driver to the business. We estimate that the total addressable market for antifungal prophylaxis in the U.S. is greater than \$2 billion.

## ***MINOCIN IV***

MINOCIN IV is an intravenous formulation of a highly differentiated tetracycline-class antibiotic with safety, tolerability and strong placement in the Infectious Diseases Society of America (“IDSA”) guidelines. MINOCIN IV is indicated for the treatment of infections caused by susceptible Gram-positive and Gram-negative organisms, including *Acinetobacter* species, *Staphylococcus aureus*, *Streptococcus* species, *Escherichia coli*, *Klebsiella pneumoniae*, *Haemophilus influenzae*, *Neisseria* species, and certain atypical pathogens, and has been on the U.S. market since 2015.

### *Market Opportunity*

MINOCIN IV addresses a defined but persistent market opportunity within the U.S. hospital anti-infectives market, particularly in the treatment of serious infections where intravenous therapy is required and alternative agents may be limited by resistance, tolerability, or route of administration. Demand for hospital-administered antibiotics remains supported by the ongoing prevalence of serious infections, including multidrug-resistant, Gram-negative organisms such as *Acinetobacter baumannii*. Hospitals continue to require multiple therapeutic options to manage these infections under antimicrobial stewardship protocols, particularly when oral therapy is not appropriate and susceptibility testing supports MINOCIN IV use.

*Acinetobacter baumannii* (“CRAB”) as an “urgent” antimicrobial resistance threat in its 2019 national Antibiotic Resistance Threats in the United States report, first listing CRAB at the highest threat level due to its limited treatment options and potential to spread resistant genes. Estimates from CDC data indicate that CRAB accounted for approximately 8,500 infections and about 700 deaths annually in the United States from 2019 – 2020, with resistant strains often impervious to multiple antibiotic classes and associated with difficult-to-treat hospital-acquired infections. CDC surveillance updates during 2021 – 2022 continued to show CRAB among key healthcare-associated resistant pathogens with infection burdens rising compared to pre-pandemic levels, reflecting ongoing clinical challenges in prevention and management. The pathogen’s resistance profile and associated mortality, combined with its designation as an urgent threat by the CDC, underscore its significance as a dangerous source of drug-resistant infection in U.S. healthcare settings.

MINOCIN IV is one of the few agents approved for treatment of *Acinetobacter* species. *Acinetobacter* infections are generally seen in the ICU, particularly in mechanically ventilated and immunocompromised patients. The IDSA Guidance on the Treatment of Antimicrobial Resistant Gram-Negative Infections lists MINOCIN IV as a recommended alternative in combination therapy for the treatment of CRAB infections when susceptibility is demonstrated, reflecting its role in multidrug regimens used to manage these difficult-to-treat infections and helping address the treatment gaps identified by the CDC.

The product’s market opportunity is driven primarily by institutional purchasing decisions, local antibiograms (hospital-specific summaries of antimicrobial susceptibility data), and infectious disease specialist prescribing patterns rather than broad empiric use. While overall antibiotic utilization in hospitals is moderated by stewardship efforts, we believe that the need for differentiated IV therapies for resistant infections, treatment-limited patients, and complex clinical scenarios supports continued demand for MINOCIN IV as part of the hospital anti-infective armamentarium.

## ***VABOMERE***

VABOMERE is an IV antibiotic that is a combination of meropenem, the leading carbapenem used in treatment of gram-negative infections, and vaborbactam, a novel beta-lactamase inhibitor that inhibits certain types of resistance mechanisms used by bacteria. VABOMERE received FDA approval in August 2017, for the treatment of patients 18 years of age and older with complicated urinary tract infections (“cUTI”), including pyelonephritis, caused by designated susceptible Enterobacteriaceae. VABOMERE was specifically developed to address gram-negative bacteria that produce beta-lactamase enzymes, particularly the *Klebsiella pneumoniae* carbapenemase (“KPC”) enzyme. In addition, we have a partnership with the Biomedical Advanced Research and Development Authority (“BARDA”) to advance VABOMERE for use in pediatrics (see “Biomedical Advanced Research and Development Authority Contract” section below for further details).

## *Market Opportunity*

The market opportunity for VABOMERE is driven by the growing global prevalence of serious Gram-negative infections, particularly those caused by carbapenem-resistant Enterobacterales (“CRE”), including infections mediated by *Klebsiella pneumoniae* carbapenemase (“KPC”)–producing organisms. KPC-producing CRE are classified by the CDC to be an urgent antimicrobial resistance threat as they represent a significant and persistent subset of carbapenem resistance in the United States and are associated with high morbidity, mortality, prolonged hospital stays, and increased healthcare costs. Hospitalized patients, including those in intensive care units or with significant comorbidities, are at heightened risk for these infections and have limited treatment options, underscoring the ongoing need for effective, targeted antibacterial therapies.

VABOMERE was designed to address this unmet medical need by combining a carbapenem antibiotic with a beta-lactamase inhibitor active against KPC enzymes, which are among the most prevalent carbapenemase enzymes in the United States. The market opportunity for VABOMERE is supported by continued clinical demand for resistance-directed therapies for KPC-producing CRE, increasing use of rapid diagnostic testing to identify specific carbapenemase enzymes, and antimicrobial stewardship practices that prioritize agents with activity against defined resistance pathways. While the antibacterial market is highly competitive and subject to pricing pressure, hospital formulary adoption and use in appropriate patient populations provide an opportunity for VABOMERE to address a defined segment of serious Gram-negative infections where limited therapeutic alternatives exist. Additionally, VABOMERE is included in the IDSA guidelines as one of the recommended options for the treatment of CRE when the isolate is susceptible and particularly when KPC — producing organisms are involved.

Purchasing decisions for VABOMERE are typically made by hospital pharmacy and therapeutics committees and are affected by factors such as clinical efficacy and safety data, labeled indications, resistance patterns within the institution, availability of alternative therapies, pricing, and reimbursement.

## **Other Commercial Products**

While not directly marketed by our sales team, the following brands have limited and targeted promotional activities, including certain market access and contracting support:

### ***ORBACTIV and KIMYRSA***

ORBACTIV and KIMYRSA (the “ORI Franchise”) are long-acting IV antibiotics indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (“ABSSSI”) caused by susceptible Gram-positive pathogens, including MRSA, with no dose adjustment for mild/moderate renal or hepatic impairment or for age, weight, gender, or race. ORBACTIV and KIMYRSA obtained U.S. marketing approval in August 2014 and March 2021, respectively.

Treatment decision-making in ABSSSI is increasingly shaped by site-of-care optimization: avoiding potentially preventable hospital admissions, shortening length of stay, and reducing the operational burden of multi-day IV regimens and OPAT logistics. ORBACTIV and KIMYRSA address these dynamics by delivering a complete course of therapy in a single dose administration, supporting use across multiple settings (*e.g.*, emergency departments, outpatient infusion centers, hospital outpatient departments) where a single-visit approach can improve adherence and reduce the need for extended IV access such as placement of a peripherally inserted central catheter (“PICC”). Within the ORI Franchise, KIMYRSA provides a 1-hour infusion option, while ORBACTIV is administered over 3 hours, enabling clinicians and health systems to select an approach aligned to workflow and capacity constraints, while maintaining single-dose therapy for eligible patients. In contrast to the current standard of care (6 to 10 days of IV therapy), which generally requires a PICC line or hospital stay, single-dose ABSSSI therapy with the ORI Franchise alternatives increases patient convenience, ensures patient adherence with a single dose, and allows for treatment in alternative, lower cost care settings.

In addition, oritavancin, the active ingredient in ORBACTIV and KIMYRSA, is a semisynthetic lipoglycopeptide antibiotic with a distinctive triple mechanism of action against susceptible Gram-positive pathogens. Specifically, oritavancin (i) inhibits transglycosylation (polymerization of peptidoglycan chains), (ii) inhibits transpeptidation (cross-linking of peptidoglycan), and (iii) disrupts bacterial cell membrane integrity, leading to rapid,

concentration-dependent bactericidal activity. This multi-targeted activity differentiates oritavancin from agents that act through a single pathway and contributes to its potency against key Gram-positive pathogens, including MRSA, as well as activity against certain organisms with reduced susceptibility to other glycopeptides

### ***BAXDELA***

BAXDELA is a novel fluoroquinolone that is approved for the treatment of adult patients with ABSSSI or community-acquired bacterial pneumonia (“CABP”). BAXDELA has a broad-labeled spectrum including *Staphylococcus aureus* (including MRSA) as well as certain Gram-negative organisms and is available to initiate therapy on either an IV or oral formulation. While we do not promote BAXDELA, our partnership with BARDA includes support to advance BAXDELA, as described below for use in pediatrics and for use against certain biothreat pathogens (see “Biomedical Advanced Research and Development Authority Contract” section below for further details).

### ***TOPROL XL***

TOPROL XL (metoprolol succinate extended-release) is a cardioselective beta-blocker indicated for the treatment of hypertension, which has been on the U.S. market since 1992. The Toprol XL brand lost market exclusivity in 2007, lending to market dynamics of a mature, highly competitive beta-blocker class, with broad availability of generic metoprolol succinate extended-release alternatives, intense payer/formulary pressure, and prescription decisions influenced by total cost of care and patient adherence considerations. While we do not actively promote TOPROL XL, there remains some brand demand which tends to concentrate in segments where prescribers and patients value a long-established extended-release option and consistent once-daily dosing in chronic cardiovascular management, but overall growth is constrained by generic substitution and pricing pressure typical of long-marketed cardiovascular therapies.

### ***Competitive Landscape***

The drug and medical device industries are highly competitive and subject to rapid and significant technological change. Competitors (and potential competitors) for our Products include large and specialty pharmaceutical and biotechnology companies and medical device companies. Many of our 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, antimicrobial resistance, or products could render our commercial products 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 FDA-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. Further, as the Company continues to demonstrate both short and long-term reductions in healthcare costs via the results from our real-world evidence study, we believe that the overall reduction in both infections and hospitalizations could drive greater utilization and create new opportunities for reimbursement. We are not aware of any potentially competitive CLSs that are approved or under development by other companies in the U.S. for primary prevention of infection. As a means to reduce infections, some dialysis providers are using anti-infective infused catheter caps and/or compounded FDA-unapproved antibiotic containing catheter lock solutions.

Across the Melinta Portfolio, critical success factors in a highly competitive anti-infective market include clear clinical differentiation and strong alignment with evolving treatment guidelines. Competitive positioning depends on demonstrating meaningful advantages versus generic and branded alternatives in areas such as spectrum of activity against resistant organisms, safety and tolerability, reduced drug — drug interactions, dosing convenience (including long-acting or infrequent dosing regimens), and suitability for both inpatient and outpatient care settings. Success is also influenced by effective engagement with key hospital stakeholders — including infectious disease physicians, antimicrobial stewardship program personnel, pharmacists, and hospital administrators — supported by compelling clinical evidence, real-world data, and health-economic value propositions. In addition, securing and preserving formulary access, navigating pricing and reimbursement pressures, and adapting to changes in standard-of-care guidelines and competitive product launches are essential to sustaining demand and market share for these products.

## Intellectual Property

Due to the length of time and expense associated with bringing new products to market, biopharmaceutical companies have traditionally placed considerable importance on obtaining and maintaining patent protection for significant new technologies, products and processes. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the U.S., a patent's term may be lengthened by Patent Term Adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO") in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent. In the U.S., and certain other countries, the patent's term may also be lengthened by patent term extension or restoration, which compensates a patentee for administrative delays in granting a regulatory approval by the FDA, or similar agency in other countries.

While we pursue patent protection and enforcement of all our Products, product candidates, and aspects of our technologies when appropriate, we also rely on trade secrets, know-how and continuing technological advancement to develop and maintain our competitive position. To protect this competitive position, we regularly enter into confidentiality and proprietary information agreements with third parties, including employees, independent contractors, suppliers and collaborators. Our employment policy requires each new employee to enter into an agreement containing provisions generally prohibiting the disclosure of confidential information to anyone outside of the Company and providing that any invention conceived by an employee within the scope of his or her employment duties is our exclusive property. We have a similar policy with respect to independent contractors, generally requiring independent contractors to enter into agreements containing provisions generally prohibiting the disclosure of confidential information to anyone outside of the Company and providing that any invention conceived by an independent contractor within the scope of his or her services is our exclusive property with the exception of contracts with universities and colleges that may be unable to make such assignments. Furthermore, our know-how that is accessed by third parties through collaborations and research and development contracts and through our relationships with scientific consultants is generally protected through confidentiality agreements with the appropriate parties.

### *DefenCath*

On August 29, 2023, the USPTO granted U.S. Patent No. 11,738,120, which was our patent application directed to a locking solution composition for treating and reducing infection and flow reduction in central venous catheters (expiring April 15, 2042). We have a supplemental patent (U.S. Patent No. 7,696,182), which we believe has potential to provide an additional layer of patent protection for DefenCath through 2042.

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

### *REZZAYO*

CorMedix holds an exclusive license from Mundipharma, our European licensor and the current holder of REZZAYO intellectual property and the NDA, to develop and sell the brand in the U.S. Under the terms of the license, we are required to make certain future milestone payments to Mundipharma (See *Contractual Obligations*, included within this Annual Report, for additional details on the arrangement with Mundipharma). REZZAYO has NCE exclusivity with GAIN extension until 2033, orphan drug exclusivity through 2035 and composition of matter and treatment patent coverage until 2038.

### *MINOCIN IV*

We have patents relating to the MINOCIN IV product formulation and certain methods of treatment comprising intravenously administering minocycline, which are set to expire between May 2031 and October 2032. We are also prosecuting other patent applications relating to minocycline formulations and methods of treatment in the U.S.

In 2020, Nexus Pharmaceuticals (“Nexus”) filed an Abbreviated New Drug Application (“ANDA”) with Paragraph IV (“PIV”) certification against the only Orange Book listed patents at the time, specifically patents ‘802 and ‘105 (“Minocin Treatment Patents”), on the alleged basis that the Minocin Treatment Patents were invalid and, in the alternative, that its ANDA did not infringe.

Melinta filed suit against Nexus in the US District Court for the Northern District of Illinois (the “Court”), asserting that the Minocin Treatment Patents were valid and accordingly, Nexus’s ANDA for its generic version of MINOCIN infringed these patents. In November 2024, the Court found that the Minocin Treatment Patents are valid, enforceable and infringed and issued a permanent injunction against the Nexus ANDA as part of that decision. Nexus subsequently filed an appeal with the U.S. Court of Appeals for the Federal Circuit. The appeal is ongoing.

Additionally, in February 2025, Melinta received a PIV certification for all four Orange Book listed patents from Gland Pharma (“Gland”) on the alleged basis that the patents were invalid, and in the alternative that its ANDA did not infringe these patents. Melinta filed a suit against Gland in the same Court in April 2025. The case is ongoing.

#### *VABOMERE*

VABOMERE received five years of NCE exclusivity following its 2017 FDA approval, with an additional five-year GAIN/QIDP extension, resulting in regulatory exclusivity through August 2027. We hold a portfolio of patents relating to VABOMERE, including the vaborbactam compound, for which we have patent coverage until 2031, and methods of treatment, for which we have coverage until 2039. We are currently prosecuting related patent applications relating to VABOMERE’s pharmaceutical composition and its use in the U.S. and in certain foreign countries.

#### *ORI Franchise*

We hold U.S. patents relating to methods of treatment expiring in 2029 and 2030, as well as a U.S. patent relating to high purity oritavancin that expires in 2035. Numerous foreign counterparts have been filed, including in Europe and Eurasia, for these more recent methods of treatment and compositions. We are also prosecuting a number of patent applications relating to the ORI Franchise and its uses in the U.S. and certain foreign jurisdictions.

#### *BAXDELA*

We have a license, both exclusive and nonexclusive, from Wakunaga Pharmaceutical Company, Ltd. to certain patents and patent applications, and to certain patents and patent applications of AbbVie Inc. We have also licensed technology from CyDex Pharmaceuticals, Inc. (now a wholly-owned subsidiary of Ligand Pharmaceuticals Incorporated) for the use of Captisol, a sulfobutylether beta-cyclodextrin excipient, in connection with BAXDELA. We have developed and patented additional technology independently. The patent portfolio for BAXDELA and delafloxacin meglumine, the active pharmaceutical ingredient in BAXDELA, is related to compositions of matter, pharmaceutical compositions, manufacturing methods and methods of use. In addition to the licensed and owned U.S. patents, the portfolio includes pending U.S. patent applications and corresponding foreign national or regional counterpart patents or applications. We expect that the patents and the patent applications in the portfolio, if issued, will expire between 2026 and 2034.

#### **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.

For DefenCath, we currently have one FDA-approved source (contract manufacturing organization, or “CMO”) for each of our two key active pharmaceutical ingredients (“APIs”), 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. With respect to heparin sodium API, the Company has identified an alternate third-party supplier and may qualify such supplier under the DefenCath NDA in the future.

The Company received FDA approval of DefenCath with finished dosage production from its European based CMO Rovi Pharma Industrial Services. In addition, the Company also qualified Siegfried Hameln as an alternate finished dosage manufacturing site and is in the process of scaling production at the facility.

Each of the products in the Melinta Portfolio has one FDA-approved contract manufacturing organization, primarily in Europe or in the U.S. The Company has ongoing technology transfers intended to reduce costs of goods sold as well as to onshore the manufacture of several of its products, which it expects to complete over the next two to three years.

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 the FDA, we could face shortages or risk with respect to producing sufficient quantities of drug product or drug substance.

### **Biomedical Advanced Research and Development Authority (“BARDA”) Contract**

In July 2023, Melinta entered into partnership with BARDA to advance BAXDELA and VABOMERE for use in pediatrics and to partner on the development of BAXDELA against certain biothreat pathogens (“BARDA-Supported Studies”). Under this agreement, BARDA reimburses certain percentages of costs incurred, as defined in the agreement, in connection with the BARDA-Supported Studies. As of December 31, 2025, BARDA has awarded a total of \$47.5 million of funding with the potential of additional funding of \$97.1 million, amounting to total funding up to \$144.6 million, if all options are exercised. If all contract options are exercised, the contract is expected to continue through 2034. Through December 31, 2025, we have recognized BARDA reimbursement totaling \$19.4 million.

The BARDA contract contains a number of terms and conditions that are customary for government contracts of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

### **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.

### **Clinical Trial Programs**

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 is 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.

## **Approval Process**

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 ("REMS") or otherwise limit the scope of any approval.

In addition, under the 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 (“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 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 (“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 responds to a written request from the FDA for such data. The data does 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.

Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For example, President Trump signed multiple executive orders aimed at reducing prescription drug costs in the U.S., including: the Lowering Drug Prices by Once Again Putting Americans First executive order issued on April 15, 2025, which provided several actions the Secretary of the Department of HHS must take to optimize healthcare regulations designed to provide access to prescription drugs at lower costs, and the Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients executive order issued on May 12, 2025, which sought to establish “most favored nation” drug pricing policy that would tie U.S. drug prices to the prices paid for drugs in other countries. The Trump administration has continued

to exert pressure on drug manufacturers to implement “most favored nation” pricing, including by suggesting that the administration may impose significant tariffs on pharmaceuticals if such manufacturers do not reach agreements to implement “most favored nation” pricing and by reaching agreements with certain drug manufacturers to offer most-favored-nation pricing on certain existing and future products. On November 6, 2025, CMS announced a new voluntary payment initiative called the GENEROUS Model (GENERating cost Reductions for U.S. Medicaid Model) a limited duration payment model conducted through the CMS Innovation Center to allow drug manufacturers to voluntarily provide coordinated supplemental rebates to state Medicaid agencies that match international prices in certain enumerated countries. Failure to participate in the model could result in less favorable Medicaid coverage against competitors that choose to participate. Additionally, on December 19, 2025, CMS issued two additional notices of proposed rulemaking to test alternative calculations for manufacturer rebates aimed at bringing drug prices closer to those paid in identified economically similar countries: the GLOBE Model (Global Benchmark for Efficient Drug Pricing) for certain Medicare Part B drugs and the GUARD Model (Guarding U.S. Medicare Against Rising Drug Costs) for certain Medicare Part D drugs. Under these proposals, CMS would replace existing domestic inflation-based rebate calculations with new rebate obligations tied to international reference pricing benchmarks in a basket of economically comparable countries.

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.

### ***Government Contracts and Regulation***

We currently contract with the federal government (see section entitled “*Biomedical Advanced Research and Development Authority Contract*” above). As a government contractor, we are subject to complex and wide-ranging federal and agency-specific regulations and contractual requirements that not only govern how we perform under the contract but also impose other requirements that affect our operations, including socioeconomic obligations such as obligations related to affirmative action and maintaining a drug-free workplace. Failure to comply with government contracting requirements could result in termination of our contract and the imposition of penalties.

### ***Foreign Regulatory Requirements***

We have not made any filings seeking approval for our Products outside of the U.S. For us to market any product outside of the U.S., 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. In lieu of this, we have licensing relationships with pharmaceutical companies outside of the U.S. under which we license rights to commercialize our Products in exchange for payments, potentially including upfront licensing fees, milestone fees and royalties on sales of the applicable Product or Products in their respective territories. The revenue associated with these licensing relationships is not expected to be material to our current or future financial statements, representing 5% or less of total revenue in 2025. For details on these arrangements, see Note 2 to the Consolidated Financial Statements in this Annual Report on Form 10-K.

### **Employees and Human Capital Resources**

As of February 28, 2026 we employed approximately 191 full-time employees, who work out of our corporate headquarters in Parsippany, NJ, our corporate office in Lake Forest, IL, or remotely in various locations throughout the U.S.

We invest in our workforce by offering competitive salaries and benefits. We endeavor to foster a strong sense of ownership by offering equity awards under our stock incentive program. We also offer comprehensive benefits for all eligible employees. We recognize and support the growth and development of our employees through a number of programs including annual performance feedback reviews and 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 389 Interpace Parkway, Suite 450, Parsippany, New Jersey, 07054.

## **Available Information**

We maintain our website at [www.cormedix.com](http://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](http://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**

*Although we achieved profitability in 2025, 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 achieved net income of approximately \$163.1 million for the year ended December 31, 2025 and incurred a net loss of approximately \$17.9 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of approximately \$176.6 million. We may not be able to sustain profitability and could incur net operating losses in future periods as we expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, clinical trials and commercialization activities increase as we commercialize our Products 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: continuing to successfully market and sell our Products in the U.S.; obtaining and/or maintaining reimbursement for our Products 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 revenues from the commercialization of our Products in the U.S. are insufficient. 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.

### **Risks Related to the Development and Commercialization of DefenCath**

*We are highly dependent on the continued successful commercialization of our lead product, DefenCath.*

Our ability to generate operating cash flow 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.

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 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, and are undergoing clinical studies to pursue an expanded use in total parenteral nutrition patients requiring catheters. For any new indication of use, all new potential customers are healthcare providers who depend upon reimbursement by government and commercial insurance payors. 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 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 DefenCath 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 our top three customers accounted for 79% of our total revenue for the year ended December 31, 2025, and we had three customers that accounted for 41%, 23% and 20% of our accounts receivable, respectively, for the year ended December 31, 2025. These customers have no purchase commitments and may cancel, change or delay purchases with little or no notice or penalty. As a result of this customer concentration, our revenue could fluctuate materially and could be materially and disproportionately impacted by product pricing and 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 business, 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.

***Our revenue and profitability may be adversely affected by DefenCath's transition from TDAPA to the post-TDAPA add-on adjustment and broader reimbursement dynamics that could have a material adverse impact on our results of operations and business.***

While DefenCath has been approved for reimbursement in certain settings, we cannot be sure that reimbursement will continue to be available for DefenCath on favorable terms or will be covered by other payers. For example, on July 1, 2026, DefenCath's TDAPA reimbursement will transition into a post-TDAPA add-on adjustment, the calculation of which is determined by CMS. As a result of the methodology utilized by CMS, the level of reimbursement provided to institutions treating dialysis patients will significantly decline, and as a result, we anticipate there will be a corresponding reduction to the net pricing for DefenCath for the third and fourth quarters of 2026. The 2027 post-TDAPA add-on adjustment will be effective on January 1, 2027. There can be no assurance that the level of reimbursement determined by CMS in the post-TDAPA add-on period will improve. Further changes in these reimbursement rates could lead to significant fluctuations in our operating income and could have a negative impact on our revenues, earnings and cash flows. Reimbursement uncertainty applies to all of our Products as well as 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 our Products or any other product lines that we develop.

Reimbursement levels are also subject to periodic CMS rulemaking, sequestration or other across-the-board Medicare payment reductions, audit and overpayment recovery activity, and evolving coverage policies, any of which could occur on short notice and may apply retroactively. If CMS changes the underlying methodologies, revises inputs or assumptions, or otherwise modifies TDAPA eligibility criteria or post-TDAPA add-on adjustments, our realized revenue, earnings and cash flows could fluctuate materially from period to period. Even if coverage remains in place, inadequate payment may limit provider adoption, restrict formulary placement, or result in purchasing constraints by dialysis organizations.

### **Risks Related to the Development and Commercialization of our other Products**

***Successful development and commercialization of our Products and new product lines is uncertain.***

The development and commercialization of our Products, and future product lines, is subject to the risks of failure and delay inherent in the development of new pharmaceutical products for the Company, our licensor and our partners, 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;

- inability to obtain third-party payor coverage or adequate reimbursement;
- 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.

Additionally, 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;
- 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, as well as post-marketing commitments imposed by regulatory authorities, such as patient registries.

Because of these risks, our development efforts and those of our licensor and our partners may not result in any future commercially viable products.

If a significant portion of our development efforts and those of our licensor and partners 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.

***Infective pathogens might develop resistance to our Products or product candidates, which would decrease the efficacy and commercial viability of that product.***

Infective pathogens, including fungi and bacteria, develop resistance over time due to genetic mutation. Many current and previous anti-infective therapies have suffered reduced efficacy over time due to the development of resistance to such drugs. It is probable that, over time, such pathogens will also develop resistance to our Products and our drug candidates. If resistance were to develop rapidly to our Products or our drug candidates, this would reduce the commercial potential for our business.

***Clinical trials and regulatory approval for our product lines are expensive, time-consuming, and uncertain, and failure or delay in obtaining approval could materially harm our business.***

To market a new drug or device product in the United States, we must demonstrate proof of safety and effectiveness in humans through “adequate and well-controlled” clinical trials and obtain FDA approval. The clinical trial and regulatory approval process is lengthy, expensive, and subject to numerous risks and uncertainties at every stage.

Clinical trials may be delayed or fail due to many factors, including: inability to manufacture sufficient quantities of qualified materials under cGMP requirements; slower than expected patient recruitment or insufficient enrollment; modifications to trial protocols or changes in regulatory requirements; lack of effectiveness or unforeseen safety

issues; suspension or termination by institutional review boards or the FDA; and adverse medical events in patients, which may or may not be related to our products. Results from early trials are not necessarily indicative of later trial outcomes, and clinical results are frequently susceptible to varying interpretations that may delay, limit, or prevent regulatory approvals.

Even after clinical trials are completed, final FDA approval of an NDA, Premarket Approval Application (“PMA”), or De Novo application may be delayed, limited, or denied for numerous reasons, including: the FDA may not find pre-clinical and clinical data sufficient or may disagree with our interpretation of such data; the FDA may require additional studies or manufacturing information; the FDA may not agree with our intended indications, study design, or proposed labeling; or manufacturing processes and facilities may be deemed to have insufficient GMP controls. Regulatory approval policies may also change, and compliance with evolving requirements may consume substantial financial and management resources.

Any failure or significant delay in clinical trials or regulatory approval for our products would delay our ability to commercialize our product lines and generate product revenues, and could cause us to abandon a product line entirely. Such outcomes could materially harm our business, financial condition, and results of operations.

***Off-label marketing or use of our Products or future product candidates may expose us to significant fines, penalties, sanctions, or product liability claims, and our reputation could be harmed.***

The FDA, United States Department of Justice (the “DOJ”), and comparable foreign authorities strictly regulate the marketing and promotional claims that are made about pharmaceutical products following approval. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or comparable foreign authorities as reflected in the product’s approved labeling and Summary of Product Characteristics. However, physicians can prescribe drugs to their patients in a manner that is inconsistent with the approved label based on the physician’s independent medical judgement. The FDA and other governmental authorities, have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed in order to resolve enforcement actions. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face large civil and criminal fines and be subject to prohibitions and restrictions, which would materially harm our business. In addition, management’s attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged.

### **Risks Related to Regulatory and Legal Compliance Matters**

***Our approved Products are, and our pipeline product lines (if approved) will be, subject to extensive post-approval regulation.***

Once a product is approved, numerous FDA-mandated 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 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 other relevant 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 actions.

***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.***

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. 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, or requiring rebates. Market acceptance and sales of our Products 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.

Federal and state governments in the U.S. have been, and may in the future consider legislative and regulatory proposals to change the U.S. healthcare system in ways that could affect our ability to commercialize our Products and future marketed products profitably. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs as it relates to prescription drugs, 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 current administration has pursued and is pursuing policies to reduce regulations and expenditures across government, including at the FDA, CMS, Health and Human Services (“HHS”) and related agencies. Recent actions include (i) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by establishing Most-Favored-Nation pricing for pharmaceutical products; (ii) imposing tariffs on imported pharmaceutical products; and (iii) as part of the MAHA Commission’s recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. These actions and policies may significantly reduce U.S. drug prices, potentially impacting pricing strategies and profitability, while increasing operational costs and compliance risks.

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. and the amount of reimbursement available from governmental agencies or other third-party payors. Any such reduction in reimbursement 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.

***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 our product lines, 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, 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 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 relating to cybersecurity and data privacy could create additional liabilities for us.***

We rely on the proper functioning of information technology systems, networks, and cloud services across our operations, and any failure, interruption, or other incident affecting the confidentiality, integrity or availability such systems or the data stored thereon, including incidents which may result from a cyber-attack (e.g., ransomware, malware, phishing, denial-of-service, or vendor compromise), could disrupt our business, result in loss or corruption of data, theft or misuse of confidential or personal information, and require significant remediation costs. 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 or class of individuals, or 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.

We also depend on third-party service providers (including cloud, SaaS, Contract Research Organizations, CMOs, logistics and analytics vendors), and incidents at these third parties — or their subcontractors — can compromise our data or disrupt operations even if our own systems are not implicated. We maintain processes to assess, identify, and manage material cybersecurity risks, which are integrated into our broader enterprise risk management program,

including with respect to incident response planning and employee training, and involve oversight of third-party risks. However, no controls can eliminate all threats, and our board and management oversee, but cannot guarantee the effectiveness of, these efforts. For more information, please see “Item 1C (Cybersecurity).” A significant cyber incident — or a series of smaller incidents — could also interrupt manufacturing and supply coordination with third parties, impair quality or safety reporting, delay clinical or commercial activities, increase insurance and cybersecurity costs, and negatively affect our results of operations and reputation.

The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide. Certain 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 increases costs and complicates compliance efforts.

***Clinical trials required for our Products and any future product lines may be expensive, 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.

From time to time, we may publicly disclose interim, topline, or preliminary data from clinical trials involving our Products, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial as well as the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability, or commercialization of the particular product candidate or product and our company in general. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain regulatory approval for, and commercialize, our product candidates and any future product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

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.

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, any 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.

***Our BARDA development contract requires ongoing funding decisions by the U.S. Government. Any reduction or discontinuation of funding of this contract could cause our business, financial condition, operating results and cash flows to suffer materially.***

In July 2023, Melinta signed a development contract with BARDA to advance two antibiotics currently FDA-approved for adults, BAXDELA® (delafloxacin) and VABOMERE® (meropenem and vaborbactam), for use in pediatrics and to advance BAXDELA for use in biodefense indications. The performance period for our BARDA contract, including all optional funding, is estimated to be 12 years. Under this contract, BARDA has committed funding of \$47.5 million to date, with the potential of additional funding of \$97.1 million, amounting to total funding up to \$144.6 million if all options are exercised.

The primary source of funds for these development programs is provided by the U.S. government and is subject to Congressional appropriations, which are generally made on a fiscal year basis, even for programs designed to continue for several years. These appropriations can be subject to a number of uncertainties, including political considerations, changes in priorities due to global pandemics, the results of elections and stringent budgetary constraints. If levels of government expenditures and authorizations for public health countermeasure preparedness decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the federal government otherwise declines to exercise its options under this contract or our other existing contracts, there could be a material adverse impact to our results of operations, financial condition, and our business.

### **Risks Related to Our Business and Industry**

#### ***We may not successfully manage the growth of our Products.***

Our success may depend upon the expansion of our operations to continue to commercialize our Products 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 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 our Products, 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.

#### ***We have pursued and may continue to pursue acquisitions. Acquisitions could be difficult to integrate, divert the attention of key personnel, disrupt our business, dilute stockholder value and impair our financial results.***

As part of our business strategy, we have pursued and may continue to pursue acquisitions of complementary businesses, products, services, technologies or strategic transactions that we believe could accelerate our ability to compete in our existing markets or allow us to enter new markets. Any of these transactions could be material to our financial condition and results of operations. The failure to successfully evaluate, execute and integrate acquisitions or otherwise adequately address these risks, we may not achieve the anticipated benefits of any such acquisition, we may incur costs in excess of what we anticipate, which could have a material adverse impact on our business and financial results.

Any potential acquisition or strategic collaboration may entail numerous risks, including but not limited to: assimilation of operations, intellectual property and drugs of an acquired company, including challenges associated with integrating new personnel; the diversion of our management's attention; retention of key employees and uncertainties in our ability to maintain key business relationships; risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and our inability to generate revenue from acquired technology and drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

If we fail to properly evaluate acquisitions or investments, we may not achieve the anticipated benefits of any such acquisitions, and we may incur costs in excess of what we anticipate. The failure to successfully evaluate, execute and integrate acquisitions or investments or otherwise adequately address these risks could materially harm our business and financial results.

***Competition and technological change may make our Products, 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 our Products or our product lines if any of such other product lines receive marketing approval.

***If we lose key management, 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. 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 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 or utilizing 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 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.

## **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.

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 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 be issued, 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.

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 or court would 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 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 or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the applicable 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 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 require us to spend time and money to address such disputes could limit our intellectual property rights and if generic entrants of our Products are approved, it could have a material adverse impact on our results of operations and financial condition.***

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. In addition to our pending litigation discussed below, we may initiate or become subject to infringement claims or litigation arising out of our patents and pending applications and those 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.

For example, generic manufacturers have sought, and may continue to seek, FDA approval to market generic versions of our Products through an abbreviated new drug application (“ANDA”). ANDA litigation and related settlement and license agreements, in some cases, may result in a loss of exclusivity for our patents prior to their expiration. The entry of generic versions of our Products may lead to market share and price erosion, which could have a material adverse impact on our results of operations and revenue. As discussed below, we are currently party to patent litigation for Minocin (minocycline) for Injection against Nexus Pharmaceuticals and Gland Pharma in which an adverse outcome could allow generic entry, which could materially harm our business, results of operations and stock price. Introduction of a generic minocycline for injection product, or a generic of any of our commercialized products, could result in increased competition, decreased sales and could have a material adverse impact on our revenue and results of operations. Please refer to “*Note 9, Commitments and Contingencies*” for a discussion of our ongoing litigation.

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 9, Commitments and Contingencies*” for additional detail on the Company’s legal proceedings.

***Our business, financial condition, and results of operations could be materially and adversely affected by an adverse outcome in the ongoing litigation.***

We are regularly involved in pending and threatened litigation, investigations, and other legal proceedings, including intellectual property, commercial, employment, securities, regulatory, and product-related claims. Litigation is inherently uncertain, can be costly and time-consuming, may divert management attention, and could result in injunctions, damages, settlements, fines, penalties, or other remedies. Insurance coverage may be unavailable or

insufficient to cover losses. Any of these outcomes, or the announcement of allegations alone, could adversely affect our reputation, cash flows, financial condition, and results of operations. Please refer to “*Note 9, Commitments and Contingencies*” for a discussion of our ongoing litigation.

### **Risks Related to Dependence on Third Parties**

***Our ability to pursue the development and commercialization of certain of our Products depends upon the continuation of certain licenses and actions taken by our licensors.***

We rely on certain licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our technology and Products. We have an exclusive license to develop and sell REZZAYO in the United States. Our license agreement also grants us nonexclusive rights to manufacture REZZAYO anywhere in the world. We are required to make payments upon reaching specified regulatory and sales milestones and to pay royalties based on net sales of products containing REZZAYO or the other compounds in a valid patent licensed under the license agreement. We are obligated to use commercially reasonable efforts to maintain regulatory approval for REZZAYO in the United States and to commercialize REZZAYO in the United States within the timeframes required by the license agreement. If we do not use commercially reasonable efforts to achieve the development and commercialization milestones for REZZAYO within the timeframes, or if we are unable to make any of the required payments, the licensor may terminate the license agreement if not cured within 60 days (or 30 days with respect to any payment breach). If our license agreement is terminated, we would lose our rights to develop and commercialize REZZAYO. Loss of our license agreement would materially and adversely affect our business, results of operations and future prospects.

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

Licenses or similar arrangements involving our research programs or any product candidates currently pose, and will continue to pose, numerous risks to us, such as our third party partners (i) have significant discretion in determining the efforts and resources that they will apply to these arrangements; (ii) may delay programs, preclinical studies or clinical trials, provide insufficient funding for programs, preclinical studies or clinical trials, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; and (iii) may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in such third party’s strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligation under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We depend on third-party suppliers and contract manufacturers for the supply and manufacture of 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 our product lines or any of their 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 our 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 have no direct control over the manufacturing of our product lines. If the contract manufacturers are unable to produce sufficient quantities of our Products, 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 align 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 on favorable terms or at all, our ability to commercialize our Products, our profitability and results of operations may be adversely affected. Our reliance on foreign suppliers poses risks due to possible shipping delays, import restrictions, trade policies and tariffs as well as foreign regulatory regimes.

We are subject to the risks associated with technology transfers, which are often required when moving manufacturing processes to new facilities or contract manufacturers. These include the potential for delays, loss of process knowledge, difficulties in replicating processes at a new site, and challenges in meeting regulatory requirements, all of which could disrupt supply or impact product quality.

In addition, we have no direct control over manufacturing costs of 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 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 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 Anti-Kickback Statute, 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 contract research organizations, 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.

***The timing of the milestone and royalty payments we are required to make to third parties is uncertain and could adversely affect our cash flows and results of operations.***

We are party to various agreements pursuant to which we are obligated to make milestone payments or pay royalties in connection with the development and commercialization of our product candidates or sales of our marketed products. The timing of our achievement of these milestones and the corresponding milestone payments, or the amount of our royalty payments, is subject to factors which are difficult to predict and of which many are beyond our control. We may become obligated to make a milestone or other payment at a time when we do not have sufficient funds to make such payment, or at a time that would otherwise require us to use funds needed to continue to operate our business, which could delay our clinical trials, curtail our operations, necessitate a scaling back of our sales and marketing efforts or cause us to seek funds to meet these obligations on terms unfavorable to us. If we are unable to make any payment when due or if we fail to use commercially reasonable efforts to achieve certain development and commercialization milestones within the timeframes required by certain of these agreements, the other party may have the right to terminate the agreement and all of our rights to develop and commercialize product candidates using the applicable technology.

### **Risks Related to our Common Stock**

***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, 2024, through December 31, 2025, the high and low sales prices for our common stock were \$17.43 and \$5.60, 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 and 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. We have been, and currently are subject to securities class-actions. Such litigation, has caused, and if instituted against us in the future 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.

### **General Risk Factors**

***Our business may be adversely affected by tariffs, trade sanctions or similar government actions.***

The imposition and ongoing discussions regarding certain trade restrictions, sanctions and tariffs on goods exported from the U.S. or imported into the U.S., as well as retaliatory measures enacted in response to such actions and related market volatility, could have a material adverse impact on our business, financial condition, results of operations and cash flows. In light of these events, there continues to exist significant uncertainty about the future relationship between the U.S. and other countries with respect to such trade policies. These developments, or the perception that any of them could occur, may have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global trade and, in particular, trade between

the impacted nations and the U.S. Any of these factors could depress economic activity, lower product demand and restrict our access to potential partners, suppliers or other third parties we seek to do business with and, in turn, have a material adverse effect on the business and financial condition of such third parties, which in turn would negatively impact us.

***We have identified a material weakness in our internal control over financial reporting, which could, if not effectively remediated, result in material misstatements in our financial statements, and a failure to meet our reporting and financial obligations.***

Effective internal control over financial reporting is necessary for us to provide reliable financial reports, prevent fraud and errors in our financial statements and operate successfully as a public company. As discussed in “Item 9A. Controls and Procedures,” our management has concluded that we did not maintain effective internal control over financial reporting as of December 31, 2025. We are actively engaged in remediating the underlying material weakness as promptly as possible. However, we cannot be certain that the current material weakness in internal control will be remediated and our internal control over financial reporting will be considered effective going forward. Because of its inherent limitations, our system of internal control over financial reporting may not prevent or detect every misstatement.

If we are unable to remediate the existing material weakness in our internal controls over financial reporting and achieve effective internal control, or if we identify additional material weaknesses in our internal control over financial reporting, we may be unable to accurately report our financial results, or report them within the timeframes required by the SEC. If this occurs, we also could become subject to sanctions or investigations by the SEC or other regulatory authorities. In addition, if we are unable to conclude that we have effective internal control over financial reporting, or if our independent registered public accounting firm is unable to provide us with an unqualified report regarding the effectiveness of our internal control over financial reporting for the year ending December 31, 2026 or annual periods thereafter, investors could lose confidence in the reliability of our consolidated financial statements. This could result in a decrease in the value of our common stock.

We also face risks associated with the cost of establishing effective internal control over financial reporting, insofar as we expect to continue to incur increased costs related to our internal control over financial reporting to remediate the above-described material weaknesses and improve further our internal control environment.

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

Failure on our part to have effective internal financial and accounting controls could cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could have a material adverse impact on the trading price of our common stock. 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 any material weaknesses or significant deficiencies are identified, the correction could require remedial measures, which could be costly and time-consuming. In addition, 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 trading price of our common stock to decline and make it more difficult for us to finance our operations and growth.

## **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. These processes are integrated into the Company's overall risk management program and systems, as overseen on a day-to-day basis by the Company's Senior Manager, IT.

We maintain a formal data protection program consistent with the National Institute of Standards and Technology Cybersecurity Framework, including 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; and
- review and monitor internal control audit reports for our significant third-party vendors to ensure sufficient controls are in place to mitigate security-related risks.

In addition, we have in place a formal cybersecurity incident response plan, which we are currently harmonizing between the two companies as a result of the Merger in the third quarter of 2025.

CorMedix has a formal process to respond to events, identify incidents, and track progress for remediation. No events, 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.

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*

Our Board of Directors (the "Board") executes its oversight responsibility for risk management both directly and through delegating oversight of certain risks to its committees. In particular, the Board has authorized the Audit Committee to oversee risks related to cybersecurity threats. As part of that oversight function, the Audit Committee oversees the Company's risk assessment and risk management policies, including related to cybersecurity and the Company's 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 25 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. Company management regularly reports to the Audit Committee on our cybersecurity program strategy and implementation, and on an ad-hoc basis, as needed, in the event of a security incident.

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**

Our corporate headquarters is located in Parsippany, New Jersey, representing a leased facility which expires in March, 2030. We have additional leased office facilities in Lake Forest, Illinois, expiring in September 2031 and an office located in Berkeley Heights, NJ which we are actively marketing for sub-lease, expiring in October 2027.

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 9, *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 2, 2026, we had approximately 61 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 has been commercializing DefenCath® (taurolidine and heparin), in the U.S., which we launched in 2024 in the hemodialysis setting. The name DefenCath is the U.S. proprietary name approved by the U.S. FDA.

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 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. 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.

DefenCath is 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). DefenCath's TDAPA began on July 1, 2024.

Looking forward, on July 1, 2026, DefenCath's TDAPA reimbursement transitions into a three-year, post-TDAPA Add-On Payment phase, the calculation of which is determined and published by CMS and will be \$2.37 for the third and fourth quarters of 2026. As a result of the methodology utilized by CMS, the level of reimbursement provided to institutions treating dialysis patients will significantly decline, and as a result, we expect a corresponding reduction to net pricing for DefenCath in the third and fourth quarters of 2026. If CMS utilizes the same methodology to calculate the 2027 post-TDAPA Add-On Adjustment, which will be effective on January 1, 2027, we estimate the value of the Add-On Adjustment will be three to five-times higher than that granted for the third and fourth quarters of 2026, which we expect may result in higher DefenCath sales prices in 2027 relative to the second half 2026. After January 1, 2027, the post-TDAPA Add-On Payment will be reassessed again and be made effective on January 1, 2028 and January 1, 2029, covering the three-year period through June 30, 2029.

### ***Acquisition of Melinta***

On August 29, 2025 (the "Closing Date"), we completed the acquisition of Melinta. The acquisition of Melinta expanded our team, commercial platform and increased the commercial portfolio with six marketed, hospital- and clinic-focused infectious disease products, comprised of REZZAYO® (rezafungin for injection), MINOCIN® (minocycline) for Injection, VABOMERE® (meropenem and vaborbactam), KIMYRSA® (oritavancin), ORBACTIV® (oritavancin), BAXDELA® (delafloxacin), and an additional well-established cardiovascular product, TOPROL-XL® (metoprolol succinate) (together, the Melinta Portfolio. REZZAYO is currently approved for the treatment of candidemia and invasive candidiasis in adults, with an ongoing Phase III study for the prophylaxis of invasive fungal infections in adult patients undergoing allogeneic blood and marrow transplantation. The completion of the Phase III study for REZZAYO is expected in 2026.

The financial results of Melinta are included in our consolidated financial statements starting on August 29, 2025. Melinta's financial results were not reflected in reported figures in the periods preceding the Closing Date. As a result, the reported results for 2025 and 2024 are not comparable. To assist with the discussion of 2025 and 2024 results on a comparable basis and provide more meaningful discussion, certain pro forma historical results are included in Note 3 to the Consolidated Financial Statements included herein. This information does not purport to reflect what our financial and operational results would have been had the acquisition been consummated at the beginning of the periods presented. In addition, further information relating to the acquisition of Melinta is included in Note 3 to the Consolidated Financial Statements included herein.

Pursuant to the terms of the Merger Agreement, we acquired Melinta via a merger in which Merger Sub merged with and into Melinta, with Melinta surviving as a wholly-owned subsidiary of the Company. In consideration for the Merger, we (i) paid to the former Melinta equity holders an aggregate of \$260.0 million in cash, subject to adjustment for estimated Company Cash and estimated Working Capital as compared to the Working Capital Target (each as defined in the Merger Agreement), and (ii) issued to certain of the former Melinta equity holders an aggregate of 3.3 million common shares of the Company (the "Merger Shares"). In addition, in connection with the Merger, we paid \$23.2 million to acquire the Toprol XL product rights, which Melinta had licensed from a third party. The total cash consideration was funded by a combination of the Company's existing cash on hand and net proceeds from the Company's \$150.0 million aggregate principal amount of convertible senior notes due 2030 (as described below).

Additionally, former Melinta equity holders are eligible to receive certain contingent payments pursuant to the terms of the Merger Agreement and the Contingent Payment Agreement, which provides for milestone and net sales-based payments. Upon the issuance of the FDA marketing approval of REZZAYO (or any product that contains the active ingredient rezafungin), for the prevention or prophylaxis of invasive fungal infections in adult patients undergoing allogeneic stem cell blood and marrow transplant or the regulatory equivalent on or prior to June 30, 2029, we shall pay, in cash or common shares, par value \$0.001 per share, of the Company at the Company's election, to the former Melinta equity holders the following payments:

- (i) if the FDA-approved labeling includes candida, \$20 million;
- (ii) if the FDA-approved labeling includes aspergillus, \$2.5 million; and
- (iii) if the FDA-approved labeling includes pneumocystis, \$2.5 million.

Further, the Contingent Payment Agreement provides that we will pay to the former Melinta equity holders tiered royalties on REZZAYO U.S. net sales and low-single-digit royalties on MINOCIN® U.S. net sales.

Additionally, on the Closing Date, the Company and the consenting Melinta members entered into a registration rights agreement (the "Registration Rights Agreement"), pursuant to which, among other things, the Company agreed to register for resale, pursuant to Rule 415 under the Securities Act, the Merger Shares, pursuant to the Contingent Payment Agreement.

### ***Convertible Notes Offering***

On August 6, 2025, the Company entered into subscription agreements with certain investors to provide for the issuance of \$150.0 million aggregate principal amount of its convertible senior notes due 2030 (the "Notes") in a private placement, exempt from registration pursuant to Section 4(a)(2) of the Securities Act. The Notes were issued on August 12, 2025 and are eligible for resale to persons reasonably believed to be qualified institutional buyers pursuant to Rule 144A of the Securities Act.

The Notes are governed by an Indenture, by and between the Company and U.S. Bank Trust Company, National Association, as trustee. The Notes bear interest at a rate of 4.00% per annum, payable semi-annually in arrears on February 1 and August 1 of each year, commencing on February 1, 2026. The Notes will mature on August 1, 2030 and are senior, unsecured obligations of the Company.

The Company used the net proceeds of the issuance of the Notes to fund a portion of the purchase price payable in connection with the Merger, including related fees and expenses. See Note 7 to the Consolidated Financial Statements for further information regarding the Notes.

### ***Follow-On Offering***

In addition, on June 30, 2025, the Company completed an underwritten public offering of common stock pursuant to the Company's universal shelf registration statement on Form S-3, selling an aggregate of 6,604,507 shares, at the price of \$12.87 per share less an underwriting discount of \$0.229 per share (the "Follow-On Offering"). The Company received aggregate net proceeds of approximately \$82.4 million after deducting the underwriting discounts and commissions and offering expenses payable by the Company. See Note 10 to the Consolidated Financial Statements for further information regarding the Follow-On Offering.

## **Financial Operations Overview**

### ***Revenue from Product Sales***

We generate product revenue from commercial sales of DefenCath to a limited number of direct customers as well as distributors and, from the Closing Date, we generate revenue from sales of the Melinta Portfolio. We recognize revenue from the sale of our Products when our direct customers obtain control of the product and is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, discounts, returns, rebates, shelf-stock adjustments and data fees. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary materially from our estimates, we will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted.

We continue to assess our estimates of variable consideration as we accumulate additional historical data and will adjust these estimates accordingly.

### ***Contract Revenue***

As a result of the Merger, we recognize revenue associated with Melinta's license and collaboration agreements for the research and development and/or commercialization of its therapeutic products in the form of licensing fees, milestone payments, royalties on sales in our partners' respective licensed territories, and sale of product inventory.

In addition, Melinta holds a partnership with BARDA, a government agency, to advance BAXDELA and VABOMERE for use in pediatrics and to partner on the development of BAXDELA against certain biothreat pathogens. Research and development services under the contract are recognized as contract revenue over time, as the performance obligation is satisfied, in accordance with the BARDA agreement. Under this contract, BARDA has awarded a total of \$47.5 million with the potential of additional funding of \$97.1 million, amounting to total funding up to \$144.6 million, if all options are exercised. If all contract options are exercised, the contract is expected to continue through 2034.

### ***Cost of Revenues***

Cost of revenues include direct and indirect costs related to the manufacturing and distribution of our Products, including product cost, packaging services, freight, and an allocation of overhead costs that are primarily fixed such as salaries, benefits and insurance. In addition, cost of revenues includes the amortization of intangible assets primarily associated with the fair value of the products acquired in the Melinta Portfolio that were recorded as a result of the Merger (see Note 3 to the Consolidated Financial Statements included herein).

### ***Research and Development Expense***

Research and development ("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; and (vi) activities relating to regulatory filings and pre-clinical studies and clinical trials. 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 our Products in the United States.

### ***Selling and Marketing Expense***

Selling and marketing (“S&M”) expense includes the cost of salaries and related costs for personnel in sales and marketing including our contract sales force, brand building, advocacy, market research and consulting costs. Selling and marketing expenses are expensed as incurred.

### ***General and Administrative Expense***

General and administrative (“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 merger-related costs, facility-related costs, insurance and professional fees for legal, patent review, consulting, and accounting services. General and administrative expenses are expensed as incurred.

### ***Interest Income***

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

### ***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).

### ***Unrealized Gains on Marketable Security***

Unrealized gains on marketable security represents the change in fair market value of our marketable equity securities.

### ***Change in Contingent Consideration***

Change in contingent consideration represents the change in fair market value of the contingent consideration liabilities in connection with the Merger. Contingent consideration in connection with the business combination is initially measured at fair value at the acquisition date and classified as a liability and subsequently remeasured at fair value at each reporting date using a probability-weighted discounted cash flow model, or Monte Carlo simulation, based on significant inputs. Changes in fair value are recognized as change in contingent consideration within other expenses in the consolidated statement of operations.

### ***Interest Expense***

Interest expense consists primarily of interest incurred on the Notes.

### ***Tax Expense / Benefit***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the 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 operating results in the period that includes the enactment date. Management assesses the realizability of deferred tax assets and records a valuation allowance if it is more likely than not that all or a portion of the deferred tax assets will not be realized.

## Results of Operations

### Comparison of the Years Ended December 31, 2025 and 2024

The following is a tabular presentation of our audited consolidated operating results for the years ended December 31, 2025 and 2024 (*in thousands*): Results for 2025 are inclusive of Melinta's operations from the acquisition date of August 29, 2025 through December 31, 2025, while the prior period does not include combined results. The below discussion of changes to our revenue and expenses compared to the prior year largely focus on material factors independent of the acquisition.

	2025	2024	Net of Change Increase (Decrease)
Revenue . . . . .	\$ 304,344	\$ 43,472	600%
Contract Revenue . . . . .	7,365	—	100%
Total Revenue . . . . .	311,709	43,472	617%
Cost of sales . . . . .	22,089	3,034	628%
Intangible Amortization . . . . .	13,872	156	8,792%
Gross profit (loss) . . . . .	275,748	40,282	585%
Operating Expenses:			
Research and development . . . . .	19,333	3,942	390%
Selling and marketing . . . . .	38,054	28,737	32%
General and administrative . . . . .	68,220	29,959	128%
Total operating expenses . . . . .	125,607	62,638	101%
Income (loss) from operations . . . . .	150,141	(22,356)	(772)%
Interest income . . . . .	3,846	2,579	49%
Foreign exchange transaction loss . . . . .	(52)	(31)	68%
Unrealized gain on marketable security . . . . .	5,364	—	100%
Other Income . . . . .	—	519	(100)%
Change in contingent consideration . . . . .	(6,501)	—	100%
Interest expense . . . . .	(2,782)	(36)	7,628%
Total other income (expenses) . . . . .	(125)	3,031	(104)%
Income (loss) before income taxes . . . . .	150,016	(19,325)	(876)%
Tax (benefit) . . . . .	(13,039)	(1,395)	835%
Net income (loss) . . . . .	163,055	(17,930)	(1,009)%
Other comprehensive (loss) income . . . . .	(88)	(3)	2,833%
Comprehensive income (loss) . . . . .	\$ 162,967	\$ (17,933)	(1,009)%

*Revenue.* Revenue for the year ended December 31, 2025 was \$311.7 million as compared to \$43.5 million for the same period in 2024, an increase of \$268.2 million, or 617%.

For the years ended December 31, 2025 and 2024, product sales were \$304.3 million and \$43.5 million, respectively, representing an increase of \$260.8 million, or 600%. Product sales during fiscal year 2024 and 2025 consist primarily 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. Revenue from the Melinta Portfolio represents \$45.5 million of product sales, net of applicable variable consideration, for the post-acquisition period, starting August 29, 2025.

In 2024, we entered into multi-year commercial supply agreements with a large and several mid-sized dialysis organizations. Each dialysis provider customized its 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. During the second quarter of 2025, the Company's largest volume customer commenced ordering, patient utilization commenced in the third quarter of 2025, driving significant sales growth in the second half of 2025 relative to the first half.

Contract revenue for 2025 is related solely to the acquired operations of Melinta after the Closing Date of August 29, 2025 and reflects \$4.2 million earned under the BARDA agreement and \$3.2 million related to milestone, royalty, and inventory revenue under Melinta’s licensing agreements.

The following is a summary of our Total Revenue between the DefenCath sales and the contribution from the Melinta Portfolio from the Closing Date of August 29, 2025 through the end of 2025. The table below represents consolidated revenue for the year ended December 31, 2025 and 2024 (*in thousands*):

	<u>2025</u>	<u>2024</u>
<b>Product Sales:</b>		
DefenCath . . . . .	\$ 258,813	\$ 43,472
Melinta Portfolio . . . . .	<u>45,531</u>	<u>—</u>
Total product sales . . . . .	304,344	43,472
Contract Revenue . . . . .	<u>7,365</u>	<u>—</u>
Total Revenue . . . . .	<u>\$ 311,709</u>	<u>\$ 43,472</u>

*Cost of Revenue.* Cost of revenue for the year ended December 31, 2025 was \$22.1 million as compared to \$3.0 million for the same period in 2024, an increase of \$19.1 million, or 628%. Cost of revenues include direct and indirect costs related to the manufacturing and distribution of DefenCath and the Melinta Portfolio, including product cost, packaging services, freight, and an allocation of overhead costs that are primarily fixed such as salaries, benefits and insurance. The increase from 2024 to 2025 is primarily driven by higher product sales and to a lesser extent, costs associated with the sales of the Melinta Portfolio.

*Intangible Asset Amortization.* Amortization of intangible assets was \$13.9 million and \$0.2 million for the year ended December 31, 2025 and 2024, respectively. The increase was primarily due to the intangible assets acquired in connection with the Merger.

*Research and Development Expense.* R&D expense for the year ended December 31, 2025 was \$19.3 million, an increase of \$15.4 million, or 390%, from \$3.9 million for the same period in 2024. The increase was due primarily to the increases in personnel and clinical trial services in support of the ongoing clinical studies initiated in the fourth quarter of 2024 as well as severance costs and the incremental cost of Melinta’s operations starting on August 29, 2025.

*Selling and Marketing Expense.* S&M expense was \$38.1 million for the year ended December 31, 2025, an increase of \$9.4 million, or 32%, from \$28.7 million for the same period in 2024. These increases were primarily due to severance costs and the incremental cost of Melinta’s operations starting on August 29, 2025 and the termination cost associated with the Syneos contract, offset by additional marketing costs related to the pre-launch and launch of DefenCath in 2024.

*General and Administrative Expense.* G&A expense for year ended December 31, 2025 was \$68.2 million, an increase of \$38.2 million, or 128%, from \$30.0 million for the same period in 2024. These increases were primarily driven by the Merger-related transaction costs, severance costs, the incremental cost of Melinta’s operations starting on August 29, 2025 including higher headcount with the combined company, non-cash charges for stock-based compensation and an increase in costs related to business development.

*Interest Income.* Interest income was \$3.8 million for the year ended December 31, 2025 compared to \$2.6 million for the same period last year, an increase of \$1.2 million, or 49%, driven by higher average cash balances.

*Unrealized Gains on Marketable Security.* Unrealized gain on marketable security represents the change in fair value for our marketable equity securities in Talphera, a publicly-traded biotechnology company, from the date that the stock was acquired to December 31, 2025. Fair value is determined based on the closing stock price of Talphera on the balance sheet date. For the year ended December 31, 2025, we recognized an unrealized gain on marketable security of \$5.4 million related to the increase in fair value of our Talphera stock.

*Change in Contingent Consideration.* For the year ended December 31, 2025, we recognized a \$6.5 million change in contingent consideration, primarily driven by the changes in the present value of expected payments resulting from discount accretion and updates to the risk-free rate used in the initial Closing Date valuation. As the Merger closed in 2025, there was no comparative amount in 2024.

*Interest Expense.* Interest expense was \$2.8 million for the year ended December 31, 2025 compared to \$0.0 million for the same period last year, an increase of \$2.8 million. This was primarily driven by the interest expense and accretion related to the Notes.

*Tax Benefit.* The tax benefit for year ended December 31, 2025 was \$13.0 million, an increase of \$11.6 million, or 835% from \$1.4 million for the same period in 2024. As of December 31, 2025, the Company partially released a valuation allowance primarily related to US Federal net operating losses (“NOLs”). The release of valuation allowance was mainly attributed to the expected utilization of historical CorMedix federal NOLs. The Company will continue to evaluate the realizability of its remaining deferred tax assets each reporting period and adjust the valuation allowance as appropriate based on changes in cumulative results, forecasts of future taxable income, or other objective evidence as required by ASC 740-10-35. The tax benefit from the release of the valuation allowance was partially offset by state taxes.

*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. The foreign entity was dissolved in 2025.

## **Liquidity and Capital Resources**

### ***Sources of Liquidity***

We achieved profitability for the year ended December 31, 2025, driven primarily by product sales of DefenCath. In addition, we received net proceeds of \$7.8 million from the issuance of 715,051 shares of common stock under our at-the-market-issuance sales agreement (“ATM program”), we raised net proceeds of \$144.3 million from the Notes offering in August 2025 and \$82.4 million from the Follow-On Offering in June 2025. We may continue to utilize external sources of cash to further fund operations. See Notes 7 and 10, respectively, to the Consolidated Financial Statements for further details on the Notes, Follow-On Offering, and ATM program.

### ***Net Cash Provided by (Used in) Operating Activities***

Net cash provided by operating activities for the year ended December 31, 2025 was \$175.0 million as compared to net cash used in operating activities of \$50.6 million for the same period in 2024. Net cash provided by operating activities was primarily attributable to the net income of \$163.1 million for the year ended December 31, 2025 compared to a net loss of \$17.9 million in the comparison period in 2024.

### ***Net Cash (Used in) Provided by Investing Activities***

Net cash used in investing activities for year ended December 31, 2025 was \$308.4 million as compared to \$21.2 million of net cash provided by investing activities for the same period in 2024. The net cash used during the year ended December 31, 2025, was mainly driven by the acquisition of Melinta.

### ***Net Cash Provided by Financing Activities***

Net cash provided by financing activities for the year ended December 31, 2025 of \$238.5 million was attributable to the Notes Offering in August 2025, the Follow-On Offering in June 2025, and from our ATM program. Net cash provided by financing activities for the year ended December 31, 2024 was \$26.3 million attributable to the net proceeds received from the sale of our common stock in our ATM program and stock option exercises.

### ***Funding Requirements and Liquidity***

Our total cash, cash equivalents and short-term investments as of December 31, 2025, was \$148.5 million, excluding restricted cash of \$1.0 million, compared with \$51.7 million as of December 31, 2024, excluding restricted cash of \$0.1 million. As of December 31, 2025, \$22.1 million of the Company’s common stock remains available for potential sale under the ATM program. Additionally, we have \$15.0 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 of accounts receivable, our cash on hand, cash equivalents and short-term investments, and through potential capital raising sources, which may be dilutive to existing stockholders. We may seek to sell additional equity or debt securities through one or more discrete transactions, but can provide no assurances that any such financing 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.

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 our Products 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.

We currently estimate that as of December 31, 2025, 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 and has a term through October 2027.

Following the Merger, the Company now has operating leases for two additional offices; a lease agreement for our corporate headquarters at 389 Interpace Parkway, Parsippany, New Jersey, which expires in March 2030, and a sublease agreement for an office facility in Lake Forest, Illinois, which expires in September 2031. The total monthly expense associated with these leases is approximately \$60,000.

In addition, following the Merger, we have finance leases for numerous vehicles that are used by certain field-based employees. The lease term for each vehicle is between 48 to 60 months with an aggregate approximate monthly expense of \$70,000.

In connection with the Merger, we are required to make certain contingent payments to the former Melinta equity holders. Upon the issuance of the FDA marketing approval of REZZAYO (or any product that contains the active ingredient rezafungin), for the prevention or prophylaxis of invasive fungal infections in adult patients undergoing allogeneic stem cell blood and marrow transplant or the regulatory equivalent (the “REZZAYO Second Indication”) on or prior to June 30, 2029, the Company shall pay, in cash or common shares, par value \$0.001 per share, of the Company at the Company’s election, to the former Melinta equity holders the following payments (the “REZZAYO Milestone”):

- (i) if the FDA-approved labeling includes candida, \$20 million;
- (ii) if the FDA-approved labeling includes aspergillus, \$2.5 million; and
- (iii) if the FDA-approved labeling includes pneumocystis, \$2.5 million.

Further, we are obligated to pay to the former Melinta equity holders tiered royalties on REZZAYO U.S. net sales and low-single-digit royalties on MINOCIN U.S. net sales.

In addition, in connection with the Merger, we assumed certain commitments under the REZZAYO License Agreement that Melinta held with its licensor Mundipharma, including a regulatory milestone of between \$30 million and \$40 million upon receipt of FDA approval for the REZZAYO Second Indication, a number of commercial milestones upon exceeding certain net sales targets, and tiered net sales-based royalties. The REZZAYO License Agreement additionally stipulates that upon the earlier of thirty-days following the receipt of the marketing approval for the prophylaxis indication or on June 30, 2028, we will assume all rights, title and interest in and to all product filings for the current product in the U.S.

In connection with the purchase of the active pharmaceutical ingredient (API) for VABOMERE, we have committed to API deliveries from the CMO in 2026 with a total cost of €5.9 million, subject to inflation adjustments.

In December 2024, the Company entered into a three-year agreement with Syneos Health Commercial Services, LLC (“Syneos”) under which Syneos agreed to provide a dedicated inpatient field sales force to exclusively promote DefenCath to hospitals and health systems. The Company paid an up-front implementation fee and was obligated to pay a fixed monthly fee. The Company signed a termination agreement, effective October 1, 2025 whereas the related services to CorMedix were completed on December 31, 2025. As of December 31, 2025, the Company has a total net obligation of \$2.3 million, consisting of \$1.3 million of accrued termination fees and \$1.6 million of unpaid expenses incurred through December 31, 2025, which will be partially offset by a security deposit of \$0.6 million. We expect complete settlement to occur during the first quarter of 2026.

### **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 judgments 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.
- We account for product revenue from the sale of our Products 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 primarily 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 specific to DefenCath. 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 our returns good policy. We have established the estimate for returns based on specific customer circumstances, industry best practices and management experiences, which will continuously be refined as new information is received. At December 31, 2025, we had \$18.3 million in accrued returns allowance, including the balance recorded for the Melinta Portfolio.

Variable consideration pertaining to accrued Medicaid rebates requires estimation as our customers may have differing utilization rates of Medicaid coverage, different utilization within States which may be in either the primary or secondary positions, together with as well as general fluctuations in patient populations over time. Based on the relatively short time since product launch of DefenCath and the inherent lag time in states’ Medicaid processing, the utilization of information the Company has received is limited and, as such, there is a lack of significant historical trends for Medicaid utilization. The Company’s accrual does take into consideration its customers’ recent actual Medicaid utilization rates as well as anticipated Medicaid utilization rates. At December 31, 2025, the Company had \$12.4 million in accrued Medicaid rebates, including the balance recorded for the Melinta Portfolio.

During the year ended December 31, 2025, a change in estimate was recorded for variable consideration pertaining to Medicaid rebates, specific to DefenCath. During the three months ended June 30, 2025, new information was obtained by the Company surrounding Medicaid utilization rates for certain states that reimburse service providers using DefenCath. The resulting change in accounting estimate negatively impacted net sales, income from continuing operations and net income for the year ended December 31, 2025. The resulting change in estimate negatively impacts full year 2025 revenue, continuing operations and net income in the amount of \$1.7 million. This impacted basic and diluted earnings per share by \$0.02 and \$0.02 per share, which would have caused earnings per share and diluted earnings per share to be \$2.27 and \$2.06 respectively, with a corresponding net income of \$164.7 million.

- As of September 30, 2025, the Company had achieved cumulative pre-tax income over the most recent three-year period, and therefore, in accordance with ASC 740, Income Taxes, management evaluated both positive and negative evidence in assessing the realizability of its deferred tax assets. In addition to the historical earnings, the Company considered factors such as the sustainability of current revenue sources, excluding potential future revenue from additional indications of our Products currently under development, and future net income projections. Based on this evidence, the Company concluded that it is more-likely-than-not (as defined in ASC 740-10-30-5(e)) that it will realize the benefit of certain deferred tax assets, related primarily to utilization of its U.S. federal NOL carryforwards, within the applicable carryforward periods provided under Internal Revenue Code (“IRC”) Section 172.

As a result of this conclusion, the Company partially released its valuation allowance previously recorded against its deferred tax assets, recognizing an income tax benefit of \$61.5 million for the year ended, December 31, 2025. The release of valuation allowance was mainly attributed to the expected utilization of historical CorMedix federal NOLs. The Company will continue to evaluate the realizability of its remaining deferred tax assets each reporting period and adjust the valuation allowance as appropriate based on changes in cumulative results, forecasts of future taxable income, or other objective evidence as required by ASC 740-10-35.

- We account for acquired businesses using the acquisition method of accounting under Business Combinations (Topic 805). With respect to business combinations, we determine the purchase price, including contingent consideration, and allocate the purchase price of acquired businesses to the tangible and intangible assets acquired and liabilities assumed, based on estimated fair values. The excess of the purchase price over the identifiable assets acquired and liabilities assumed is recorded as goodwill.

We engaged a third-party professional service provider to assist us in determining the fair values of the purchase consideration, assets acquired, and liabilities assumed. Such valuations require management to make significant estimates and assumptions, especially with respect to contingent liabilities associated with the purchase price and intangible assets, such as developed product rights and in-process research and development programs. Critical estimates that we have used in valuing these elements include, but are not limited to, future expected cash flows using valuation techniques (i.e., Monte Carlo simulation models) and discount rates. Management’s estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable.

We record the different elements of contingent consideration resulting from a business combination at their respective fair values on the acquisition date. The purchase price of Melinta included contingent consideration related to certain tiered royalty payments based on future net sales, as well as to regulatory milestones associated with the acquired products. Over time, increases in fair value from the passage of time are accreted and recorded as non-cash interest expense in the consolidated statements of operation.

Changes to contingent consideration obligations, other than the passage of time, may result from adjustments related, but not limited, to changes in discount rates and the number of remaining periods to which the discount rate is applied, updates in the assumed achievement or timing of any regulatory milestone or changes in the probability of certain clinical events, changes in our forecasted sales of products acquired, and changes in the assumed probability associated with regulatory approval. At the end of each reporting period, we evaluate the need to remeasure the contingent consideration and, if appropriate, we revalue these obligations and record increases or decreases in their fair value in selling, general and administrative expenses within the accompanying consolidated statements of operations.

Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, any change in the assumptions described above, could have a material impact on the amount we may be obligated to pay as well as the results of our consolidated results of operations in any given reporting period.

**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**

**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.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting during our year ended December 31, 2025, 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.

**Internal Controls Assessment**

In connection with the preparation of our annual consolidated financial statements for the year ended December 31, 2025, management identified a deficiency in its internal control over financial reporting related to the operational effectiveness of an internal control to ensure adequate and timely review of significant, non-routine transactions.

During the third quarter of 2025, the Company had recently completed a large acquisition and a convertible debt offering, and as a result, encountered numerous and competing financial reporting demands with a limited number of finance resources and with heavy reliance on a third-party accounting firm. The capacity constraints of our team at this time contributed to the control deficiency, which resulted in an immaterial error in the measurement of equity-based consideration and goodwill that were recorded on the Company's consolidated balance sheet as of September 30, 2025 in connection with the acquisition of Melinta. The Company made appropriate corrections of this error during the preparation of the Company's consolidated financial statements for the year ended December 31, 2025.

While the error did not result in a material misstatement or a restatement of the Company's consolidated financial statements, management concluded that there is a reasonable possibility that a material misstatement could have occurred without being prevented or detected on a timely basis, and therefore, the control deficiency was deemed to be a material weakness.

### ***Managements' Internal Controls Conclusions***

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, 2025, based on the criteria 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 not effective as of December 31, 2025 due to the material weakness described above.

In addition, 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 material weakness described above, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not 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.

The Company excluded Melinta from our assessment of internal control over financial reporting as of December 31, 2025, because it was acquired by the Company in a business combination during 2025. Total assets and total revenues of Melinta, a wholly-owned subsidiary, represent 62 percent and 17 percent, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2025.

### ***Remediation Efforts***

Management has initiated remediation measures designed to address the material weakness identified above. These measures include the implementation of an enhanced review control over the accounting for significant non-routine transactions, including the preparation of contemporaneous technical accounting memoranda and enhanced management review and approval procedures.

In connection with remediation efforts, management will evaluate its workforce capacity relative to resourcing needs to determine if additional resources, including both internal and external to the Company, are necessary to facilitate timely analysis and review of significant non-routine transactions. In addition, Management believes that the integration of the financial systems and streamlining the combined-company close process this year will create additional capacity within the finance function to support the remediation efforts.

The material weakness will be considered remediated once the applicable controls have been fully implemented, have operated for a sufficient period of time, and have been tested for operating effectiveness.

## **Item 9B. Other Information**

### **Rule 10b5-1 Plans**

During the quarter ended December 31, 2025, 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.

## **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 2025 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](http://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 2025 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 2025 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 2025 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 2025 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:

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Report of Independent Registered Public Accounting Firm (PCAOB ID # 199).....	F-2
Report of Independent Registered Public Accounting Firm (PCAOB ID # 688).....	F-5
Consolidated Balance Sheets as of December 31, 2025 and 2024.....	F-6
Consolidated Statements of Operations and Comprehensive Income (Loss) Years Ended December 31, 2025 and 2024.....	F-7
Consolidated Statements of Changes in Stockholders' Equity Years Ended December 31, 2025 and 2024.....	F-8
Consolidated Statements of Cash Flows Years Ended December 31, 2025 and 2024.....	F-9
Notes to Consolidated Financial Statements.....	F-11

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:

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Registrant's Form</b>	<b>Dated</b>	<b>Exhibit Number</b>	<b>Filed or Furnished Herewith</b>
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	
2.1	Agreement and Plan of Merger, dated as of August 7, 2025, by and among CorMedix Inc., Melinta Therapeutics, LLC, Coriander BidCo LLC and Deerfield Private Design Fund IV, L.P., solely in its capacity as representative, agent and attorney-in-fact of the Company Members	8-K	08/07/2025	2.1	
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	Third Amended and Restated Certificate of Designation of the Series E Convertible Preferred Stock of CorMedix Inc., dated August 6, 2025.	10-Q	8/07/2025	3.1	
4.1	Specimen of Common Stock Certificate	S-1/A	3/19/2010	4.1	
4.2	Description of Capital Stock of CorMedix Inc.				X

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Registrant's Form</b>	<b>Dated</b>	<b>Exhibit Number</b>	<b>Filed or Furnished Herewith</b>
4.3	Form of Indenture, to be entered into by and between CorMedix Inc. and U.S. Bank Trust Company, National Association	8-K	08/07/2025	4.1	
4.4	Form of 4.00% Convertible Senior Notes due 2030 of CorMedix Inc. (included in Exhibit 4.1)	8-K	08/07/2025	4.2	
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	Backstop Agreement, dated November 9, 2017, between CorMedix Inc. and the investor named therein	8-K	11/13/2017	10.2	
10.4	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	
10.5	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	
10.6	Securities Purchase Agreement, dated December 31, 2018, between CorMedix Inc. and the investor named therein	8-K	1/03/2019	10.1	
10.7	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	
10.8	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	
10.9+	Amended and Restated 2019 Omnibus Stock Incentive Plan	S-8	10/26/2022	99.1	
10.10+	Amendment No. 1 to the Amended and Restated CorMedix Inc. 2019 Omnibus Stock Incentive Plan	8-K	11/21/2024	10.1	
10.11+	Amendment No. 2 to the Amended and Restated CorMedix Inc. 2019 Omnibus Stock Incentive Plan.	10-Q	11/12/2025	10.5	
10.12+	2021 Executive Bonus Plan	8-K	12/23/2021	10.1	
10.13	Contingent Payment Agreement, dated August 29, 2025, by and among Deerfield Private Design Fund IV, L.P., Deerfield Private Design Fund III, L.P., CorMedix Inc., a Delaware corporation, Melinta Therapeutics, LLC, and Deerfield Private Design Fund IV, L.P., a Delaware limited partnership, solely in its capacity as representative	8-K	9/2/2025	10.1	
10.14	Registration Rights Agreement, dated August 29, 2025, by and among CorMedix Inc., Deerfield Private Design Fund IV, L.P., Deerfield Private Design Fund III, L.P. and each other Holder (as defined in the Registration Rights Agreement)	8-K	9/2/2025	10.2	
10.15+	Executive Employment Agreement, dated December 12, 2023, between CorMedix Inc. and Beth Zelnick Kaufman.	10-K	3/25/2025	10.16	

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Registrant's Form</b>	<b>Dated</b>	<b>Exhibit Number</b>	<b>Filed or Furnished Herewith</b>
10.16+	Employment Agreement by and between CorMedix, Inc. and Susan Blum, dated August 28, 2025	8-K	9/2/2025	10.3	
10.17+	Employment Agreement by and between CorMedix, Inc. and Elizabeth Hurlburt, dated August 29, 2025	8-K	9/2/2025	10.4	
10.18+	Employment Agreement by and between CorMedix, Inc. and Matthew David, dated August 31, 2025	8-K	9/2/2025	10.5	
10.19+	Amended and Restated Employment Agreement by and between CorMedix, Inc. and Joseph Todisco, dated January 5, 2026.				X
19.1	Insider Trading Policies and Procedures				X
21.1	List of Subsidiaries				X
23.1	Consent of Independent Registered Public Accounting Firm (CBIZ CPAs P.C)				X
23.2	Consent of Independent Registered Public Accounting Firm (Marcum LLP)				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	
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 5, 2026

By: /s/ Joseph Todisco  
 Joseph Todisco  
 Chief Executive Officer  
 (Principal Executive Officer)

March 5, 2026

By: /s/ Susan Blum  
 Susan Blum  
 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:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Joseph Todisco</u> Joseph Todisco	Chief Executive Officer, Director and Chairman of the Board (Principal Executive Officer)	March 5, 2026
<u>/s/ Susan Blum</u> Susan Blum	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2026
<u>/s/ Myron Kaplan</u> Myron Kaplan	Lead Independent Director	March 5, 2026
<u>/s/ Janet Dillione</u> Janet Dillione	Director	March 5, 2026
<u>/s/ Gregory Duncan</u> Gregory Duncan	Director	March 5, 2026
<u>/s/ Alan Dunton</u> Alan Dunton	Director	March 5, 2026
<u>/s/ Steven Lefkowitz</u> Steven Lefkowitz	Director	March 5, 2026
<u>/s/ Robert Stewart</u> Robert Stewart	Director	March 5, 2026

**CORMEDIX INC. AND SUBSIDIARIES**

**FINANCIAL STATEMENTS**

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## Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of  
CorMedix Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of CorMedix Inc. (the “Company”) and Subsidiaries as of December 31, 2025, the related consolidated statements of operations and comprehensive income (loss), stockholders’ equity and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the “financial statements”). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Notes 2 and 8 to the financial statements, the Company adopted ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures* (“ASU 2023-09”). We have also audited the adjustments to the 2024 financial statements to retrospectively adjust the disclosures for the adoption of ASU 2023-09 in 2025. In our opinion, such retrospective adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2024 financial statements of the Company other than with respect to these retrospective adjustments, and accordingly, we do not express an opinion or any other form of assurance on the 2024 financial statements taken as a whole.

### Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

### Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

## Variable Consideration: Revenue Recognition

### *Critical Audit Matter Description*

As discussed in Note 2 of the 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, chargebacks and Medicaid rebates in the same period as the related sale occurs. At December 31, 2025, the Company had \$35 million in accrued returns, chargebacks and Medicaid rebates.

Auditing the product returns, chargebacks and Medicaid rebates liabilities is challenging because of the subjectivity of certain assumptions required to estimate the liabilities. In calculating the appropriate accrual amount, the Company considers historical returns and payments by product as a percentage of their historical sales as well as any significant changes in sales trends, the lag in payment timing, changes in rebate contracts, an evaluation of the current Medicaid laws and interpretations, the percentage of products that are sold via Medicaid, and product pricing. Given variability in prescription drug costs and variability in prescription data, historical information may not be predictive for management to estimate the variable consideration and thus, management supplements its historical data analysis with qualitative adjustments based upon current expectations, particularly for select products which contribute the largest portion of the Company's revenue.

### *How We Addressed the Matter in Our Audit*

We obtained an understanding and evaluated the procedures over management's process for the estimation of sales returns, Medicaid rebates and chargebacks. Our audit procedures included, among others, evaluating for reasonableness the significant assumptions used in the product profiles including the contractual terms of the chargeback rates, Medicaid pricing information and other regulatory factors. Our testing involved assessing the historical accuracy of management's estimates by comparing actual activity to previous estimates and performing analytical procedures, based on internal and external data sources, to evaluate the completeness of the reserves. We estimated the reserves using internal information and historical data and compared the result to the Company's estimated reserves. Additionally, our procedures included reviewing a sample of contracts, testing a sample of product returns, chargebacks and Medicaid rebate payments and testing the underlying data used in management's evaluation.

## **Auditing the Fair Value of Contingent Consideration and Intangible Assets Acquired in a Business Combination**

### *Critical Audit Matter Description*

As described in Note 3 to the financial statements, the Company completed the acquisition of Melinta Therapeutics, LLC on August 29, 2025 for total consideration of \$453.7 million and included fair value of contingent consideration of \$95.9 million. The Company accounted for this transaction as a business combination under the acquisition method of accounting whereby the fair value of the consideration transferred was allocated to the assets acquired, including intangible assets, excluding goodwill, of \$391.1 million and assets and liabilities assumed based upon their acquisition date fair values. Management estimated the fair value of the contingent consideration liability using the probability weighted outcome and discounting the estimated payments and the Monte Carlo simulation for the product royalties. Management estimated the fair value of the intangible assets using the Multi-Period Excess Earnings Method valuation technique for all marketed products and in-process research and development whereby residual forecasted cash flows expected to be derived from the intangible asset over the economic life of the asset, adjusted for expected attrition, are discounted to present value.

We identified the valuation of the contingent consideration and intangible assets at the acquisition date as a critical audit matter because of the significant assumptions management used in estimating the fair values, including forecasted cash flows and the selection of a discount rates used. Auditing management's assumptions involved a high degree of auditor judgment and an increased audit effort, including the use of valuation specialists, due to the impact these assumptions could have on the accounting estimates.

### *How We Addressed the Matter in Our Audit*

We obtained an understanding and evaluated the procedures over management's technical accounting analysis and valuation process. We inspected the governing agreements for the transaction and evaluated the application of the Company's technical accounting analysis including evaluating the terms and management's conclusion on the interpretation and application of the relevant accounting literature. We tested the reasonableness of management's forecasted cash flows used in the valuation of the intangible assets and contingent consideration. This testing included analyzing historical revenue trends, margins, and capital expenditures and comparing them to the forecasted amounts. With the assistance of our valuation specialists, we evaluated the reasonableness of the valuation methodology used, the reasonableness of the key inputs and assumptions to develop the fair value measurements, and verified the accuracy and completeness of the underlying data utilized.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2014 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Morristown, New Jersey

March 5, 2026

## 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, before the effects of the retrospective adjustments to the disclosures for the adoption of ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (“ASU 2023-09”) as discussed in Notes 2 and 8 to the consolidated financial statements, the accompanying consolidated balance sheet of CorMedix Inc. (the “Company”) and Subsidiaries as of December 31, 2024, the related consolidated statements of operations and comprehensive income (loss), stockholders’ equity and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the “financial statements”) (the 2024 financial statements before the effects of the adjustments discussed in Notes 2 and 8 to the financial statements are not presented herein). In our opinion, based on our audit, the financial statements, before the effects of the retrospective adjustments to the disclosures for the adoption of ASU 2023-09 as discussed in Notes 2 and 8 to the financial statements, present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

We were not engaged to audit, review, or apply any procedures to the retrospective adjustments to the disclosures for the adoption of ASU 2023-09 as discussed in Notes 2 and 8 to the financial statements and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those retrospective adjustments were audited by CBIZ CPAs P.C.

### Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

We have served as the Company’s auditor from 2014 to 2025.

Morristown, New Jersey  
March 25, 2025

**CORMEDIX INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
(In Thousands, Except Share Data)

	<b>December 31,</b>	
	<b>2025</b>	<b>2024</b>
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents . . . . .	\$ 144,837	\$ 40,651
Short-term investments . . . . .	3,694	11,037
Account receivables, net . . . . .	171,233	51,654
Inventories . . . . .	29,716	7,600
Prepaid expenses and other current assets (including restricted cash of \$656 and \$0 at December 31, 2025, and December 31, 2024) . . . . .	17,571	3,633
<b>Total current assets</b> . . . . .	<b>367,051</b>	<b>114,575</b>
Property and equipment, net . . . . .	5,959	1,829
Other long-term assets (including restricted cash of \$332 and \$105 at December 31, 2025, and December 31, 2024, net of current) . . . . .	23,816	105
Goodwill . . . . .	30,002	—
Intangible asset, net . . . . .	379,072	1,844
Deferred tax assets . . . . .	16,276	—
Operating lease right-of-use assets, net . . . . .	3,020	493
Finance lease- right-of-use assets, net . . . . .	946	—
<b>TOTAL ASSETS</b> . . . . .	<b>\$ 826,142</b>	<b>\$ 118,846</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable . . . . .	\$ 7,884	\$ 1,720
Accrued expenses . . . . .	161,921	31,952
Contingent Consideration, short-term . . . . .	3,015	—
Operating lease liabilities, short-term . . . . .	853	168
Financing lease liability, short-term . . . . .	596	—
<b>Total current liabilities</b> . . . . .	<b>174,269</b>	<b>33,840</b>
Convertible senior notes, net of deferred financing costs . . . . .	144,626	—
Contingent Consideration, net of current portion . . . . .	99,101	—
Operating lease liabilities, net of current . . . . .	2,253	349
Finance lease liabilities, net of current . . . . .	586	—
<b>TOTAL LIABILITIES</b> . . . . .	<b>420,835</b>	<b>34,189</b>
<b>COMMITMENTS AND CONTINGENCIES (Note 9)</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock – \$0.001 par value: 2,000,000 shares authorized; 91,623 and 136,623 shares issued and outstanding at December 31, 2025 and 2024, respectively . . . . .	—	—
Common stock – \$0.001 par value: 160,000,000 shares authorized at December 31, 2025 and 2024; 79,260,667 and 64,411,295 shares issued and outstanding at December 31, 2025 and 2024, respectively . . . . .	79	64
Accumulated other comprehensive gain . . . . .	3	91
Additional paid-in capital . . . . .	581,800	424,132
Accumulated deficit . . . . .	(176,575)	(339,630)
<b>TOTAL STOCKHOLDERS' EQUITY</b> . . . . .	<b>405,307</b>	<b>84,657</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b> . . . . .	<b>\$ 826,142</b>	<b>\$ 118,846</b>

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

**CORMEDIX INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**  
(In Thousands, Except Per Share Data)

	December 31,	
	2025	2024
<b>Revenue:</b>		
Product sales, net . . . . .	\$ 304,344	\$ 43,472
Contract revenue . . . . .	7,365	—
Total Revenues . . . . .	311,709	43,472
Cost of sales (exclusive of amortization of intangibles) . . . . .	22,089	3,034
Amortization of intangibles . . . . .	13,872	156
Gross profit . . . . .	275,748	40,282
<b>Operating Expenses:</b>		
Research and development . . . . .	19,333	3,942
Selling and marketing . . . . .	38,054	28,737
General and administrative . . . . .	68,220	29,959
Total operating expenses . . . . .	125,607	62,638
<b>Income (Loss) From Operations</b> . . . . .	150,141	(22,356)
<b>Other Income (Expense):</b>		
Interest income . . . . .	3,846	2,579
Foreign exchange transaction loss . . . . .	(52)	(31)
Unrealized gain on marketable security . . . . .	5,364	—
Other income . . . . .	—	519
Change in contingent consideration . . . . .	(6,501)	—
Interest expense . . . . .	(2,782)	(36)
Total other income (expense) . . . . .	(125)	3,031
<b>Net Income (Loss) Before Income Taxes</b> . . . . .	150,016	(19,325)
Income Tax (benefit) . . . . .	(13,039)	(1,395)
<b>Net Income (Loss)</b> . . . . .	163,055	(17,930)
<b>Other Comprehensive Income (Loss):</b>		
Unrealized (loss) from investments . . . . .	(2)	(5)
Foreign currency translation gain (loss) . . . . .	(86)	2
Total other comprehensive (loss) . . . . .	(88)	(3)
<b>Comprehensive Income (Loss)</b> . . . . .	\$ 162,967	\$ (17,933)
<b>Net Income (Loss) Per Common Share – Basic</b> . . . . .	\$ 2.25	\$ (0.30)
<b>Net Income (Loss) Per Common Share – Diluted</b> . . . . .	\$ 2.04	\$ (0.30)
<b>Weighted Average Common Shares Outstanding – Basic</b> . . . . .	72,034	58,872
<b>Weighted Average Common Shares Outstanding – Diluted</b> . . . . .	80,308	58,872

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

**CORMEDIX INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
(In Thousands)

	Common Stock		Preferred Stock – Series C-3, Series E, Series F and Series G		Accumulated Other Comprehensive Gain (Loss)	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
<b>Balance at December 31, 2023</b> . . .	54,938	\$ 55	182	\$ —	\$ 94	\$ 391,693	\$ (321,700)	\$ 70,142
Stock issued in connection with ATM sale of common stock, net . . . . .	3,050	3	—	—	—	18,879	—	18,882
Stock issued in connection with the exercise of pre-funded warrants . . . . .	2,501	3	—	—	—	—	—	3
Stock issued in connection with options exercised . . . . .	1,358	1	—	—	—	7,723	—	7,724
Conversion of Series G preferred stock to common stock . . . . .	2,502	2	(45)	—	—	(2)	—	—
Issuance of vested restricted stock, net of shares withheld for employee withholding taxes . . . . .	84	—	—	—	—	(290)	—	(290)
Cancellation of shares held in escrow . . . . .	(22)	—	—	—	—	—	—	—
Stock-based compensation . . . . .	—	—	—	—	—	6,129	—	6,129
Other comprehensive loss . . . . .	—	—	—	—	(3)	—	—	(3)
Net loss . . . . .	—	—	—	—	—	—	(17,930)	(17,930)
<b>Balance at December 31, 2024</b> . . .	64,411	\$ 64	137	\$ —	\$ 91	\$ 424,132	\$ (339,630)	\$ 84,657
Stock issued in connection with ATM sale of common stock, net . . . . .	715	1	—	—	—	7,787	—	7,788
Stock issued in connection with options exercised . . . . .	1,511	2	—	—	—	6,387	—	6,389
Stock issued in connection with public offering, net . . . . .	6,605	6	—	—	—	82,364	—	82,370
Stocks issued in connection with Melinta acquisition . . . . .	3,324	3	—	—	—	49,289	—	49,292
Conversion of Series G preferred stock to common stock . . . . .	2,502	3	(45)	—	—	(3)	—	—
Issuance of vested restricted stock, net of shares withheld for employee withholding taxes . . . . .	193	—	—	—	—	(1,988)	—	(1,988)
Stock-based compensation . . . . .	—	—	—	—	—	13,832	—	13,832
Elimination of cumulative translation adjustment upon closing of wholly-owned subsidiary . . . . .	—	—	—	—	(84)	—	—	(84)
Other comprehensive loss . . . . .	—	—	—	—	(4)	—	—	(4)
Net income . . . . .	—	—	—	—	—	—	163,055	163,055
Balance at December 31, 2025 . . .	<u>79,261</u>	<u>79</u>	<u>92</u>	<u>—</u>	<u>3</u>	<u>581,800</u>	<u>(176,575)</u>	<u>405,307</u>

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

**CORMEDIX INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In Thousands)

	<b>December 31,</b>	
	<b>2025</b>	<b>2024</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net Income (loss) . . . . .	\$ 163,055	\$ (17,930)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation . . . . .	13,832	6,129
Change in right-of-use assets . . . . .	438	148
Depreciation . . . . .	677	154
Amortization of intangible . . . . .	13,872	156
Change in contingent consideration . . . . .	6,501	—
Change in fair value of equity securities . . . . .	(5,364)	—
Deferred income taxes . . . . .	(25,797)	—
Amortization of debt finance costs . . . . .	398	—
Provision for current expected credit losses . . . . .	252	137
Gain on liquidation of foreign entity . . . . .	(86)	—
Changes in operating assets and liabilities:		
Increase in account receivables . . . . .	(90,924)	(51,791)
Increase in inventory . . . . .	(3,478)	(5,493)
Increase in prepaid expenses and other current assets . . . . .	(2,061)	(2,399)
(Decrease) Increase in accounts payable . . . . .	3,329	(2,560)
Increase in accrued expenses . . . . .	100,771	22,985
Decrease in operating lease liabilities . . . . .	(308)	(151)
Payment of contingent liability . . . . .	(61)	—
Net cash provided by (used in) operating activities . . . . .	175,046	(50,615)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisitions of businesses, net of cash acquired . . . . .	(308,511)	—
Investment in equity securities . . . . .	(5,000)	—
Purchase of short-term investments . . . . .	(47,952)	(26,769)
Maturity of short-term investments . . . . .	55,293	48,116
Purchase of equipment . . . . .	(2,260)	(116)
Net cash provided by (used in) investing activities . . . . .	(308,430)	21,231
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from sale of common stock from public offering, net . . . . .	82,370	—
Proceeds from senior convertible notes . . . . .	150,000	—
Proceeds from sale of common stock from at-the-market program, net . . . . .	7,788	18,882
Payment of employee withholding taxes on vested restricted stock units . . . . .	(1,988)	(290)
Proceeds from exercise of pre-funded warrants . . . . .	—	3
Proceeds from exercise of stock options . . . . .	6,389	7,724
Payment of debt issuance costs associated with the convertible notes . . . . .	(5,729)	—
Payment of contingent consideration liabilities . . . . .	(189)	—
ROU financing lease fees . . . . .	(188)	—
Net cash provided by financing activities . . . . .	238,453	26,319
Foreign exchange effects on cash . . . . .	—	(2)
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS . . . . .</b>	<b>105,069</b>	<b>(3,067)</b>
<b>CASH AND CASH EQUIVALENTS AND RESTRICTED CASH – BEGINNING OF YEAR . . . . .</b>		
	40,756	43,823
<b>CASH AND CASH EQUIVALENTS AND RESTRICTED CASH – END OF YEAR . . . . .</b>		
	<b>\$ 145,825</b>	<b>\$ 40,756</b>

**CORMEDIX INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS — (Continued)**  
**(In Thousands)**

	December 31,	
	2025	2024
Cash paid for interest . . . . .	\$ 17	\$ 36
<b>Supplemental Disclosure of Non-Cash, Investing, and Financing Activities:</b>		
Liability related to license agreement . . . . .	\$ —	\$ 2,000
Unpaid debt issuance costs associated with the convertible notes . . . . .	43	—
Issuance of common stock for Melinta acquisition . . . . .	49,292	—
Fair value of contingent payments . . . . .	95,865	—
ROU assets and liabilities for finance lease . . . . .	203	—
Fair value of assets acquired from Melinta . . . . .	513,977	—
Liabilities assumed from Melinta . . . . .	45,430	—
Goodwill recognized on Melinta . . . . .	30,002	—

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

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1 — Organization and Description of Business:**

***Organization and Business:***

CorMedix Inc. (“CorMedix” or the “Company”) was incorporated in the State of Delaware on July 28, 2006. The Company is a biopharmaceutical company focused on developing and commercializing therapeutic products for life-threatening diseases and conditions. The Company commercializes its lead product, DefenCath® (taurolidine and heparin) in the United States. CorMedix launched the product commercially in 2024 in both the hospital inpatient and outpatient hemodialysis settings of care.

On August 7, 2025, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) to acquire Melinta Therapeutics, LLC, a Delaware limited liability company (“Melinta”), which transaction closed on August 29, 2025 (the “Merger”). The acquisition of Melinta expanded the Company’s team and commercial platform and increased the commercial portfolio with six marketed, hospital- and clinic-focused infectious disease products, comprised of REZZAYO® (rezafungin for injection), MINOCIN® (minocycline) for Injection, VABOMERE® (meropenem and vaborbactam), KIMYRSA® (oritavancin), ORBACTIV® (oritavancin), BAXDELA® (delafloxacin), and an additional well-established cardiovascular product, TOPROL-XL® (metoprolol succinate) (together, the “Melinta Portfolio”, and, together with DefenCath, “our Products”). REZZAYO is currently approved for the treatment of candidemia and invasive candidiasis in adults, with an ongoing Phase III study for the prophylaxis of invasive fungal infections in adult patients undergoing allogeneic blood and marrow transplantation. The completion of the Phase III study for REZZAYO is expected in 2026.

The financial results of Melinta are included in the Company’s consolidated financial statements starting August 29, 2025. Further information relating to the acquisition of Melinta, including the related financing transaction, is included in Note 3.

**Note 2 — Summary of Significant Accounting Policies:**

***Basis of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, including the Company’s wholly owned subsidiary CorMedix Europe GmbH which was dissolved during the year ended December 31, 2025. All significant intercompany accounts and transactions have been eliminated in consolidation.

***Use of Estimates***

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles (“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 The more significant areas in which estimates and the exercise of judgment include: variable consideration for product returns and Medicaid utilization rates; realization of receivables, valuation of inventory; valuation and measurement of contingent consideration, in-process research and development (“IPR&D”), amortizable intangibles, and goodwill in connection with business combinations; 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 2025 presentation.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

***Business Combinations***

The Company accounts for business combinations in accordance with FASB Accounting Standard Codification Topic No. 805, Business Combinations (“ASC 805”), which requires that all business combinations be accounted for using the acquisition method of accounting. Under this method, the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree are recognized at their fair values as of the acquisition date. The excess of the total purchase consideration over the fair value of the identifiable net assets acquired is recorded as goodwill.

In evaluating whether a transaction represents the acquisition of a business, the Company applies the guidance in ASC 805, considering whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If not, the Company evaluates whether the acquired set includes an input and a substantive process that together significantly contribute to the ability to create outputs. Transactions that meet these criteria are accounted for as business combinations; otherwise, they are accounted for as asset acquisitions under ASC 805-50.

For the acquisition of a business, the purchase price is allocated to the assets acquired and liabilities assumed based on their estimated fair values at the acquisition date. The Company conducts a valuation analysis to determine the fair value of significant tangible and intangible assets acquired, including marketed product values, trademarks, and IPR&D. Management determines the fair values of working capital accounts, property and equipment, and certain other assets and liabilities based on available information and market data.

During the measurement period, which may be up to one year from the acquisition date, the Company may record adjustments to the fair value of these tangible and intangible assets acquired and liabilities assumed, with the corresponding offset to goodwill. In addition, uncertain tax positions and tax-related valuation allowances are initially established in connection with a business combination as of the acquisition date. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to the Company’s consolidated statements of operations.

***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. 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. Also, 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.

A roll forward of allowance for credit losses for the years ended December 31, 2025 and December 31, 2024 is as follows:

	<b>Year Ended December 31,</b>	
	<b>2025</b>	<b>2024</b>
Beginning Balance . . . . .	\$ 137	\$ —
Melinta portfolio beginning balance. . . . .	244	—
Provision for expected credit losses . . . . .	252	137
Write-offs or recoveries . . . . .	(18)	—
Ending Balance . . . . .	\$ 615	\$ 137

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

***Concentrations***

The following table summarizes net revenue from each of the Company’s customers, who individually represent at least 10% of total revenue.

	<b>Year Ended December 31,</b>	
	<b>2025</b>	<b>2024</b>
Customer A . . . . .	38%	86%
Customer B . . . . .	20%	9%
Customer C . . . . .	21%	0%

The following table summarizes accounts receivable concentrations for each of the Company’s customers, who individually represent at least 10% of total accounts receivable.

	<b>December 31, 2025</b>	<b>December 31, 2024</b>
	Customer A . . . . .	20%
Customer B . . . . .	23%	12%
Customer C . . . . .	41%	0%

For DefenCath, the Company currently has one FDA-approved source (contract manufacturing organization, or “CMO”) for each of its two key active pharmaceutical ingredients (“APIs”), 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 that has been in place since August 2018. 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.

The Company received FDA approval of DefenCath with finished dosage production from its European based 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 DefenCath. In addition, the Company also qualified Siegfried Hameln as an alternate finished dosage manufacturing site and is in the process of scaling up production at the facility.

Each of the products in the Melinta Portfolio has one FDA-approved contract manufacturing organization, primarily in Europe or in the United States. The Company has ongoing technology transfers intended to reduce costs of goods sold as well as to onshore the manufacture of several of its products, which it expects to complete over the next two to three years.

***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 often 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:

	<b>December 31,</b>	
	<b>2025</b>	<b>2024</b>
Cash and cash equivalents. . . . .	144,837	\$ 40,651
Restricted cash, (included in prepaid expenses and other current assets). . . . .	656	—
Restricted cash, (included in other long-term assets). . . . .	332	105
Total cash, cash equivalents and restricted cash . . . . .	<u>145,825</u>	<u>\$ 40,756</u>

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

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, 2025 or December 31, 2024.

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. In addition, the Company holds marketable equity securities in Talphera, Inc., ("Talphera") a publicly-traded biotechnology company and has elected the fair value option for accounting for this investment. The related unrealized gain pertaining to Talphera is recorded in Other income. During the fourth quarter of 2025, the Company's CEO was appointed to the Board of Directors of Talphera, and as such, Talphera is considered a related party for any subsequent transactions. The Company has no related party transactions with Talphera to date.

As of December 31, 2025 and 2024, all of the Company's investments had contractual maturities of less than one year. The following table summarizes the amortized cost, unrealized gains and losses and the fair value at December 31, 2025 and 2024 (in thousands).

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Fair Value
<u>December 31, 2025:</u>				
Money Market Funds included in Cash				
Equivalents . . . . .	\$ 4,805	\$ —	\$ —	\$ 4,805
Commercial Paper . . . . .	3,694	—	—	3,694
Total December 31, 2025 short-term assets . .	<u>\$ 8,499</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 8,499</u>
<u>December 31, 2024:</u>				
Money Market Funds included in Cash				
Equivalents . . . . .	\$ 23,122	\$ —	\$ —	\$ 23,122
U.S. Government Agency Securities . . . . .	11,033	—	4	11,037
Total December 31, 2024 short-term assets . .	<u>\$ 34,155</u>	<u>\$ —</u>	<u>\$ 4</u>	<u>\$ 34,159</u>

***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, accounts payable and accrued expenses. The carrying value of certain financial instruments, primarily cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses 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

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

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 on a reoccurring basis as of December 31, 2025 and 2024 (in thousands):

	<u>Carrying Value</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<u>December 31, 2025:</u>				
Money Market Funds and Cash Equivalents. . .	\$ 4,805	\$ 4,805	\$ —	\$ —
Commercial Paper. . . . .	3,694	—	3,694	—
Total December 31, 2025, short-term assets. .	<u>8,499</u>	<u>4,805</u>	<u>3,694</u>	<u>—</u>
Marketable Equity Securities . . . . .	10,364	10,364	—	—
Contingent Consideration liability . . . . .	102,116	—	—	102,116
<u>December 31, 2024:</u>				
Money Market Funds and Cash Equivalents. . .	\$ 23,122	\$ 23,122	\$ —	\$ —
U.S. Government Agency Securities. . . . .	11,037	11,037	—	—
Total December 31, 2024 short-term assets . .	<u>\$ 34,159</u>	<u>\$ 34,159</u>	<u>\$ —</u>	<u>\$ —</u>

***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. The Company dissolved its only foreign subsidiary during the fourth quarter of 2025. 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 loss of \$0.1 million in the year ended December 31, 2025 and a gain of \$0.0 million for the year ended December 31, 2024.

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 restricted cash as of December 31, 2025 was comprised of \$0.7 million in VAT refunds and \$0.3 million in lease security deposits associated with the ROU operating lease. The VAT refunds are reported in prepaid expenses and other current assets while the lease security deposits are reported in other long-term assets. The VAT was related to bank guarantees issued to the Italian Tax Authority (“ITA”) for VAT refunds authorized and received in 2022 and 2023. The bank guarantees will remain in place until the expiry of statute of limitations imposed by the ITA, which is typically 3 years after the refund was received.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

The Company’s restricted cash of \$0.1 million as of December 31, 2024 related solely to a lease security deposit.

***Prepaid expenses and other current assets***

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

***Debt Issuance Costs***

Debt issuance costs represent legal and other direct costs incurred in connection with the issuance of the Company’s convertible senior notes due 2030. These costs are recorded as contra-notes payable on our balance sheet and amortized as a non-cash component of interest expense using the effective interest method over the term of the loan agreement (see Note 7 — Convertible Senior Notes).

***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 our Products prior to FDA approval to support the preparation for commercial launch are 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 stated at the lower of cost or estimated net realizable value. Inventory is valued on a first-in, first-out basis and consists primarily of material costs, third-party manufacturing costs, overhead — principally the cost of managing the company’s manufacturers — and related transportation costs. 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 forecasted 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 as of December 31, 2025 or 2024 respectively.

Inventories consist of raw materials (including labeling and packaging), work-in-process, and finished goods. Inventories consist of the following (in thousands):

	<b>December 31, 2025</b>	<b>December 31, 2024</b>
Raw materials . . . . .	\$ 3,635	\$ 1,111
Work in progress . . . . .	11,691	3,528
Finished goods . . . . .	14,390	2,961
Total . . . . .	<u>\$ 29,716</u>	<u>\$ 7,600</u>

The pre-commercial inventory previously expensed as R&D prior to FDA approval, which has a book value of \$0, consists of certain raw materials and inventory at various stages of completion with a fair value approximating \$3.8 million and \$5.3 million as of December 31, 2025 and 2024, respectively.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

***Revenue Recognition***

The Company recognizes revenue from the sale of its Products 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 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;
- Shelf-stock adjustments;
- Administrative and data fees.

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 certain 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.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

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 (12 months for the legacy Melinta Portfolio). 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 the Company's Products 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 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.

Medicaid and Commercial Rebates — The Company is or may become subject to negotiated discount obligations to different GPO, direct purchasers, other commercial organizations or government programs, including Medicaid. 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.

Shelf-stock adjustments — The Company is subject to quarterly shelf-stock adjustments with certain direct customers to account for contract price changes as related to quarterly decreases to our published Average Selling Price ("ASP"). Inventory levels subject to shelf-stock adjustment are determined based on current customer utilization rates and current inventory levels at the customer. Shelf-stock adjustments are recorded as accrued expenses on the balance sheet.

Administrative and data fees — The Company is subject to negotiated administrative fees and data fees with certain direct and indirect customers.

Provisions for the revenue variable consideration described above totaled \$355.8 million and \$24.1 million for the year ended December 31, 2025 and 2024 respectively. As of December 31, 2025 and December 31, 2024, total accrued reserves and allowances to accounts receivable on the balance sheet associated with variable consideration were \$132.4 million and \$23.2 million, respectively.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

A roll forward of the significant categories of variable consideration deductions for the years ended December 31, 2025 and 2024, respectively is as follows:

	<u>Volume Incentive Rebates</u>	<u>Medicaid</u>	<u>Distribution Service Fees</u>	<u>Accrued Shelf-stock Liability</u>	<u>Accrued Returns Allowance</u>	<u>Chargebacks</u>
Balance at December 31, 2023 . . . . .	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Provisions related to sales recorded in the period . . . . .	21,582	42	335	—	746	63
Credits/payments issued during the period . . . . .	(664)	—	(33)	—	—	—
Balance at December 31, 2024 . . . . .	\$ 20,918	\$ 42	\$ 302	\$ —	\$ 746	\$ 63
Melinta portfolio beginning balances . . . . .	81	1,608	2,107	—	11,817	1,708
Provisions related to sales recorded in the period . . . . .	113,336	11,448	37,510	9,599	7,629	28,900
Credits/payments issued during the period . . . . .	(48,334)	(3,002)	(34,139)	(7,344)	(1,901)	(26,367)
Effect of change in estimate . . . . .	—	2,322	—	—	—	—
Balance at December 31, 2025 . . . . .	<u>\$ 86,001</u>	<u>\$ 12,418</u>	<u>\$ 5,780</u>	<u>\$ 2,255</u>	<u>\$ 18,291</u>	<u>\$ 4,304</u>

During the year ended December 31, 2025, a change in estimate was recorded for variable consideration pertaining to Medicaid rebates. During the three months ended June 30, 2025, new information was obtained by the Company surrounding Medicaid utilization rates for certain states that reimburse service providers using DefenCath. The resulting change in accounting estimate negatively impacted net sales, income from continuing operations and net income for the year ended December 31, 2025. During 2025, net income was impacted by \$1.7 million, basic and diluted earnings per share were negatively impacted by \$0.02 and \$0.02 per share, which would have caused earnings per share and diluted earnings per share to be \$2.27 and \$2.06 respectively, with a corresponding net income of \$164.7 million.

***License Agreement***

In connection with the Merger, the Company acquired Melinta's license and collaboration agreements for the R&D and/or commercialization of its therapeutic products. The terms of these agreements may include nonrefundable licensing fees, funding for research and development and manufacturing, milestone payments and royalties on any product sales derived from the collaborations in exchange for the delivery of licenses and rights to sell Melinta's products within specified territories outside the United States. Because the partners in these agreements are deemed to be customers under ASC 606, the consideration associated with any performance obligations is accounted for as revenue under ASC 606. Such revenue is classified as Contract Revenue in the Consolidated Statement of Operations.

In addition, in connection with these license and collaboration agreements, the Company recognizes revenue from the sale of bulk raw materials and work-in-process inventory to its partners when it transfers title of the product to such partners. Contract revenue and sales of inventory to partners are classified as Contract Revenue in the Consolidated Statement of Operations.

***Government Contract Revenue***

In connection with the Melinta Portfolio, the Company now holds contracts in partnership with BARDA, a government agency, to advance research and development of certain of our Products. All aspects of the BARDA contract represent a transaction with a customer to obtain services that are an output of the Company's ordinary activities in exchange for consideration, and therefore, the arrangement is accounted for in accordance with ASC 606.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

The Company recognizes government contract revenue as services are performed under in accordance with ASC 606. Revenue and related reimbursable expenses are presented on a gross basis in the Company's Consolidated Statements of Operations. The related reimbursable expenses are expensed as incurred as research and development expenses. See Note 11 — BARDA Agreement for details of the agreement.

***Intangible Assets and Goodwill***

Intangible assets represent the fair value of identifiable intangible assets primarily in connection with the Merger (see Note 3). The Company also holds rights under the License and Assignment Agreement with ND Partners, LLP, which were recorded at cost (see Note 9 — Commitments and Contingencies for further discussion). The Company amortizes the cost of intangible assets on a straight-line basis over the estimated economic life of each asset, generally the patent lives of each associated product (remaining amortization periods are between 5 and 9 years).

As of December 31, 2025, gross product right intangible assets and the related accumulated amortization were as follows:

	<u>Gross Amount</u>	<u>Accumulated Amortization</u>	<u>Net Carrying Value</u>	<u>Weighted- Average Remaining Amortization Period (years)</u>
<b>December 31, 2025</b>				
Product licensing rights . . . . .	\$ 250,100	\$ (14,028)	\$ 236,072	5.9
Indefinite-lived asset . . . . .	143,000	—	143,000	N/A
<b>Intangible asset-net . . . . .</b>	<u>\$ 393,100</u>	<u>(14,028)</u>	<u>379,072</u>	
<b>December 31, 2024</b>				
Product licensing rights . . . . .	2,000	(156)	1,844	8.9
<b>Intangible asset-net . . . . .</b>	<u>2,000</u>	<u>(156)</u>	<u>1,844</u>	

The amortization expense of acquired intangible assets for each of the following periods are expected to be as follows:

<u>Year ending December 31,</u>	<u>Amortization Expense</u>
2026 . . . . .	41,200
2027 . . . . .	41,200
2028 . . . . .	41,200
2029 . . . . .	41,200
2030 . . . . .	37,833
2031 and thereafter . . . . .	33,439
<b>Total . . . . .</b>	<u>\$ 236,072</u>

Amortization of product rights intangible assets, which is included in cost of goods sold, was \$13.9 million and \$0.2 million for year ended December 31, 2025 and 2024 respectively.

Indefinite-lived assets and goodwill are not amortized but are subject to an impairment review annually and more frequently when indicators of impairment exist. The Company operates as one reporting unit/one segment, thus the goodwill is deemed to be enterprise goodwill.

Goodwill represents the excess of the purchase price over the fair value of identifiable net assets acquired in the business combination completed on August 29, 2025. Goodwill and indefinite lived intangible assets are not amortized and are evaluated for impairment at least annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the fair value of a reporting unit is less than its carrying amount.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

The Company has elected October 1 as its annual goodwill and indefinite lived impairment testing date.

Since goodwill was recognized on August 29, 2025, and the Company's annual testing date is October 1<sup>st</sup>. Management performed a qualitative assessment of events and circumstances for the period between the acquisition date and October 1, 2025 and determined that no triggering events or indicators of impairment occurred. Accordingly, no impairment loss was recognized.

***Impairment of Long-Lived Assets***

Long-lived assets consist primarily of property and equipment, and intangible assets with definite lives. The Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that the carrying amount of an asset or group of assets may not be fully recoverable at the lowest level of identifiable cash flows. If impairment indicators are present, the Company assesses whether the future estimated undiscounted cash flows attributable to the assets in question are greater than their carrying amounts. If these future estimated cash flows are less than carrying value, it then measures an impairment loss for the amount that carrying value exceeds fair value of the assets. For the year ended December 31, 2025 and 2024, the Company recorded no impairment of long-lived assets.

***Leases***

The Company accounts for leases in accordance with ASC 842, *Leases*. At the inception of a contract, the Company determines whether the arrangement contains a lease by assessing whether there is an identified asset and whether the Company has the right to control the use of that asset during the term of the arrangement.

The Company recognizes a right-of-use ("ROU") asset and a corresponding lease liability for all leases with a term greater than 12 months. ROU assets and lease liabilities are measured at the present value of future lease payments at the lease commencement date, discounted using the rate implicit in the lease, or, if that rate is not readily determinable, the Company's incremental borrowing rate.

Leases are classified as operating or finance leases at commencement. For operating leases, lease expense is recognized on a straight-line basis over the lease term within operating expenses. The related ROU assets and lease liabilities are presented separately on the balance sheet. For finance leases, interest expense on the lease liability and amortization of the ROU asset are recognized separately within interest expense and depreciation and amortization expense, respectively. Lease liabilities are remeasured if there are changes to the lease term, payments, or other relevant assumptions.

***Income (Loss) Per Common Share***

Income (loss) per common share requires consideration of the two-class method when an entity has participating securities. 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, participating pro-rata in the earnings of the Company as if the Series E preferred stock was converted into common shares of the Company. As a result, the Series E preferred stock meets the definition of a participating security, and the Company is required to apply the two-class method. The Company's convertible debt is a contingently participating security. The dividends are contingent and only paid to holders of the convertible debt if dividends declared are equal or greater than the share price. If this occurs, the Company may be required to apply 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. Since the Series E preferred stock and convertible debt do not have contractual obligations that require participation in the Company's losses, the two-class method is not required for periods in which Company has a net loss.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

Basic income (loss) per common share excludes dilution and is computed by dividing net income (loss) by the weighted average number of common shares, including applicable participating securities, outstanding during the period. For the year ended December 31, 2025, basic income per common share is calculated assuming the Series E preferred stock was converted into common shares and participates in the earnings of the Company on a pro-rata basis. The Company's convertible debt is excluded from the weighted average shares outstanding for purposes for determining income (loss) per common share as there have been no conversion for the year ended December 31, 2025. The Company's convertible debt was not included in the basic income (loss) per common share under the two-class method because no contingent dividends were declared. As a result, net income for the year ended December 31, 2025 is allocated pro-rata between the Company's weighted average outstanding common shares and Series E preferred stock (on an as-if converted basis). On an as-if converted basis, the Series E preferred stock weighted average shares is equal to 439,010 common shares of the Company and would be allocated \$1.0 million of the Company's earnings for the year ended December 31, 2025.

For periods of net income, diluted net income per share is computed using the more dilutive of the treasury method or two-class method. Because the Company's Series E preferred stock does not contain non-forfeitable rights to dividends, the "two-class method" results in the same diluted net income per share as the "treasury method." Diluted net income (loss) per common share reflects the potential dilution that would 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. The Company calculates dilutive potential common shares using the treasury stock method for stock options and restricted units, which assumes the Company will use the proceeds from the exercise of stock options and vesting of restricted stock units to repurchase shares of common stock to hold in its treasury stock reserves. The Company calculates dilutive potential common shares using the if-converted method for preferred stock and convertible debt, which assumes they are converted at the beginning of the period (or at time of issuance, if later).

For the year ended December 31, 2024, the two-class method was not required since the Company was in a net loss position and the participating securities do not have contractual obligations that require participation in the Company's losses.

A reconciliation of the Company's basic and diluted income (loss) per common share is as follows (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2025</b>	<b>2024</b>
<b>Numerator:</b>		
Net income (loss) . . . . .	\$ 163,055	\$ (17,930)
Less: Allocation of undistributed income of Series E securities. . . . .	(988)	—
Undistributed income (loss) available to common stockholders . . . . .	\$ 162,067	\$ (17,930)
<b>Denominator:</b>		
Basic weighted average common shares outstanding . . . . .	72,034	58,872
Effect of Series E dilutive securities . . . . .	439	—
Effect of stock Options and restricted stock dilutive securities . . . . .	3,533	—
Effect of Convertible Senior Notes dilutive securities . . . . .	4,302	—
Diluted weighted average common shares outstanding . . . . .	<u>80,308</u>	<u>58,872</u>

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as they would be antidilutive (in thousands):

	December 31,	
	2025	2024
	(Number of Shares of Common Stock Issuable)	
Series C-3 non-voting preferred stock . . . . .	—	4
Series E voting preferred stock . . . . .	—	392
Series G voting preferred stock . . . . .	—	2,502
Shares issuable for payment of deferred board compensation . . . . .	—	49
Shares underlying outstanding stock options . . . . .	78	6,282
Shares underlying restricted stock units . . . . .	563	292
Total potentially dilutive shares . . . . .	641	9,521

***Stock-Based Compensation***

Stock-based compensation 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 conditions. Restricted stock unit (“RSU”) compensation is based upon the fair value of the Company’s common stock on the date of the grant for RSU’s that vest upon service conditions. Performance stock units (“PSU’s”) which vest upon market and service conditions, utilize a Monte-Carlo simulation model. Stock-based compensation is recognized as expense over the requisite service period on a straight-line basis. See Note 10.

***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.

***Income Taxes***

Estimated deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities, using enacted tax rates, as well as any net operating loss or tax credit carry forwards expected to reduce taxes payable in future years. A valuation allowance is provided when it is more likely than not that all or some portion of the estimated deferred tax assets will not be realized. While the Company considers future taxable income in assessing the need for the valuation allowance, in the event that the Company anticipates that it will be able to realize the estimated deferred tax assets in the future in excess of its net recorded amount, an adjustment to the provision for deferred tax assets would increase income in the period such determination was made. Similarly, in the event that the Company anticipates that it will not be able to realize the estimated deferred tax assets in the future considering future taxable income, an adjustment to the provision for deferred tax assets would decrease income in the period such determination was made. Changes in the valuation allowance from period to period are included in the Company’s tax provision in the period of change.

The Company accounts for income taxes regarding uncertain tax positions and recognizes interest and penalties related to uncertain tax positions in income tax expense in the consolidated statements of operations and comprehensive income.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2 — Summary of Significant Accounting Policies: (cont.)**

***Recently Issued and Adopted Accounting Pronouncements***

***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. CorMedix adopted this guidance retrospectively in annual reporting period ending December 31, 2025. The adoption impacted the CorMedix’s income tax disclosures (see Note 8 — Income Taxes).

***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 2025-11***

In November 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*, which clarifies interim disclosure requirements. The guidance is effective for CorMedix’s interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. CorMedix is assessing the impact of adopting this guidance on its consolidated financial statements.

***ASU 2024-03***

In November 2024, the FASB issued ASU 2024-03, *Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40)*, which requires public business entities to provide additional disaggregated disclosures of certain expense categories included in income statement captions. The guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively. CorMedix is currently evaluating the impact of adopting this guidance on its consolidated financial statement disclosures.

***ASU 2025-05***

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which provides a practical expedient for estimating expected credit losses on current trade receivables and contract assets arising from revenue transactions. The guidance is effective for CorMedix’s annual reporting period beginning after December 15, 2025, with early adoption permitted, and must be applied prospectively. CorMedix is evaluating the impact of this guidance on its consolidated financial statements.

**Note 3 — Acquisition of Melinta:**

On August 29, 2025 (the “Closing Date”), the Company completed the acquisition of Melinta, pursuant to that certain Agreement and Plan of Merger with Melinta, Coriander BidCo LLC, a Delaware limited liability company and a wholly owned subsidiary of the Company (“Merger Sub”), and Deerfield Private Design Fund IV, L.P., a Delaware limited partnership, solely in its capacity as representative, agent and attorney-in-fact of the Melinta equity holders. Pursuant to the terms of the Merger Agreement, the Company acquired Melinta via a merger in which Merger Sub merged with and into Melinta, with Melinta surviving as a wholly-owned subsidiary of the Company.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 3 — Acquisition of Melinta:** (cont.)

In consideration for the Merger, the Company (i) paid to the former Melinta equity holders an aggregate of \$260 million in cash, subject to adjustment for estimated Company Cash and estimated Working Capital as compared to the Working Capital Target (each as defined in the Merger Agreement), and (ii) issued to the to certain of the former Melinta equity holders an aggregate of 3.3 million of common shares of the Company. In addition, in connection with the Merger, the Company paid \$23.2 million to acquire the Toprol XL product, which Melinta had licensed from a third party. The total cash consideration in connection with the Merger Agreement was funded by a combination of the Company’s existing cash on hand and net proceeds from the Company’s \$150 million Convertible Notes Offering (see Note 7 for details on the Convertible Notes Offering).

Additionally, the former Melinta equity holders are eligible to receive certain contingent payments pursuant to the terms of the Merger Agreement and the Contingent Payment Agreement, which provides for milestone and net sales-based payments. Upon the issuance of the U.S. Food and Drug Administration (“FDA”) marketing approval of REZZAYO (or any product that contains the active ingredient rezafungin), for the prevention or prophylaxis of invasive fungal infections in adult patients undergoing allogeneic stem cell blood and marrow transplant or the regulatory equivalent (the “REZZAYO Second Indication”) on or prior to June 30, 2029, the Company shall pay, in cash or common shares, par value \$0.001 per share, of the Company at the Company’s election, to the former Melinta equity holders the following payments (the “REZZAYO Milestone”):

- (i) if the FDA-approved labeling includes candida, \$20 million;
- (ii) if the FDA-approved labeling includes aspergillus, \$2.5 million; and
- (iii) if the FDA-approved labeling includes pneumocystis, \$2.5 million.

Further, the Contingent Payment Agreement provides that the Company will pay to the former Melinta equity holders tiered royalties on REZZAYO U.S. net sales and low-single-digit royalties on MINOCIN U.S. net sales (each the “REZZAYO Royalties” and “MINOCIN Royalties”).

The Merger is accounted for using the acquisition method of accounting for business combinations under ASC 805, *Business Combination*, with CorMedix representing the accounting acquirer under this guidance. The estimates relating to the allocation of the purchase price are preliminary through the conclusion of the measurement period, which will be no longer than one year from the Closing Date.

*Summary of Consideration Transferred*

The following tables summarizes the total consideration for the acquisition of Melinta under the Merger Agreement, net of cash, cash equivalents and restricted cash acquired of \$44.9 million

Cash Consideration paid to Melinta equity holders . . . . .	\$ 285,292
Cash Consideration paid to acquire Toprol XL. . . . .	23,219
Fair value of common shares of CorMedix. . . . .	49,292
Fair value of contingent payments . . . . .	95,865
Total consideration transferred . . . . .	<u>\$ 453,668</u>

The fair value of the contingent payments of \$95.9 million includes the REZZAYO Milestone and the REZZAYO and MINOCIN Royalties (together, the “Royalties”). The Company estimated the fair value of the REZZAYO Milestone by probability-weighting each outcome and discounting the estimated payment back to the Closing Date. Key assumptions used in the valuation included probability of milestone achievement, the estimated timing of approval, an estimated weighted-average cost of capital, and the estimated timing of the REZZAYO Milestone payment occurring in 2027.

In the fourth quarter of 2025, the Company revised the fair value of common stock issued in connection with the Merger to properly reflect the stock price on the Closing Date. This revision resulted in an increase to equity and goodwill of approximately \$9.3 million.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 3 — Acquisition of Melinta:** (cont.)

The Company estimated the fair value of the REZZAYO Royalties using a Monte Carlo simulation framework. Specifically, the Company simulated future net sales assuming a Geometric Brownian Motion framework, and these simulated metrics were used to determine the applicable percentage of REZZAYO Royalties. The fair value of the MINOCIN Royalties is linear with no thresholds, caps, tiers, or carry forwards, and was estimated using the Scenario Based Method. For each method, the Royalties were calculated based on the contractual terms and then discounted from each payment date back to Closing Date. Key assumptions used in the valuation included projected net sales, the estimated duration of the related cash flows, and an estimated weighted-average cost of capital. Royalties payments are expected to occur until the expiration of patent or regulatory exclusivity in the late 2030's.

During the year ended, the Company recognized transaction costs related to the Merger of \$10.2 million. These costs were primarily associated with financial advisory, legal and other professional services related to the Acquisition and are reflected within general and administrative expenses in our consolidated statements of operations.

The preliminary allocation of the purchase price to acquired assets and liabilities assumed based on their estimated fair values as of Closing Date is reflected in the table below. Goodwill represents the expected synergies resulting from acquiring the remaining interests in the acquirees that do not qualify for separate recognition as intangible assets. The goodwill is not deductible for tax purposes as it was a stock acquisition.

**Acquired assets and (liabilities) assumed**

<b>Assets</b>	
Cash, cash equivalents and restricted cash . . . . .	\$ 44,881
Accounts Receivable . . . . .	28,907
Inventory . . . . .	18,639
Prepaid expenses and current assets . . . . .	11,146
Property and equipment, net . . . . .	2,403
Intangible assets . . . . .	391,100
Other long-term assets . . . . .	16,901
<b>Liability</b>	
Accounts payable . . . . .	(2,835)
Accrued expenses . . . . .	(29,011)
Other current liabilities . . . . .	(1,246)
Deferred tax liability . . . . .	(9,521)
Other long term liabilities . . . . .	(2,817)
<b>Net assets acquired</b> . . . . .	<u>468,547</u>
Purchase price consideration . . . . .	<u>498,549</u>
<b>Goodwill</b> . . . . .	<u>\$ 30,002</u>

In the preliminary purchase price allocation, the Company identified intangible assets associated with marketed product values and in-process research and development, the fair value of which were \$248.1 million, and \$143.0 million, respectively. In determining the fair value of these intangible assets, the Company considered many factors, including financial forecasts associated with each of the products, the estimated duration of the related cash flows, and an estimated weighted-average cost of capital. The estimated net cash flow attributed to each marketable and licensed product is discounted back to Closing Date using a discount rate of approximately 15%. The marketed product values will be amortized on a straight-line basis over their estimated useful lives, on a weighted-average basis, of 6.2 years. The in-process research and development relates to the future cash flows associated with the REZZAYO Second Indication if and when approved by the FDA, the fair value of which was determined using probability-weighted, discounted cash flows using a discount rate of 17%.

The amount of revenue attributable to the Melinta business included in consolidated statements of operations for the year ended December 31, 2025 is \$52.9 million.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 3 — Acquisition of Melinta:** (cont.)

*Fair value measurement of contingent consideration liability*

Consideration paid in a business combination may include potential future payments that are contingent upon the acquired business achieving certain levels of earnings in the future (“contingent consideration”). Contingent consideration liabilities are measured at their estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded as Other income in the consolidated statements of operations. Fair value as of the date of acquisition is estimated based on projections of expected future cash flows of the acquired business. The Company estimates the contingent consideration liability using the Probability-Weighted Discounted Cash Flows, Monte Carlo simulation framework, and Scenario Based Method approach for REZZAYO Milestone payments, REZZAYO Royalties, and MINOCIN Royalties, respectively. These approaches require the Company to make estimates and assumptions regarding the future cash flows and profits. Changes in these estimates and assumptions could have a significant impact on the amounts recognized.

The following table summarizes the change in fair value, as determined by Level 3 inputs, for the contingent consideration liability using unobservable Level 3 inputs for the year ended December 31, 2025:

	<b>Contingent Consideration</b>
Balance as of August 29, 2025 . . . . .	\$ 95,865
Payments against contingent consideration . . . . .	(250)
Change in fair value of contingent consideration liability . . . . .	6,501
Balance as of December 31, 2025. . . . .	<u>\$ 102,116</u>

For the year ended December 31, 2025, we recognized a \$6.5 million change in contingent consideration, primarily driven by the changes in the present value of expected payments resulting from discount accretion and updates to the risk-free rate used in the initial Closing Date valuation as of August 29, 2025. The following table summarizes key assumptions and inputs used in the fair value simulation as of the valuation dates:

<b>Valuation Dates</b>	<b>December 31, 2025</b>	<b>August 29, 2025</b>
Risk-free rate over simulated period . . . . .	4.30%	4.41%
Net sales of REZZAYO product volatility . . . . .	75.00%	75.00%
Net sales REZZAYO product discount rate (continuous) . . . . .	13.15%	13.20%
Net sales Minocin product discount rate (continuous) . . . . .	8.75%	8.65%
Earnout payment discount rate (continuous) . . . . .	7.13%	7.32%
REZZAYO Milestone payment discount rate . . . . .	6.25%	6.55%

*Unaudited Pro Forma Financial Information*

The following unaudited pro forma financial information presents the combined results of operations of CorMedix and Melinta as if the Merger occurred at the beginning of the years presented. The unaudited pro forma financial information includes impact of certain adjustment related to changes from the purchase of Toprol XL product which was previously licensed to Melinta, amortization of intangibles, transaction related cost incurred, stock compensation expenses, interest expense on related borrowings, and related income tax effects. The unaudited pro forma financial information presented does not include any impact of transaction synergies. The unaudited pro forma financial information is presented for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place on the date indicated or of results that may occur in the future.

	<b>2025</b>	<b>2024</b>
Total Revenue . . . . .	\$ 401,321	\$ 163,442
Net Income . . . . .	\$ 138,616	\$ (55,253)
Net Income Per Common Share – Basic . . . . .	\$ 1.91	\$ (0.94)
Net Income Per Common Share – Diluted . . . . .	\$ 1.75	\$ (0.94)

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 3 — Acquisition of Melinta:** (cont.)

The unaudited pro forma financial information presented above includes the following adjustments:

Year ended December 31, 2025:

- Elimination of \$1.7 million of licensing fees and profit sharing costs associated with the Toprol XL brand
- Elimination of \$10.5 million of acquisition related expenses
- Elimination of historical stock compensation expense of \$18.9 million
- Inclusion of intangible asset amortization of \$25.9 million
- Net impact of new convertible notes payable of \$0.4 million
- \$1.6 million tax effect on proforma adjustments

Year ended December 31, 2024:

- Elimination of \$2.9 million of licensing fees and profit sharing costs associated with the Toprol XL brand
- Inclusion of \$10.5 million of acquisition related expenses
- Elimination of historical stock compensation expense of \$0.6 million
- Inclusion of intangible asset amortization of \$38.9 million
- Net impact of new convertible notes payable of \$0.5 million
- \$12.7 million tax benefit on proforma adjustments

*Post-Employment Benefit Costs*

In connection with the Merger, the Company eliminated certain positions across both CorMedix and Melinta personnel and incurred associated severance costs under its benefit plans. The Company incurred an associated \$4.1 million of severance expenses during the year ended December 31, 2025. The Company had \$3.6 million of related severance on its balance sheet and is included in Accrued Expenses at December 31, 2025. The Company expects to pay all severance associated with the Merger by December 31, 2026.

**Note 4 — Other Prepaid Expenses and Current Assets:**

*Other Prepaid Expenses and Current Assets*

Other prepaid expenses and current assets consist of the following:

	<b>December 31, 2025</b>	<b>December 31, 2024</b>
Prepaid API (short-term) . . . . .	\$ 9,054	\$ 1,039
FDA filing fee . . . . .	2,653	450
Insurance . . . . .	1,977	342
Restricted Cash . . . . .	656	—
Commercial . . . . .	1,026	666
Subscriptions and Other . . . . .	2,205	1,136
Total . . . . .	<u>\$ 17,571</u>	<u>\$ 3,633</u>

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 5 — Other Long term Assets:**

*Other Long Term Assets*

Other long term consist of the following:

	<b>December 31, 2025</b>	<b>December 31, 2024</b>
Restricted Cash (long-term) . . . . .	332	105
Prepaid API (long-term) . . . . .	13,029	—
Marketable Equity Securities . . . . .	10,364	—
Other . . . . .	91	—
Total . . . . .	<u>\$ 23,816</u>	<u>\$ 105</u>

**Note 6 — Accrued Expenses:**

*Accrued Expenses*

Accrued expenses consist of the following:

	<b>December 31, 2025</b>	<b>December 31, 2024</b>
Accrued gross-to-net-deductions . . . . .	\$ 120,071	\$ 21,860
Payroll related liabilities (including severance) . . . . .	16,853	6,530
License agreement payable . . . . .	804	2,000
Professional and consulting fees . . . . .	6,264	865
Income tax payable . . . . .	12,758	—
Manufacturing related . . . . .	546	573
Accrued interest . . . . .	2,332	—
Other . . . . .	2,293	124
Total . . . . .	<u>\$ 161,921</u>	<u>\$ 31,952</u>

**Note 7 — Convertible Senior Notes:**

*Convertible Senior Notes*

On August 12, 2025, the Company completed a private placement offering of \$150 million aggregate principal amount of its 4.00% Convertible Senior Notes due 2030 (the “Notes”). The Notes were issued at par and mature on August 1, 2030. The Company incurred \$5.7 million in financing costs related to the issuance, resulting in net proceeds of \$144.3 million. The financing costs will be amortized over the term of the Notes up to the face value of \$150 million.

The Notes bear interest at a rate of 4.00% per annum, payable semi-annually in arrears on February 1 and August 1, commencing on February 1, 2026 through August 1, 2030. The Notes are senior unsecured obligations of the Company and rank equally in right of payment with all of the Company’s future senior unsecured indebtedness.

The Company may, at its option, redeem all or any portion of the Notes for cash at 100% of the principal amount of such Notes, plus accrued and unpaid interest, at any time on or after August 4, 2028, provided that the last reported sale price of the Company’s common stock is at least 130% of the conversion price on each of at least 20 trading days (whether or not consecutive) during the 30 consecutive trading days ending on, and including, the trading day immediately prior to the date the redemption notice is given, as well as on the trading day immediately preceding such notice.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 7 — Convertible Senior Notes:** (cont.)

Holders may convert their Notes into shares of the Company’s common stock at their option for any reason on or after May 1, 2030 and prior to the close of business on the second scheduled trading day immediately preceding the maturity date, or prior to the close of business on the business day immediately preceding May 1, 2030 under the following circumstances:

- **Stock Price Condition:** During any calendar quarter commencing after the quarter ending September 30, 2025, if the last reported sale price per share of the Company’s common stock exceeds 130% of the conversion price for at least 20 trading days (whether or not consecutive) during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter.
- **Trading Price Condition:** During the five consecutive business days immediately following any five consecutive trading day period (the “Measurement Period”), if the trading price per \$1,000 principal amount of Notes for each trading day of the Measurement Period is less than 98% of the product of the last reported sale price per share of common stock and the conversion rate on such trading day.
- **Distribution of Rights or Assets:** If the Company distributes to all or substantially all holders of its common stock (i) rights, options, or warrants to subscribe for or purchase shares of common stock at a price per share less than the average sale price for the ten consecutive trading days preceding the announcement, or (ii) assets or securities of the Company (other than pursuant to a stockholder rights plan prior to separation), where the value of such distribution exceeds 10% of the last reported sale price per share of common stock on the trading day immediately before the announcement.
- **Fundamental Change or Share Exchange Event:** Upon the occurrence of a Fundamental Change, Make-Whole Fundamental Change (prior to May 1, 2030), or Share Exchange Event as defined in the Indenture governing the Notes (other than a merger or business combination solely to change the Company’s jurisdiction of incorporation that does not constitute a Fundamental Change or Make-Whole Fundamental Change).
- **Redemption:** If the Company calls any Note for redemption, the holder may convert such Note.

The initial conversion rate for the Notes was set at the time of closing and is equal to 74.2515 shares of common stock per \$1,000 principal amount of Notes. The initial conversion price is subject to adjustment as described in the Indenture governing the Notes, not to exceed 96.5269 shares of common stock per \$1,000 principal amount of Notes. Upon conversion, the Company will settle its conversion obligation in cash, shares of common stock, or a combination thereof, at the Company’s election.

Convertible senior notes payable are comprised of the following as of December 31, 2025:

	<b>December 31, 2025</b>
Convertible senior note payable . . . . .	\$ 150,000
Less debt discounts . . . . .	(5,374)
Convertible senior note payable, net . . . . .	\$ 144,626

As of December 31, 2025 accrued interest on Notes was \$2.3 million. During the year ended December 31, 2025, the Company amortized debt discount of \$0.4 million to interest expense.

**Note 8 — Income Taxes:**

The Company’s U.S. and foreign loss before income taxes are set forth below (in thousands):

	<b>December 31,</b>	
	<b>2025</b>	<b>2024</b>
United States . . . . .	\$ 150,016	\$ (19,066)
Foreign . . . . .	—	(259)
Total . . . . .	\$ 150,016	\$ (19,325)

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 8 — Income Taxes:** (cont.)

The income tax (benefit)/expense consisted of the following

	December 31,	
	2025	2024
Current tax expense:		
Federal . . . . .	\$ 2,721	\$ —
State . . . . .	10,037	(1,395)
Foreign . . . . .	—	—
Total current . . . . .	<u>\$ 12,758</u>	<u>\$ (1,395)</u>
Deferred tax expense . . . . .		
Federal . . . . .	(28,883)	—
State . . . . .	3,086	—
Foreign . . . . .	—	—
Total deferred . . . . .	<u>\$ (25,797)</u>	<u>\$ —</u>
Total income tax (benefit) . . . . .	<u>\$ (13,039)</u>	<u>\$ (1,395)</u>

The Company's deferred tax assets consist of the following (are tax effected):

	December 31,	
	2025	2024
Deferred tax assets		
Net operating loss carryforwards – Federal . . . . .	\$ 117,135	\$ 55,778
Net operating loss carryforwards – State . . . . .	37,811	2,820
Net operating loss carryforwards – Foreign . . . . .	—	10
Capitalized licensing fees . . . . .	31	86
Interest expense . . . . .	6,656	—
Stock-based compensation . . . . .	3,952	2,976
Accrued compensation . . . . .	3,495	1,601
Section 174 capitalization . . . . .	—	5,159
Sales Return . . . . .	7,756	210
Tax Credit . . . . .	3,385	—
Inventory reserve . . . . .	256	—
Other . . . . .	616	528
Total gross deferred tax assets . . . . .	<u>181,093</u>	<u>69,168</u>
Less valuation allowance . . . . .	<u>(113,330)</u>	<u>(69,168)</u>
Total Deferred tax assets net of valuation allowance . . . . .	<u>\$ 67,763</u>	<u>\$ —</u>
Deferred tax liabilities		
In Process R&D . . . . .	(36,281)	—
Intangible asset . . . . .	(15,206)	—
Total gross deferred tax liabilities . . . . .	<u>(51,487)</u>	<u>—</u>
Net deferred tax assets . . . . .	<u>16,276</u>	<u>—</u>

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, 2025 was (\$44.2) million as a result of the acquisition of Melinta and its NOLs.

The tax benefit for year ended December 31, 2025 was \$13.0 million, an increase of 11.6 million, or 835% from 1.4 million for the same period in 2024. As of December 31, 2025, the Company partially released a valuation allowance of \$61.5 million primarily related to US Federal net operating losses. The release of valuation allowance

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 8 — Income Taxes:** (cont.)

was mainly attributed to the expected utilization of historical CorMedix federal NOLs. The Company will continue to evaluate the realizability of its remaining deferred tax assets each reporting period and adjust the valuation allowance as appropriate based on changes in cumulative results, forecasts of future taxable income, or other objective evidence as required by ASC 740-10-35.

The Company has not completed a formal study to determine whether ownership changes, as defined under Section 382 of the Internal Revenue Code, have occurred that could limit the utilization of its net operating loss carryforwards and other tax attributes. Until such a study is completed, the Company cannot determine the extent to which its tax attributes may be subject to annual limitations. The Company does not expect the results of study to have material effects of the financial statements for the year ended December 31, 2025.

As a result of the Merger, Melinta experienced a Section 382 ownership change on August 29, 2025. This ownership change limits our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the ownership change and may continue to limit our ability to utilize such attributes in the future.

The Company recognizes income tax benefits associated with uncertain tax positions, when, in our judgment, it is more likely than not that the position will be sustained upon examination by a taxing authority. For a tax position that meets the more likely than not recognition threshold, the Company initially and subsequently measures the tax benefit as the largest amount that judged to have a greater than 50% likelihood of being realized upon ultimate settlement with the taxing authority. The Company accrues interest and penalties related to uncertain tax positions in income tax expense. The Company has concluded that there are no uncertain tax positions requiring recognition in its financial statements as of December 31, 2025.

The Company files its federal and state income tax returns with the Internal Revenue Service and the relevant state taxing authorities. The Company is no longer subject to U.S. federal income tax examinations for tax years prior to 2022 and is no longer subject to state income tax examinations for tax years prior to 2021. As of December 31, 2025, there are no ongoing federal or state income tax audits

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

	<b>December 31,</b>	
	<b>2025</b>	<b>2024</b>
Federal. . . . .	\$ 557,786	\$ 265,610
State. . . . .	\$ 636,556	\$ 41,090
Foreign . . . . .	\$ —	\$ 38

Approximately \$91.5 million of net operating losses generated will expire in 2026 through 2037 for Federal purposes whereas the operating losses for state purposes will start to expire in 2025. 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. Our federal and state operating loss carry forwards include windfall tax deductions from stock option exercises.

The Company’s foreign earnings, if any, are derived from its foreign subsidiaries which were dissolved in the year ended December 31, 2025 and there was no income during the year.

The following table summarizes the Company’s effective tax rate for the periods indicated:

	<b>December 31,</b>	
	<b>2025</b>	<b>2024</b>
Profit (Loss) before income taxes. . . . .	\$ 150,016	\$ (19,325)
Provision (Benefit) for income taxes . . . . .	\$ (13,039)	\$ (1,395)
Effective tax rate . . . . .	(8.7)%	7.2%

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 8 — Income Taxes:** (cont.)

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

	2025		2024	
	Amount	Percent	Amount	Percent
U.S. federal statutory tax rate . . . . .	\$ 31,503	21.0%	\$ (4,058)	21.0%
State and local income tax (net of federal) <sup>(a)</sup> . . .	10,367	6.9%	(1,395)	7.2%
Foreign tax effects . . . . .	—	0.0%	57	(0.3)%
Effects of changes in tax laws or rates enacted in the current period . . . . .	—	0.0%	—	0.0%
Changes in valuation allowances: . . . . .	(60,713)	(40.5)%	675	(3.5)%
Non-taxable or non-deductible items				
Stock compensation . . . . .	(851)	(0.6)%	1,473	(7.6)%
Transaction Cost . . . . .	2,122	1.4%	—	0.0%
Officer's Compensation . . . . .	1,646	1.1%	332	(1.7)%
Change in Fair Value of Contingent Liability . . . . .	1,365	0.9%	—	—
Other non-taxable or non-deductible items . . . . .	507	0.4%	186	(1.0)%
Other adjustments:				
Stock compensation prior year true-up . .	79	0.1%	1,318	(6.8)%
Other . . . . .	936	0.6%	17	(0.1)%
Effective tax rate . . . . .	<u>\$ (13,039)</u>	<u>(8.7)%</u>	<u>\$ (1,395)</u>	<u>7.2%</u>

(a) State taxes in Tennessee, Kentucky and California made up the majority (greater than 50 percent) of the tax effect in this category in 2025. State taxes in New Jersey made up the majority (greater than 50 percent) of the tax effect in this category in 2024.

Individual jurisdictions equaling 5% or more of the total income taxes paid (net of refunds) for the year ended December 31, 2025 include Tennessee at \$28 thousand, Texas at \$18 thousand, South Carolina at \$5 thousand and Massachusetts at \$4 thousand.

Income taxes paid:

	December 31,	
	2025	2024
U.S. Federal . . . . .	—	—
U.S. State and Local . . . . .	62	6
Total Taxes paid . . . . .	<u>\$ 62</u>	<u>\$ 6</u>

**Note 9 — 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.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 9 — Commitments and Contingencies:** (cont.)

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 Defendants' motion to dismiss without prejudice and granted Lead Plaintiff leave to amend the complaint.

On April 22, 2024, the 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 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 filed its motion to dismiss the third amended complaint on June 6, 2024. The motion to dismiss was fully briefed on August 21, 2024.

On August 19, 2025, the Court issued a revised opinion and order, denying the CorMedix Defendants' motion to dismiss the third amended complaint. Since then, the case has proceeded to discovery.

On August 26, 2025, the parties proposed a revised Pretrial Scheduling Order, which the Court so-ordered on August 27, 2025. Among other things, the Scheduling Order provides for the (i) substantial completion of document production by January 27, 2026; (ii) completion of fact discovery by June 25, 2026; and (iii) completion of expert discovery by December 28, 2026.

The parties participated in a mediation before Michelle Yoshida, Esq. of Phillips ADR on November 18, 2025, which did not result in a settlement.

On December 1, 2025, in response to, among other things, the death of an Officer Defendant, Lead Plaintiff filed an Unopposed Motion for Leave to Amend the complaint, which the Court granted on December 17, 2025. The CorMedix Defendants filed their answer to the Fourth Amended Consolidated Class Action Complaint on January 2, 2026.

*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 duty, abuse of control, and waste of corporate assets against the individual defendants, and a claim for contribution for purported violations of Sections 10(b) and 21D of the Exchange Act against certain defendants. 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 was pending.

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. The complaint names as 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.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 9 — Commitments and Contingencies: (cont.)**

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. The complaint names as 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 duty.

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 provisions of the Order to Stay that was previously entered in the *Voter* litigation on January 21, 2022 applied to the consolidated derivative action.

On August 19, 2025, the Court issued a revised opinion and order denying the CorMedix Defendants' motion to dismiss the third amended complaint in the securities litigation. On November 10, 2025, the derivative plaintiffs filed a verified consolidated shareholder derivative complaint (the "Consolidated Complaint"), which alleges that during the relevant period (October 16, 2019 — August 8, 2022), the Individual Defendants, made or caused to be made materially false and misleading statements regarding CorMedix's business and operations, specifically relating to purported manufacturing deficiencies during the Relevant Period that the Individual Defendants knew or should have known would impact the FDA approval of the developmental drug "DefenCath" prior to its ultimate approval by the FDA.

The Consolidated Complaint asserts claims for breach of fiduciary duty and unjust enrichment. On this basis, the Consolidated Complaint seeks unspecified damages and corporate governance reforms.

On November 18, 2025, the parties participated in a mediation before Michelle Yoshida, Esq. of Phillips ADR. On December 20, 2025, the parties signed a binding settlement term sheet. On January 19, 2026, the parties executed a binding stipulation of settlement, which, if approved, would resolve the case.

The plaintiffs in a new and separate action — the *Jhoe* action (discussed below) — filed a motion to intervene and stay this case on December 18, 2025. On January 6, 2026, the plaintiffs filed their opposition to the motion to intervene and stay. The *Jhoe* plaintiff filed his reply on January 13, 2026. That motion remains pending and will be decided on the papers.

On January 19, 2026, the plaintiffs filed their Unopposed Motion for Preliminary Approval of Settlement ("Preliminary Approval Motion"). Following an exchange of letters, on February 3, 2026, the *Jhoe* plaintiff filed his purported opposition to the Preliminary Approval Motion raising, among other things, various objections to the proposed settlement. On February 10, 2026, the plaintiffs filed their reply in further support of preliminary approval of the proposed settlement, in which Defendants joined and advanced additional arguments in favor of preliminary approval. The Preliminary Approval Motion remains pending and will be decided on the papers.

*Raval v. Baluch, Case No. UNN-L-003721-25 (N.J. Super Ct. Law Div.)*

On or about September 26, 2025, a purported shareholder, derivatively and on behalf of CorMedix, filed a shareholder derivative complaint in the Law Division of the Union County Superior Court of New Jersey, in a case entitled, *Raval v. Baluch, et al.*, Case No. UNN-L-003721-25 (N.J. Super Ct. Law Div.) (the "State Derivative Litigation"). The complaint names as defendants Khoso Baluch, Janet Dillione, Alan W. Dunton, Myron Kaplan, Steven Lefkowitz, Paulo F. Costa, Gregory Duncan, Matthew David, and Phoebe Mounts, along with CorMedix as Nominal Defendant. The complaint alleges breaches of fiduciary duty, waste of corporate assets, and abuse of control against the defendants and contains similar allegations to the previously-filed consolidated derivative complaint pending in federal court. The *Raval* complaint seeks unspecified money damages, governance reforms, and costs and expenses. On October 22, 2025, the parties filed a proposed Stipulation and Consent Order, which the Court entered on the same day. The Stipulation and Consent Order provided that Plaintiff would have until December 4, 2025 to file an amended complaint or designate the complaint as operative. On December 4, 2025, Plaintiff filed a notice with the Court designating its September 26, 2025 complaint as the operative complaint.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 9 — Commitments and Contingencies:** (cont.)

The parties attended a mediation before Michelle Yoshida, Esq. of Phillips ADR on November 18, 2025. On December 20, 2025, the parties signed a binding settlement term sheet. On January 5, 2026, the parties filed a Stipulation and Consent Order Staying Action staying the case pending approval of the settlement in the federal derivative action, which the court entered on the same day. On January 19, 2026, the parties signed a stipulation of settlement. This action will be dismissed in the event that the proposed settlement is approved by the court in the federal derivative action.

*Jhoe v. Todisco, et al.*, C.A. No. 2025-1367-PAF (Del. Ch.)

On November 24, 2025, an action was initiated under seal by Robert Jhoe, a purported shareholder of the Company, asserting claims derivatively and on behalf of CorMedix. A public version of the complaint was filed on December 1, 2025. The complaint names as defendants Khoso Baluch, Janet D. Dillione, Alan W. Dunton, Robert Cook, Myron Kaplan, Steven Lefkowitz, Paulo F. Costa, Greg Duncan, Matthew David, Phoebe Mounts, John L. Armstrong, and Joseph Todisco, along with the Company as Nominal Defendant.

The complaint asserts claims for breach of fiduciary duty, aiding and abetting breach of fiduciary duty, unjust enrichment, and waste. Mr. Jhoe made a books-and-records demand on CorMedix pursuant to Section 220 of the Delaware General Corporation Law prior to initiating this action, and the complaint purports to quote and cite board-level materials in support of Mr. Jhoe's claims. It seeks unspecified damages and costs along with certain governance reforms.

On December 29, 2025, the defendants moved to stay or dismiss this action, pending approval of the settlement in the federal derivative action. On January 15, 2026, the parties filed a Stipulation and Proposed Order Governing the Briefing Schedule for the Motion to Dismiss or Stay, which the court so-ordered the following day. Per the Stipulation, Defendants filed their Opening Brief on February 16, 2026. Further, Plaintiff's Opposition Brief is due on March 18, 2026 and Defendants' Reply is due on April 2, 2026.

On February 27, 2026, the parties filed a stipulation and proposed order to stay this case — including the Motion to Dismiss or Stay — pending decisions by the court in the New Jersey derivative case on two motions: (i) Mr. Jhoe's Motion to Intervene and (ii) the plaintiffs' Motion for Preliminary Approval of Settlement, which Mr. Jhoe opposes. The stipulation, which the court so-ordered on March 2, 2026, further provides that following the New Jersey court's decisions on these motions, the parties in the Jhoe case will confer regarding appropriate next steps and update the court accordingly.

***Melinta Legal Proceedings***

Melinta markets MINOCIN, which is indicated for the treatment of certain bacterial infections. Melinta holds Orange Book listed patents for MINOCIN, including two formulation patents (patents 11,944,634 and 12,161,656) issued in 2024.

In 2020, Nexus Pharmaceuticals ("Nexus") filed an Abbreviated New Drug Application ("ANDA") with Paragraph IV ("PIV") certification against the only Orange Book listed patents at the time, specifically patents '802 and '105 ("Minocin Treatment Patents"), on the alleged basis that the Minocin Treatment Patents were invalid and, in the alternative, that its ANDA did not infringe.

Melinta filed suit against Nexus in the US District Court for the Northern District of Illinois (the "Court"), asserting that the Minocin Treatment Patents were valid and accordingly, Nexus's ANDA for its generic version of MINOCIN infringed these patents. In November 2024, the Court found that the Minocin Treatment Patents are valid, enforceable and infringed and issued a permanent injunction against the Nexus ANDA as part of that decision. Nexus subsequently filed an appeal with the U.S. Court of Appeals for the Federal Circuit. The appeal is ongoing.

Additionally, in February 2025, Melinta received a PIV certification for all four Orange Book listed patents from Gland Pharma ("Gland") on the alleged basis that the patents were invalid, and in the alternative that its ANDA did not infringe these patents. Melinta filed a suit against Gland in the same Court in April 2025. The case is ongoing.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 9 — Commitments and Contingencies: (cont.)**

***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 \$0.3 million 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. Under the ND License Agreement, the maximum aggregate amount of cash payments due upon achievement of applicable milestones was \$2.5 million, with the balance being \$2 million as of March 31, 2025. The initial licensing fee of \$0.3 million, the fair value of the 5% equity interest (7,996 shares of the Company's common stock) and an additional \$0.5 million, 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 million and a license agreement liability of \$2 million, which was included within accrued expenses in the Company's consolidated balance sheet as of December 31, 2024. In May 2025, the Company paid the final milestone liability in the aggregate amount of \$2 million.

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, the Company will have an irrevocable, perpetual, fully paid-up, royalty-free exclusive license to the NDP Technology in such country.

***Melinta Commitments***

Melinta is party to several license agreements, under which it will be required to make payments based on the achievement of agreed-upon milestones or circumstances. As of December 31, 2025, Melinta was not obligated to make any of the future payments discussed below.

*Wakunaga Pharmaceutical Co., Ltd.* In May 2006, Wakunaga and Melinta executed a license agreement under which Melinta acquired rights to certain patents, patent applications, and other intellectual property related to BAXDELA. Melinta is obligated to pay royalties to Wakunaga on sales of BAXDELA. Under the license, Melinta has the right to grant sublicenses, although Wakunaga is entitled to a substantial portion of non-royalty income received from a sublicense of the Wakunaga technology. Wakunaga has certain termination rights, should Melinta fail to perform its obligations under the agreement, it becomes subject to bankruptcy or similar events, or Melinta's business is transferred or sold and the successor requires us to terminate a substantial part of its development activities under the agreement. Melinta has the right to terminate the license for cause upon six months' written notice to Wakunaga. Unless earlier terminated, the license agreement will continue in effect on a country-by-country and product-by-product basis until Melinta is no longer required to pay any royalties, which is the later of the date the manufacture, use or sale of a licensed product in a country is no longer covered by a valid patent claim, or a specified number of years following the first commercial sale in such country.

*CyDex Pharmaceuticals, Inc.* In November 2010, Melinta entered into a license and supply agreement with CyDex Pharmaceuticals, Inc. (now a wholly-owned subsidiary of Ligand Pharmaceuticals Incorporated, both hereafter referred to as Ligand) under which Melinta obtained an exclusive right, under certain patents and patent applications, to use Ligand's beta sulfobutyl cyclodextrin, Captisol, in the development and commercialization of a BAXDELA product. In addition, under the terms of the license agreement, Melinta obtained a nonexclusive license to Ligand's

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 9 — Commitments and Contingencies:** (cont.)

Captisol data package. Melinta is obligated to pay royalties to them based on our sales of BAXDELA. Melinta is obligated to certain diligence requirements and have the right to grant sublicenses to third parties. The license agreement provides for future payments to Ligand upon the achievement of a future commercial milestone, and obligations to make percentage royalty payments in the single digits based on net sales, if any, of the licensed product. Additionally, Melinta has agreed to purchase our requirements of Captisol from Ligand for use in a BAXDELA product, with pricing established pursuant to a tiered pricing schedule. Ligand has certain rights to terminate the agreement following a cure period, should Melinta fail to perform our obligations under the agreement. In addition, Ligand may terminate the agreement immediately if Melinta fails to pay milestones or royalties due under the agreement or if Melinta becomes subject to bankruptcy or similar events. Melinta has the right to terminate the license upon 90 days' written notice to Ligand. Unless earlier terminated, the agreement will continue in effect until the expiration of our obligation to pay royalties. Such obligation expires, on a country-by-country basis, over a specified number of years following the expiration date of the last valid claim of a licensed product in the country of sale; if there has never been a valid claim of a licensed product in the country of sale, then such number of years after the first sale of the licensed product in such country.

*AstraZeneca AB ("AZ").* In connection with the acquisition of Toprol XL, the seller assigned its rights, title, interests and obligations for the Toprol product in the U.S. under the supply and license agreements with AZ to Melinta, as a wholly-owned subsidiary of the Company. AZ is obligated to supply the Toprol product to Melinta in accordance with the supply agreement, and Melinta is obligated to pay royalties based on net sales of the Toprol product.

*Mundipharma.* In July 2022, Melinta entered into a license agreement with Cidara Therapeutics ("REZZAYO License Agreement") (who in April 2024 sold all of its rights in REZZAYO to Napp Pharmaceutical Group Limited ("Napp"), a member of Mundipharma independent associated companies) to acquire an exclusive license to develop and sell REZZAYO in the U.S. Napp acquired of all assets and rights related to rezafungin globally, including ongoing development and distribution, while commercialization rights to rezafungin in the United States remain licensed to Melinta.

As of December 31, 2025, the commitments under the REZZAYO License Agreement include a regulatory milestone of between \$30 million and \$40 million upon receipt of the marketing approval for the prophylaxis indication, a number of commercial milestones upon exceeding certain net sales targets, and net sales-based royalties. The agreement additionally stipulates that upon the earlier of thirty-days following the receipt of the marketing approval for the prophylaxis indication or on June 30, 2028, Napp shall assign and transfer to Melinta all rights, title and interest in and to all product filings for the current product in the U.S. Following the first anniversary of the contract effective date, Melinta may terminate this agreement, in its sole discretion, upon 90 days prior written notice; otherwise, this agreement shall expire on the expiration of Melinta's obligation to pay royalties to Napp when there is no valid claim of the licensed patent rights in the United States.

In connection with the purchase of the active pharmaceutical ingredient (API) for VABOMERE, Melinta has committed to API deliveries from the CMO in 2026 with a total cost of €5.9 million, subject to inflation adjustments.

***Other Commitments***

In December 2024, the Company entered into a three-year agreement with Syneos Health Commercial Services, LLC ("Syneos") under which Syneos agreed to provide a dedicated inpatient field sales force to exclusively promote DefenCath to hospitals and health systems. The Company paid an up-front implementation and was obligated to pay a fixed monthly fee. The Company signed a termination agreement, effective October 1, 2025 whereas the related services to CorMedix were completed on December 31, 2025. As of December 31, 2025, the Company has a total net obligation of \$2.3 million, consisting of \$1.3 million of accrued termination fees and \$1.6 million of unpaid expenses incurred through Q4 2025, which will be partially offset by a security deposit of \$0.6 million. We expect complete settlement to occur in Q1 2026.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 10 — Stockholders’ Equity:**

***Common Stock***

On May 9, 2024, the Company filed a shelf registration statement (the “2024 Shelf Registration Statement”) for the issuance of up to \$150 million 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 million 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. During the year ended December 31, 2025, the Company sold an aggregate of 715,051 shares of its common stock under the 2024 ATM program and realized aggregate net proceeds of approximately \$7.8 million. As of December 31, 2025, approximately \$22.1 million of the Company’s common stock remains available for sale under its 2024 ATM program, with \$15 million of capacity remaining under its 2024 Shelf Registration Statement for the issuance of Company securities.

On June 30, 2025, the Company completed a Follow on Offering of common stock pursuant to the Company’s universal shelf registration statement on Form S-3, selling an aggregate of 6,604,507 shares, at the price of \$12.87 per share less an underwriting discount of \$0.229 per share. The Company received aggregate net proceeds of approximately \$82.4 million after deducting the underwriting discounts and commissions and offering expenses payable by the Company. The Company intends to use the proceeds for general corporate purposes, which may include working capital, expenses related to research and the development of product candidates, and potential strategic transactions, including acquisitions, joint ventures or collaborations, involving companies, products or assets that complement our business. No payments were made by the Company to directors, officers or persons owning 10% or more of the Company’s common stock or to their associates, or to the Company’s affiliates. In addition, the Company granted the underwriter a 30-day option to purchase an additional 15% of the shares of its common stock offered in the offering, which expired unexercised.

On August 29, 2025, the Company issued 3,323,833 shares of common stock in connection with the Merger and has registered an additional 3,000,000 shares of common stock that may be issuable, at the Company’s election, upon the achievement of the REZZAYO Milestone in connection with the Merger (see Note 3).

During the years ended December 31, 2025 and 2024, 45,000 and 44,999 shares of Series G preferred stock were converted to 2,502,062 and 2,502,005 shares of common stock, respectively.

***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, 2025			As of December 31, 2024		
	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	\$ 62.76	5,624,739	89,623	\$ 49.20	\$ 4,409,452
Series G .....	—	\$ —	—	45,000	\$ 187.36	\$ 8,431,200
Total .....	<u>91,623</u>		<u>5,644,739</u>	<u>136,623</u>		<u>\$ 12,860,652</u>

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 10 — Stockholders' Equity:** (cont.)

In July 2025, the stated value of the Series E Convertible Preferred Stock was amended from \$49.20 to \$62.76 per share.

The following rights, privileges, terms and conditions apply to the outstanding preferred stock at December 31, 2025:

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.

*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.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 10 — Stockholders' Equity:** (cont.)

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 5.5787 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 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 \$62.76 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.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 10 — Stockholders’ Equity:** (cont.)

*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.

***Restricted and Performance Stock Units***

The Company has granted restricted stock units (“RSUs”) to certain employees and non-employee directors and performance stock units (“PSUs”) to certain executive employees as compensation for services. The grant date fair value of the RSUs is based upon the fair value of the Company’s common stock on the date of the grant for RSUs that vest upon service or performance conditions. For RSUs that vest upon market conditions, the grant date fair value of RSUs is based upon a Monte-Carlo simulation model.

During the year ended December 31, 2025 and 2024 the Company granted 1,747,308 and 283,333 RSUs to its employees and non-employee directors with service based vesting conditions and a weighted average grant date fair value of \$11.10 and \$3.47 per share respectively. Compensation expense related to these RSUs is recognized on a straight-line basis over the vesting period. As of the year ended, December 31, 2015, and 2024, the Company had 1,550,883 and 291,494 shares unvested with a weighted average fair value of \$10.50 and \$3.44, respectively.

During the year ended December 31, 2025 and 2024, 371,166 and 145,574 RSUs vested, respectively, of which 193,032 and 84,559 shares of common stock were issued by the Company, respectively, and 178,134 and 61,015 shares, respectively, were withheld in lieu of withholding taxes.

In addition to the RSUs noted above, during the year ended December 31, 2025, the Company granted 487,500 PSUs to its executive officers with market performance and service based vesting conditions and, as such, the grant date fair value of \$11.79 was calculated using a Monte-Carlo simulation model. Of the total PSUs granted, 62,500 of these PSUs were forfeited in August 2025 due to the resignation of an employee. During the year ended December 31, 2025, 33,220 additional shares were the result of the end of the Period 1 measurement period. As of December 31, 2025, 458,220 PSUs are outstanding, which have a weighted average fair value of 11.79. The following key assumptions were used to determine the fair value of the PSUs granted during the period:

<b>Assumption</b>	<b>Period 1</b>	<b>Period 2</b>	<b>Period 3</b>
Share price . . . . .	\$ 8.10	N/A	N/A
Equity volatility. . . . .	71.2%	69.7%	87.0%
Remaining term at time of valuation (years) . . . . .	0.99	1.99	2.99
Dividend yield. . . . .	0%	0%	0%
Risk-free rate. . . . .	4.13%	4.20%	4.25%

Compensation expense related to these PSUs is recognized on a straight-line basis over the requisite service period, regardless of whether the market condition is ultimately satisfied.

As of December 31, 2025, the Company had 2,009,103 outstanding RSUs and PSUs. As of December 31, 2025, unrecognized compensation expense related to unvested RSUs and PSUs was \$14.3 million, which will be recognized over a weighted average remaining period of 1.7 years as of December 31, 2025.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 10 — Stockholders’ Equity:** (cont.)

***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 year ended December 31, 2024, the Company granted ten-year qualified and non-qualified stock options to its officers, directors, employees and consultants in the aggregate of 2,196,167 shares of the Company’s common stock under the 2019 Plan. The weighted average exercise price of these options was \$3.80. The Company did not grant any stock options during the year ended December 31, 2025.

During the years ended December 31, 2025 and 2024, the Company issued 1,510,887 and 1,357,802 shares of common stock, respectively, as a result of the exercise of stock options. The Company realized net proceeds of \$6.4 million and \$7.7 million, respectively, from the exercise of stock options with a weighted average exercise price of \$4.22 and \$5.69 per share, respectively.

During the year ended December 31, 2025 no stock options were issued. As of December 31, 2025, there was approximately \$2.3 million in total unrecognized compensation expense related to stock options granted, which will be recognized over an expected remaining weighted average period of 1.0 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.

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:

	<b>Year Ended December 31,</b>	
	<b>2025</b>	<b>2024</b>
Risk-free interest rate . . . . .	N/A	3.60% – 4.65%
Expected volatility . . . . .	N/A	93.2% – 100.5%
Average Expected term (years) . . . . .	N/A	6 years
Expected dividend yield . . . . .	N/A	0.0%
Weighted-average grant date fair value of options granted during the period . .	N/A	\$ 3.04

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 10 — Stockholders' Equity:** (cont.)

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, 2025 and 2024 (in thousands except share data):

	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
Granted . . . . .	2,196,167	\$ 3.80	—	—
Exercised . . . . .	(1,357,802)	\$ 5.69	—	\$ 3,750
Expired/Cancelled . . . . .	(418,932)	\$ 12.27	—	—
Forfeited . . . . .	(348,548)	\$ 3.68	—	—
Outstanding at December 31, 2024 . . . . .	<u>6,282,393</u>	<u>\$ 4.46</u>	<u>7.8</u>	<u>\$ 23,568</u>
Granted . . . . .	—	\$ —	—	—
Exercised . . . . .	(1,510,887)	\$ 4.22	—	\$ 11,149
Expired/Cancelled . . . . .	(28,741)	\$ 19.16	—	—
Forfeited . . . . .	(220,944)	\$ 4.13	—	—
Outstanding at December 31, 2025 . . . . .	<u>4,521,821</u>	<u>\$ 4.46</u>	<u>7.7</u>	<u>\$ 32,532</u>
Vested at December 31, 2025 . . . . .	<u>3,208,698</u>	<u>\$ 4.72</u>	<u>6.5</u>	<u>\$ 22,321</u>
Expected to vest in the future . . . . .	<u>1,313,123</u>	<u>\$ 3.85</u>	<u>7.7</u>	<u>\$ 10,211</u>

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 Compensation***

Total stock-based compensation expense recognized in the consolidated statements of operations is as follows:

Award type	Year Ended December 31,	
	2025	2024
RSUs . . . . .	\$ 8,197	\$ 690
PSUs . . . . .	1,644	—
Stock options . . . . .	3,991	5,439
Total . . . . .	<u>\$ 13,832</u>	<u>\$ 6,129</u>

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 10 — Stockholders’ Equity:** (cont.)

The following table represents the allocation of stock-based compensation expense by financial statement line item:

<b>Financial statement line item</b>	<b>Year Ended December 31,</b>	
	<b>2025</b>	<b>2024</b>
Cost of sales . . . . .	\$ 513	\$ 270
Research and development . . . . .	709	438
Selling and marketing . . . . .	1,690	582
General and administrative . . . . .	10,920	4,839
Total . . . . .	<u>\$ 13,832</u>	<u>\$ 6,129</u>

During the year ended December 31, 2025, \$0.9 million of expense related to stock option and RSUs pertained to equity modifications for employees who were provided notice of Merger-related terminations.

***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, 2025 and 2024, no compensation was deferred under this plan.

On September 17, 2025, the Board approved the termination and liquidation of the plan in accordance with IRC Section 409A. As of the termination date, one director participated in the plan. All accrued benefits under the plan will be distributed on the date that is one business day following the twelve-month anniversary of the termination date.

**Note 11 — BARDA Agreement:**

In July 2023, Melinta entered into partnership with BARDA to advance BAXDELA and VABOMERE for use in pediatrics and to partner on the development of BAXDELA against certain biothreat pathogens (BARDA-Supported Studies). Under this contract, BARDA reimburses Melinta certain percentages of costs incurred, as defined in the agreement, in connection with the BARDA-Supported Studies. BARDA has awarded a total of \$47.5 million of funding with the potential of additional funding of \$97.1 million, amounting to total funding up to \$144.6 million, if all options are exercised. If all contract options are exercised, the contract is expected to continue through 2034. Through December 2025, Melinta has recognized BARDA reimbursement totaling \$19.4 million.

There are two performance obligations under the BARDA contract, which are research and development services performed for (a) BAXDELA and VABOMERE pediatric studies and (b) BAXDELA biodefense studies. These research and development services were performance obligations because they are distinct within the context of the contract; that is, the services are separately identifiable from other obligations within the arrangement. In addition, the transaction prices included within the BARDA contract were equivalent to the standalone selling price of the research and development services and would be allocated. Therefore, research and development services are recognized as contract revenue over time, as the performance obligation is satisfied, in accordance with the BARDA agreement. The Company recognized \$4.2 million of contract revenue under the BARDA agreement for the year-ended December 31, 2025.

**CORMEDIX INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 12 — Segment Reporting:**

The Company has determined that it has one reportable segment — Drug Product primarily sold in the United States with contract revenue consisting of BARDA in the US and product, royalty and milestone revenues outside of the US.

The Company’s Chief Executive Officer is the Chief Operating Decision Maker (“CODM”). The CODM manages the Company’s business activities as a single 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.

	<b>Year Ended December 31,</b>	
	<b>2025</b>	<b>2024</b>
<b>Research and development:</b>		
Employee expense . . . . .	\$ 7,756	\$ 2,455
Other research and development . . . . .	11,577	1,487
Total research and development . . . . .	19,333	3,942
<b>Selling and marketing</b>		
Employee and contracted employee expense . . . . .	\$ 22,618	\$ 13,494
Other selling and marketing . . . . .	15,436	15,243
Total selling and marketing expense . . . . .	38,054	28,737
<b>General and administrative</b>		
Employee expense . . . . .	\$ 32,584	\$ 18,321
Other general and administrative . . . . .	35,636	11,638
Total general and administrative expense . . . . .	68,220	29,959
<b>Total operating expenses</b> . . . . .	<b>\$ 125,607</b>	<b>\$ 62,638</b>

The CODM also reviews DefenCath sales separately from sales from the Melinta Portfolio; the following table sets forth the breakdown of sales:

	<b>Year Ended December 31,</b>	
	<b>2025</b>	<b>2024</b>
<b>Product Sales:</b>		
DefenCath . . . . .	\$ 258,813	\$ 43,472
Melinta Portfolio . . . . .	45,531	—
Total product sales . . . . .	304,344	43,472
Contract Revenue . . . . .	7,365	—
Total Revenues . . . . .	311,709	43,472